A STUDY OF BIOSECURITY INTERNATIONAL INSTRUMENTS IN THE CONTEXT OF THE INTERNATIONAL SUSTAINABLE DEVELOPMENT LAW PRINCIPLES AND IN RELATION TO GENETICALLY-MODIFIED ORGANISMS

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THESIS SUBMITTED IN FULFILMENT OF THE REQUIREMENTS FOR THE DEGREE OF DOCTOR OF PHILOSOPHY

FACULTY OF SCIENCE
UNIVERSITY OF MALAYA
KUALA LUMPUR

2017

UNIVERSITY OF MALAYA

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Matric No: **SHB 100018**

Name of Degree: **Doctor of Philosophy**

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ABSTRACT

International biosecurity agreements and initiatives have coexisted disparately reflecting the sectorial approach of management. This approach is no longer feasible because it is unable to deal with an arising biosecurity matter that encroaches across multiple sectors. The purpose of this study is to analyse whether principles of international law from the New Delhi Declaration of Principles of International Law Relating to Sustainable Development, in short International Sustainable Development Law (ISDL) holds the solution in linking different biosecurity sectors and their respective international agreements and initiatives together in the context of genetically modified organisms (GMOs) for coherent management among international organisations. This study is qualitative. The doctrinal research approach applies to determine the status of sustainable development in international law, to the treaties and case laws used in this study through a document and textual analysis. The socio-legal approach is utilised because this study combines the area of law with biosecurity. A content analysis applies to secondary resources. The provisions of the Cartagena Protocol on Biosafety (CPB), Biological Weapons Convention (BWC), International Health Regulations 2005 (IHR 2005), the World Health Organisation's (WHO's) laboratory biosecurity and biopharming initiatives are examined to detect the existence of explicit and implicit elements of ISDL principles. The results from this study indicate that the CPB, BWC, IHR 2005 all reflect the principle of integration in enabling cooperation with other international organisations while collaboration depends on the political will of states. This study found that most of the principles of ISDL have directly been reflected in the CPB and IHR 2005 while indirectly embedded in the BWC. For the BWC, a United Nations (UN) resolution has prescribed the adoption of ISDL principles in the Delhi Declaration. This study's contribution to the scopus of knowledge is through offering an international law approach utilising ISDL principles in uniting the disparate sectors of international biosecurity agreements and

initiatives. This complements the holistic biosecurity definition being proposed in uniting various sectors with a UN coordinating mechanism bringing biosecurity international organisations and agencies together. The findings of the BWC as a biosecurity international arms control agreement achieving the goal of sustainable development contribute to the sparse literature linking international arms control and sustainable development law. This also challenges the understanding of ISDL being limited to international environmental, economic and social law. This study also found that the WHO's laboratory biosecurity and biopharming initiatives are related to the CPB and BWC through the principle of integration. Elaboration of the IHR 2005, laboratory biosecurity and biopharming initiatives also significantly contribute towards the current scholarly literature of international health and sustainable development law.

ABSTRAK

Perjanjian dan inisiatif biosekuriti peringkat antarabangsa wujud secara berasingan dan mencerminkan pendekatan pengurusan bersektor. Pendekatan ini tidak lagi relevan kerana tidak mampu menangani hal-hal berkenaan biosekuriti yang berbangkit dan merentasi pelbagai sektor. Kajian ini bertujuan untuk menganalisa sama ada Perisytiharan New Delhi berkenaan Prinsip Undang-undang Antarabangsa yang Berkaitan dengan Pembangunan Lestari merupakan penyelesaian dalam mengaitkan sektor biosekuriti yang berbeza dan perjanjian antarabangsa serta inisiatifnya dalam konteks organisma yang diubahsuaikan secara genetik (GMO) bagi membolehkan pengurusan yang jelas dalam kalangan organisasi antarabangsa. Kajian ini bersifat kualitatif. Pendekatan secara penyelidikan doktrin digunakan dalam penentuan kedudukan pembangunan lestari dari segi undang-undang antarabangsa, kepada perjanijan-perjanjian dan kes mahkamah dalam kajian ini melalui analisis dokumen dan tekstual. Pendekatan sosioperundangan digunakan kerana kajian ini menggabungkan bidang undang-undang dengan biosekuriti. Analisis kandungan diaplikasikan kepada sumber sekunder. Peruntukan Protokol Cartagena berkenaan Biokeselamatan (CPB), Konvensyen Senjata Biologi (BWC), Peraturan Kesihatan Antarabangsa 2005 (IHR 2005) dan biosekuriti makmal serta inisiatif biopertanian oleh Pertubuhan Kesihatan Sedunia (WHO) dikaji untuk mengesan kewujudan prinsip ISDL yang tersurat dan tersirat. Hasil kajian ini menunjukkan bahawa CPB, BWC, dan IHR 2005 semuanya mencerminkan prinsip integrasi dalam membolehkan kerjasama dengan organisasi antarabangsa yang lain manakala kerjasama ini bergantung pada kehendak politik negara-negara berkenaan. Kajian ini juga mendapati bahawa kebanyakan prinsip ISDL secara langsungnya tercermin pada CPB dan IHR 2005 manakala secara tidak langsungnya terangkum oleh BWC. Bagi BWC, suatu resolusi Pertubuhan Bangsa-bangsa Bersatu (PBB) telah menyarankan penggunaan prinsip ISDL dalam Perisytiharan Delhi. Kajian ini menyumbang kepada ilmu melalui pendekatan

undang-undang antarabangsa yang menggunakan prinsip ISDL dalam mengaitkan perjanjian antarabangsa dan inisiatif biosekuriti yang berbeza. Ini melengkapkan definisi biosekuriti holistik yang dicadangkan untuk menyatukan pelbagai sektor, dengan menggunakan mekanisme penyelaras oleh PBB yang menyatukan organisasi dan agensi biosekuriti pada peringkat antarabangsa. Hasil kajian BWC sebagai perjanjian biosekuriti yang mengawal senjata antarabangsa, yang mencapai matlamat pembangunan lestari, telah menyumbang kepada kesusasteraan terhad terhadap maklumat yang mengaitkan pengawalan senjata antarabangsa dengan undang-undang pembangunan lestari. Ini juga mencabar pemahaman bahawa ISDL terhad kepada undang-undang alam sekitar, ekonomi dan sosial antarabangsa. Kajian ini juga mendapati bahawa biosekuriti makmal dan inisiatif biopertanian oleh WHO itu berkait dengan CPB dan BWC menerusi prinsip integrasi. Penghuraian berkenaan IHR 2005, biosekuriti makmal dan inisiatif biopertanian juga menyumbang secara ketara kepada bahan ilmiah terkini berkaitan dengan kesihatan antarabangsa dan undang-undang pembangunan lestari.

ACKNOWLEDGEMENTS

I wish to express my deepest gratitude, to Allah Subhanahu Wa Ta'ala for giving me the patience, strength and guidance in enabling this thesis to be completed. This thesis completion benefitted from the advice and constructive comments from my supervisors, Professor Datuk Azizan Baharuddin, Associate Professor Dr. Siti Nurani Mohd Noor, Associate Professor Dr. Chan Kok Gan and Dr. Nor Anita Abdullah especially who has been a good listener throughout the challenging times in completing this thesis. Special thanks to Pn. Lisdar Abdul Wahid, the librarian at the University of Malaya (UM) for guidance on the citation and Chris Chang at CRYSTAL, UM for assisting me with the selection of ISI journals for publication

I am also equally grateful to the Chair, History, Politics and Securities Research Centre (POSH), Faculty of Social Sciences and Humanities (FSSK) and the Dean of FSSK, National University of Malaysia (UKM) in supporting me to finish this thesis to completion, for the funding to attend conferences and publish part of my thesis as journals and proceedings. Special thanks also to my friends in UKM namely Professor Dr. Latifah Amin, Prof. Madya Dr. Sarah Aziz Abdul Ghani, Dr. Anisah Che Ngah, Dr. Rohani Abdul Rahim, Dr. Ho Chiew Ping and Dr. Jamaei Hj. Hamil for your encouragement. I am also grateful to Vincent Cheong Jai Wei, Shima Sani and Brian Chong for the formatting of this thesis. I am particularly indebted to my mother, Laily Rohaini Abdul Majid and other family members namely my aunties, Hajah Laily Rafeah Abdul Majid, Latifah Abdul Majid, my cousins Harith Sham and Fazli Mohd. Yassin for your forthtitude, faith and words of encouragement to finish this thesis. I am also grateful to my illustrious cats, Droopy, Husky and Kitty for their wonderful antics during my times of gloom. Thank you all.

Marina Abdul Majid, 4 April 2017.

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1925 Geneva Protocol	Geneva Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare 1925
Aarhus Convention	Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters
ABS	Access and Benefit Sharing
African Convention	1968 African Convention on the Conservation of Nature and Natural Resources
AIA	Advanced Informed Agreement
AIDS	Acquired Human Immunodeficiency Syndrome
American Media	American Media, Incorporated
ATAS	Academic Technology Approval Scheme
ATCC	American Type Culture Collection
Basel Convention	Basel Convention on the Transboundary Movements of Hazardous Waste and Their Disposal
BCH	Biosafety Clearing House
BG	*Bacillus globiggi*
BRCs	Biological Resource Centres
BSL-3	Biosafety Level Three
BSL-4	Biosafety Level Four
BWC	Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction/ Biological Weapons Convention
CARU	Administrative Commission of the River Uruguay
CBD	Convention on Biological Diversity
CBDR	Common but differentiated responsibilities
CBMs	Confidence Building Measures

CDC	Centres for Disease Control and Prevention
CIA	Central Intelligence Agency
CISDL	Centre for International Sustainable Development Law
COE	Council of the European Union
COP-MOP	Conference of Parties Serving as the Meeting of Parties to the Protocol
CPB	Cartagena Protocol on Biosafety
CSCAP	Council for Security Cooperation in the Asia-Pacific
CSD	Commission of Sustainable Development
CSR	Corporate Social Responsibility
CTITF	Counter Terrorism Implementation Task Force
CTR	Cooperative Threat Reduction
DDT	Dichlorodiphenyltrichloroethane
Delhi Declaration	New Delhi Declaration of Principles of International Law Relating to Sustainable Development
DENR	Department of Environment and Natural Resources, Philippines
DNA	Deoxyribonucleic Acid
DOE	Department of Energy
DPA	Department of Political Affairs
DSD	Division for Sustainable Development
DURC	Dual Use Research of Concern
E.coli	*Escherichia coli*
EA	Environmental Assessment
EAggEC	*Entero Aggregative Escherichia coli*
EBSA	European Biosafety Association
ECBS	Expert Committee on Biological Standardisation

ECHR	European Court of Human Rights
EHEC	Enterohemorrhagic strain bacterium Escherichia coli
EIA	Environmental Impact Assessment
EIS	Environment Impact Statement
EMC	Erasmus Medical Centre
ENVISEC	Environment and Security Initiative
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FBI	Federal Bureau of Investigation
Forest Principles	Authoritative Statement of Principles for a Global Consensus on the Management, Conservation and Sustainable Development of All Types of Forests
FSRA	Final Supplementary Risk Assessment
G20	Group of 20
G77	Group of Seventy Seven
GACP	Guidelines on Good Agricultural and Collection Practices
GAPs	Good Agricultural Practices
GCP	Good Collection Practices
GCR	Global Catastrophic Risk
GEF	Global Environmental Facility
GMOs	Genetically Modified Organisms
GMPs	Good Manufacturing Practices
GPO	Government Printing Office
hCoV-EMC	human betacorona virus 2c EMC
HHS, US	Department of Health and Human Services, United States
HIV/AIDS	Human Immuno Deficiency Syndrome
IAEA	International Atomic Energy Agency

IBCs	Institutional Biosafety Committees
IBRPs	International Biological Reference Preparations
ICBMs	Intercontinental Ballistic Missiles
ICCPB	Intergovernmental Committee for the Cartagena Protocol on Biosafety
ICJ	International Court of Justice
ICRC	International Committee of the Red Cross
IDLO	International Development Law Organisation
IEDs	Improvised Explosive Devices
IHR	International Health Regulations
IHR 2005	International Health Regulations 2005
IIED	International Institute for Environment and Development
IISD	International Institute for Sustainable Development
ILA	International Law Association
ILC	International Law Commission
IMF	International Monetary Fund
INFOSAN	International Food Safety Authorities Network
IPPC	International Plant Protection Convention
IRBs	Institutional Review Boards
ISDL	International Sustainable Development Law
ISP	Intersessional Process
ISU	Implementation Support Unit
ITLOS	International Tribunal of the Law of the Sea
ITPGRFA	International Treaty on Plant Genetic Resources in Food and Agriculture
ITTA	International Tropical Timber Agreement
IUBMB	International Union of Biochemistry and the Molecular Biology

IUPAC	International Union of Pure and Applied Chemistry
JE	Japanese Encephalitis
JI	Jemaah Islamiah
Kyoto Protocol	Kyoto Protocol to the United Nations Framework Convention on Climate Change
LLNL	Lawrence Livermore National Laboratory
LMOs	Living Modified Organisms
LSE	London School of Economics and Political Science
MARU	Middle America Research Unit
MDG	Millennium Development Goals
MEA	Multilateral Environmental Accords
MNC	Multinational Corporation
Montreal Protocol	Montreal Protocol on Substance that Deplete the Ozone Layer
MTA	Material Transfer Agreement
NAM	Non-Aligned Movement
NATO	North Atlantic Treaty Organisation
NBF	National Biosafety Framework
NEPA	National Environmental Policy Act, United States
NGO	Non-Governmental Organisation
NIH, US	National Institute of Health, United States
NRA	National Regulatory Authorities
NRC	National Research Council
NSABB	National Security Advisory Board for Biosecurity
NTI	Nuclear Threat Initiative
ODA	Official Development Assistance
OECD	Organisation for Economic Cooperation and Development

OHCHR	Office of the United Nations High Commissioner for Human Rights
OIE	World Organisation for Animal Health
OPCW	Organisation for the Prohibition of Chemical Weapons
OSCE	Organisation for Security and Cooperation in Europe
PCA	Permanent Court of Arbitration
PhD	Doctoral degree
PHEIC	Public Health Emergency of International Concern
PIC	Prior Informed Consent
PIPF	Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits
PrepCom	Prepatory Committee
Ramsar Convention	Ramsar Convention on Wetlands
Rio Declaration	Rio Declaration on Environment and Development
RKI	Robert Koch Institute
RMC	Rajneeshee Medical Corporation
SARS	Severe Acute Respiratory Syndrome
SBSTTA	Subsidiary Body on Scientific, Technical and Technological Advice
SDGs	Sustainable Development Goals
SIPRI	Stockholm International Peace Research Institute
SOP	Standard Operation Procedure
SPS	Sanitary and Phytosanitary Agreement
SPS Programme	Science for Peace and Security Programme
Stockholm Declaration	Declaration of the United Nations Conference on the Human Environment
STS	Science and Technology Studies

TB	Tuberculosis
TBT	Technical Barriers to Trade Agreement
TED	Turtle Excluder Device
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UDT	Universal Detection Technology
UK	United Kingdom
UKE	University Medical Centre Hamburg-Eppendorf
UKM	National University of Malaysia
UM	University of Malaya
UN	United Nations
UN Charter	Charter of the United Nations
UNCAC	United Nations Convention against Corruption
UNCCD	United Nations Convention to Combat Desertification
UNCED	United Nations Conference on Environment and Development
UNCHE	United Nations Conference on the Human Environment
UNCLOS	United Nations Convention on the Law of the Sea
UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Programme
UNEP	United Nations Environment Programme
UNFCCC	United Nations Framework Convention for Climate Change
UNGA	United Nations General Assembly
UNHCHR	United Nations High Commissioner for Human Rights
UNODA	United Nations Office for Disarmament Affairs
UNODC	United Nations Office on Drug Cooperation

UNOG	United Nations Office at Geneva
UNSC	United Nations Security Council
UNSCOM	United Nations Special Commission
US	United States
USAMRIID	United States Army Medical Research Institute
USNAS	United States National Academy of Sciences
VBMs	Valuable Biological Materials
VCLT	Vienna Convention on the Law of Treaties
VCSPAD	Vienna Convention on State Succession in Respect of State Property, Archives and Debts
VEE	Venezuelan Equine Encephalitis
WCED	World Commission on Environment and Development
WFC	World Future Council
WHO	World Health Organisation
WMD	Weapons of Mass Destruction
World Heritage Convention	1972 Convention for the Protection of the World Cultural and Natural Heritage
WSSD	World Summit on Sustainable Development
WTC	World Trade Centre
WTO	World Trade Organisation

CHAPTER 1: INTRODUCTION

1.1 Introduction

This study seeks to understand the problem of a persisting sectorial approach among different biosecurity sectors, as reflected within and among selected international biosecurity agreements and initiatives. This study will attempt to analyse whether the introduction or existence of principles of international law from the New Delhi Declaration of Principles of International Law Relating to Sustainable Development (hereinafter Delhi Declaration; International Law Association [ILA], 2002) is able to integrate different biosecurity sectors towards recognising the interrelationship within and among selected international biosecurity agreements and initiatives for a better cooperation. The Cartagena Protocol on Biosafety (CPB, 2000), the Convention on the Prohibition of the Development, Protection and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction (in short: the Biological Weapons Convention or BWC, 1972), the International Health Regulations 2005 (IHR 2005, 2005), and the World Health Organisation's (WHO's) laboratory biosecurity and biopharming initiatives have all been selected because their specific sectoral functions require that interlinkages be formed among them as biosecurity is multifaceted.

The principles of the Delhi Declaration have been chosen because they provide an effective means of gauging whether international biosecurity agreements and initiatives equally address the environment, trade, economic and social development issues through integration. The principles of the Delhi Declaration also have inferences to issues of development between developed and developing states and within states as well. It is anticipated that the findings of this study can provide some useful insights into international organisations and states bureaucracy, and that the key to a coherent management of biosecurity, legally and policy-wise, lies with the adoption of the ISDL

principles among related international agreements and initiatives. The methodology for this study is qualitative: hence a doctrinal, socio-legal approach through a documentary, textual and content analysis.

This chapter begins with a look at the background and context of this study. This is followed by the problem statement, statement of purpose, accompanying research questions and objectives. Also included in this chapter is the scope, operational definition of biosecurity, the justification and contribution to the literature, and an outline of chapters.

1.2 Context and Background

The international regulation of biosecurity is very complex, as it consists of a whole range of international agreements binding on states, as well as non-binding initiatives voluntarily adhered to by states. Managing these various international biosecurity agreements and initiatives are competent international organisations and agencies that form the institutional framework with respective mandates that are sector-specific. A major flaw in the sectorial approach is that it fails to recognise the interrelatedness of different international agreements and initiatives in view of a more coherent management.

Indeed, some impediments towards recognising the complementary role of biosecurity international agreements and initiatives include the question of whether member states have a vested interest in international cooperation since they will decide the issues put on the agenda of international organisations that monitor these international instruments (Rhodes, 2008a, p. 45). Other possible reasons are the unwillingness to encroach upon the jurisdiction of other biosecurity organisations, financial constraints, lack of expertise in another biosecurity area, and the attitude of the individuals that hold key positions within these international organisations (Rhodes, 2008a, pp. 45-48).

As a result of the continued segregated and sectorial approach to biosecurity, negative ramifications include the lack of clarity concerning which international agreements should actually apply when they lack self-referencing to one another and should these agreements address the same issues, leading to confusion among states over which international regulations are applicable (Rhodes, 2008a, pp. 165-166). Other implications include the need to reconcile contradictory provisions within international agreements, for while these agreements may address the same issue, they may prescribe different actions to be taken, creating uncertainty among state implementers (Rhodes, 2008a, pp. 165-166). For instance, the development and testing of genetically modified biological agents on an island may invoke CPB provisions as there are environmental ramifications but may also invoke the BWC provisions. States may be confused as to which international agreements will be applicable, and this needs to be clarified by the respective international organisations through cooperation and discussion so as to provide valuable advice to states. Subsequently, the fragmentation of international biosecurity regulations encourages states to identify the best forum for their dispute settlement among international agreements, namely a forum that will guarantee them victory in a dispute (Rhodes, 2008a, pp. 166-167). Besides, the disjunction in international biosecurity agreements and initiatives leads to overlaps, especially concerning provisions on scientific and technical assistance to developing states, sometimes resulting in the duplication of efforts (Rhodes, 2008a, p. 167). As a remedy to the incohesiveness in biosecurity governance, Rhodes (2008a, p. 172) pointed out that cooperation between international agreements and international organisations monitoring them is needed but cautions that support from member states is crucial to its success.

This calls for an extended scope to biosecurity that bridges the boundaries between the fragmented sectors. Meyerson and Reaser (2002a, 2002b), for instance, favour an expanded scope to biosecurity that not only addresses the public health impacts of

biological weapons and infectious diseases but also incorporates agricultural biosecurity, thereby extending its boundaries to cover quarantined pests, invasive alien species, and genetically modified organisms (GMOs).[1]

Likewise, Koblentz (2010, p. 108) also favours a comprehensive approach to biosecurity because it "offers an overarching concept for an otherwise fragmented field". An extended biosecurity scope also provides an umbrella framework under which scholars and practitioners from a wide range of disciplines, agencies, sectors, organisations and states can cooperate with one another in developing strategies that prevent, prepare and respond to naturally-occurring and man-made diseases (Koblentz, 2010, p. 108). An expanded scope of biosecurity also offers a framework to assess and compare the dangers posed by different biological threats (Koblentz, 2010, p. 108). This shows an increasing awareness that biosecurity can no longer be approached sectorally because biosecurity problems encroaches upon varying sectors.

In this regard, there must be a suitable means which is able to resolve the sectorial approach to biosecurity within and among international agreements and initiatives. Indeed, Stannard, Graaff, Randell, Lallas and Kenmore (2004, pp. 426-427) have reiterated the integrative role that sustainable development can play in empowering and consolidating international biosecurity agreements in the areas of agriculture and the environment, such as the International Plant Protection Convention (IPPC, 1951) and the Convention on Biological Diversity (CBD, 1992). The scholarly work by Rhodes (2007) is of relevance in interconnecting sector-specific international agreements in biosecurity and sustainability.

[1] Article 3(h) of the CPB (2000) defines living modified organisms (LMOs) as "any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology". For the purpose of this study, LMOs will also be understood to mean genetically modified organisms (GMOs) which refers to both the living and non-living forms of microorganisms being modified through genetic engineering. It is here acknowledged that although the CPB uses the term LMOs, since GMOs are more commonly used, this term will be used throughout this study.

Building on the assumption by Stannard et al. (2004) and Rhodes (2007, 2008b) that sustainable development can link together different biosecurity sectors and their respective international agreements and initiatives, this study will analyse whether the introduction or existence of principles of international law in the Delhi Declaration can play a reconciliatory role among the CPB (2000), BWC (1972), IHR 2005, and WHO's laboratory biosecurity and biopharming initiatives. These are the seven principles of the Delhi Declaration: (i) the duty of states to ensure sustainable use of natural resources, (ii) the principle of equity and the eradication of poverty, (iii) the principle of common but differentiated responsibilities, (iv) the principle of the precautionary approach to human health, natural resources and the ecosystems, (v) the principle of public participation and access to information and justice, (vi) the principle of good governance, and (vii) the principle of integration (ILA, 2002).

These principles of the Delhi Declaration are used as analytical tools, for the assumption here is that their presence within the texts of international biosecurity agreements and initiatives can be considered integral to matters of biosecurity such as the impacts on the environment, trade, health, inter- and intra-generational equity within and among states, the precautionary approach, security and arms control, public participation, good governance, as well as common but differentiated responsibilities among states. If and when each international biosecurity agreement and initiative incorporates these principles directly or indirectly wherever applicable in its text, it not only addresses the multidimensional aspects of any biosecurity problem but also leads towards achieving the objective of sustainable development.

For this study, different forms of biosecurity sectors with their respective international agreements and initiatives such as the CPB (environment), BWC (arms control), IHR 2005, and WHO's laboratory biosecurity and biopharming initiatives (health) were selected. The CPB (2000) has been associated with the agricultural biosecurity sector by

the Food and Agriculture Organisation of the United Nations (FAO) which defined it as "a strategic and integrated approach that encompasses the policy and regulatory frameworks (including instruments and activities) for analysing and managing relevant risks to human, animal and plant life and health, and associated risks to the environment" (FAO, 2007, p. 3). For their part, the BWC (1972) and IHR 2005 are associated with the biosecurity of biotechnology, understood by the United States National Academy of Sciences (USNAS) as "security against the inadvertent, inappropriate, or intentional malicious or malevolent use of potentially dangerous biological agents or biotechnology, including the development, production, stockpiling, or use of biological weapons as well as natural outbreaks of newly emergent and epidemic diseases" (N.R.C. Committee, 2006, p. 32). Additionally, there is the WHO's initiative of laboratory biosecurity defined as "the protection, control and accountability for valuable biological materials (VBMs) within laboratories, in order to prevent their unauthorised access, loss, theft, misuse, diversion or intentional release" (WHO, 2006, p. iv).

In this regard, focusing on the aforementioned international agreements and initiatives is justified by the need to analyse whether they can regard a wide array of issues affecting biosecurity and whether they are integrative to other areas besides their own. While these international biosecurity agreements and initiatives are currently segregated with minimal interaction among them, coordination of their scope of work through cooperation among international organisations and agencies managing them is crucial. Only by complementing each other's mandate will a biosecurity problem with multiple effects across sectors be dealt with effectively through a coordinated approach.

Therefore, this study intends to shed light on whether the incorporation or presence of the principles of international law from the Delhi Declaration within the text of these international biosecurity agreements and initiatives, wherever applicable, can reduce the negative effects of a sectorial approach towards sustainable development.

1.3 Problem Statement

There is a problem with the governance of biosecurity being dealt with in a sectorial manner by international organisations and agencies and their respective mandates. Despite the need to deal with biosecurity holistically by building interlinkages among sectors, together with their respective international agreements and initiatives, in order to be able to resolve any biosecurity issue encroaching across multiple sectors, recognition of the interrelationship barely exists while the sectorial approach still persists. These specific international biosecurity agreements and initiatives include the BWC (arms control), CPB (environment), IHR 2005 (health), and WHO's laboratory biosecurity and biopharming (health) initiatives, all of which have their own specialisation. This problem has negatively impacted the governance of these international organisations, as respective agencies and policy makers fail to obtain a comprehensive picture of complex biosecurity issues spanning across sectors, and in so doing render them unsolvable unless connections are facilitated among the various international instruments. Possible causes of this problem include nonchalant member states with no vested interest in ensuring coordination among international biosecurity instruments, the reluctance among international biosecurity organisations to encroach on each other's mandate, the unhelpful attitude of those holding office, financial constraints, and a lack of expertise in other biosecurity areas (Rhodes, 2008a, pp. 45-48).

One consequence of this is the inability to deal with a biosecurity problem that spans across sectors because multiple international instruments may be applied simultaneously. However, states and custodians of these international instruments are unclear on how to reconcile the contradictory provisions in international biosecurity agreements, as they prescribe different actions to be taken in dealing with the same issue. For instance, a genetically modified biological agent meant as a vaccine to be tested on open ground causes environmental contamination, thereby invoking the CPB and BWC because this

involves the development and testing of a biological agent having dual use, i.e. it may be channelled towards a biological weapon. Since both international biosecurity agreements are applicable, custodians must coordinate and cooperate in advising states over the coverage of these international instruments so as to avoid overlapping jurisdictions while respecting each other's mandate in executing their prescribed duties. Therefore, a qualitative study utilising the seven principles from the Delhi Declaration of International Sustainable Development (ISDL) through a textual analysis that interprets their presence among provisions of the aforementioned international biosecurity instruments should proffer the means of interlinking the various sectors and the broad issues they address, thus allowing them to complement each other's role. In anticipation, international organisations, agencies and states should practically apply these seven principles from the Delhi Declaration of ISDL, as this is one solution toward enjoining disparate biosecurity sectors with their respective international instruments.

1.4 Purpose Statement

The purpose of this study is to determine whether principles of international law in the Delhi Declaration of ISDL can provide a solution towards linking together the different biosecurity sectors and their respective international agreements and initiatives within the context of GMOs for a coherent management among international organisations.

It is anticipated that the application of these principles of the Delhi Declaration can help international organisations and policy makers to better understand the interconnectedness of different biosecurity sectors and their respective international agreements and initiatives in view of a better biosecurity management.

1.5 Research Questions

To shed light on this problem, the following research questions are raised:

i) What are the scope, limitations, relevant recommendations and risk management practices that would be needed to harmonise the various biosecurity sectors and their respective international instruments?

ii) What principles of international law can be gleaned from the New Delhi Declaration of Principles of International Law Relating to Sustainable Development?

iii) How are the principles of international law in the Delhi Declaration of ISDL being reflected in the selected international biosecurity agreements and initiatives?

1.6 Objectives

This research has the following objectives:

i) To determine the scope and limitations, as well as to suggest relevant recommendations and risk management practices to harmonise various biosecurity sectors and their respective international instruments;

ii) To identify the principles of international law in the Delhi Declaration of ISDL;

iii) To analyse the relevant provisions from selected international biosecurity agreements and initiatives that reflect the principles of international law in the Delhi Declaration, wherever applicable.

1.7 Scope of Study

This study analyses the CPB, BWC, IHR 2005, WHO's laboratory biosecurity and biopharming initiatives (representing different biosecurity sectors) as a case study and not

a whole assortment of other international biosecurity instruments beyond the scope and word limitation of this study. This study does not focus on pests and diseases brought by plants and animals but only on human diseases and food safety, thereby eliminating the need to refer to the IPPC and World Organisation for Animal Health (OIE) initiatives on biosecurity. Elaboration of the CPB will strictly focus on genetic engineering and will not be extended to synthetic biology, doing away with the need to refer to documents on the latter.

As to the BWC, the analysis focuses on peacetime rather than warfare, doing away with the need to refer to international humanitarian law.

The application of principles of the Delhi Declaration is mainly restricted to provisions of international biosecurity agreements at the expense of WHO's non-binding documents on laboratory biosecurity and biopharming.

This study does not intend to cover a whole range of issues and debates associated with sustainable development. A brief historical overview regarding the evolution of sustainable development, its status in international law and its relevance to ISDL is provided.

This study will not attempt to analyse how the provisions of international biosecurity agreements and principles of the Delhi Declaration are implemented among states. The resources used for this study have also been set to a time limitation no later than 2016.

1.8 Operational Definition of Biosecurity

In line with this study's purpose of integrating various international biosecurity agreements and initiatives bridging across three sectors, a broad definition of biosecurity is used throughout this study, as laid out in the following:

> *Biosecurity is an integrative overarching concept addressing the overlap between different sectorial aspects of biosecurity ranging from biosafety and laboratory biosecurity; agricultural biosecurity*

protection from biological harm occurring naturally or artificially (diseases, pests, food safety and agroterrorism); the unintentional and intentional misuse of select biological agents, toxins, biotechnological knowledge and equipment for benevolent or malevolent purposes, such as bioterrorism and biological warfare requiring risk management practices, both binding and non-binding initiatives, as forms of defence to prevent, reduce or eliminate biological threats.

Notably, this study's proposed definition of biosecurity draws a distinction between laboratory biosecurity and agricultural biosecurity, as the latter not only covers diseases and pests but food safety, too. Agroterrorism, understood as "the deliberate introduction of an animal or plant disease with the goal of generating fear, causing economic losses, and/or undermining social stability" (Monke, 2004, p. 1), has been added to this definition of biosecurity because the FAO's definition fails to acknowledge the misuse of biotechnology that can harm agricultural crops and the food supply chain. Added to this definition is biological warfare since some states are still secretly churning biological agents into biological weapons (Bolton, 2002). The risk management practices being proposed for biosecurity cover both binding and non-binding initiatives referring to relevant policies, laws and current administrative actions or those to be newly formulated and implemented. These risk management practices are designed to prevent, reduce or eliminate any biological threat that endangers the national security of any state. Further elaboration on the reason for adopting such a broad definition and scope of biosecurity will be made in Chapter 4.

1.9 Justification and Contribution to the Literature

The rationale for this study is to uncover a suitable means to assist and convince international organisations, policy makers, academics and other stakeholders that

adopting principles from the Delhi Declaration of ISDL can bring together disparate international biosecurity agreements and initiatives with a view towards improving existing practice and policy for a coherent management.

This study also makes a significant contribution at the theoretical level in analysing biosecurity international agreements and the ISDL itself. The analysis of the BWC and IHR 2005 in light of the principles of the Delhi Declaration significantly contributes to the existing sparse literature linking international arms control law, international health law and ISDL, as scholars to date have hardly delved in-depth into this grey area, rendering this study more relevant than ever as an attempt to fill in an existing gap. This study's analysis of the CPB provisions from the angle of bioterrorism and biological warfare also enriches the sparse literature in this area, as the CPB has mostly been analysed within the context of GMOs in agriculture.

This study's approach of utilising the principle of integration in ISDL to facilitate convergence among different international biosecurity instruments differs from previous attempts that used other means such as multilateralism, global governance and global policy networks (Al-Rodhan, Nazaruk, Finaud & Mackby, 2008), and epistemic communities (Mariani, 2007). As such, enjoining different international biosecurity instruments through the principle of integration in ISDL makes a significant contribution not only in the area of ISDL but biosecurity studies as well.

The holistic biosecurity definition proposed in this study, one that combines that of the FAO, WHO and USNAS with a view to being adopted by relevant international organisations, policy makers and academics, makes a unique contribution to biosecurity studies, especially since previous definitions have tended to be highly sectorial.

1.10 Outline of the Chapters

Overall, the whole study is divided into ten chapters, with the contents of each chapter briefly elaborated below:

(a) Chapter 1 gives an introduction to the whole study with a look at the context and background, the problem and purpose statement, research questions and objectives. The scope of the study, its justification and contribution to the literature are also covered here. An operational definition of biosecurity as well as an outline of the various chapters are also provided.

(b) Chapter 2 elaborates on the literature review covering the following subtopics: (i) The Biosecurity Sectors and Associated International Agreements and Initiatives; (ii) Situating Biosecurity in the Broader Realm of Security; (iii) Awareness of Connecting International Agreements and Initiatives Across Biosecurity Sectors; (iv) Previous Means of Linking Biosecurity International Agreements and Initiatives Across Sectors; (v) Sustainable Development as an Integrator of Biosecurity Sectors; (vi) Current Application of the Principles of the Delhi Declaration among Biosecurity International Agreements and Initiatives; (vii) Research Gap; and (viii) Summary. Chapter 2 also explains the conceptual framework formulated for this study, which was derived after an extensive literature review was conducted.

(c) Chapter 3 explains the methodology used in this study. The research design is divided into the following subtopics: (i) The epistemological position; (ii) The research methodologies; and (iii) The research methods. A brief conclusion draws this chapter to a close.

(d) Chapter 4 further introduces the different sectors of biosecurity with their associated international agreements and initiatives in light of genetic engineering and the current limitations of biosecurity as approached from segmented sectors. Through an

analysis of the German *Escherichia Coli* (*E.Coli)* case, the weaknesses of approaching biosecurity as segregated sectors become clear. This requires a holistic biosecurity definition if the current mindset and approach to biosecurity are to change. This has been assisted by a United Nations (UN) coordination mechanism that is able to build linkages among international organisations and agencies that manage respective international agreements and initiatives, allowing them to collaborate with one another towards a more coherent management policy-wise at the international level.

(e) Chapter 5 introduces a brief history of sustainable development, the meaning of sustainable development, the principles of the Delhi Declaration of ISDL that will be used to evaluate the CPB, BWC, IHR 2005, and WHO's laboratory biosecurity and biopharming initiatives in Chapters 6-8, the implementation of ISDL, and the status of sustainable development in international law.

(f) Chapter 6 examines the CPB, primarily as an international agreement on agricultural biosecurity, even though it also inquires whether other forms of biosecurity issues like bioterrorism, biological warfare and laboratory biosecurity can similarly be addressed directly or indirectly among the CPB's provisions and in light of the principles from the Delhi Declaration of ISDL so as to come up with one that merges such disparate biosecurity areas.

(g) Chapter 7 similarly analyses the BWC, primarily as an international biosecurity agreement that addresses biological warfare, bioterrorism, agricultural and laboratory biosecurity, as well as diseases in light of the principles of international law from the Delhi Declaration of ISDL.

(h) Chapter 8 examines WHO's IHR 2005, laboratory biosecurity and biopharming initiatives against the seven principles from the Delhi Declaration of ISDL, wherever these principles become applicable. These WHO biosecurity initiatives are evaluated in

as much as they relate to the CPB and BWC, in line with the intention of bringing together disparate biosecurity sectors, as well as their respective international agreements and initiatives.

(i) Chapter 9 discusses the findings of this research. This chapter integrates and synthesises the notable conclusions from previous chapters.

(j) Chapter 10 is the concluding chapter which summarises the key findings of this study. This chapter will also put forth some recommendations and identify areas for further research within the realm of international biosecurity agreements and initiatives.

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

The purpose of this study is to determine whether principles of international law in the New Delhi Declaration of Principles of International Law Relating to Sustainable Development (hereinafter Delhi Declaration; International Law Association [ILA], 2002) can provide a solution that links together the different biosecurity sectors and their respective international agreements and initiatives within the context of genetically modified organisms (GMOs) for a more coherent management among international organisations.

In line with the purpose of this study, a review of the relevant literature will proceed according to the following subtopics: (2.2) The Biosecurity Sectors and Associated International Agreements and Initiatives, (2.3) Situating Biosecurity in the Broader Realm of Security, (2.4) Awareness of Connecting International Agreements and Initiatives across Biosecurity Sectors, (2.5) Previous Means of Linking Biosecurity International Agreements and Initiatives Across Sectors, (2.6) Sustainable Development as an Integrator of Biosecurity Sectors, (2.7) Current Application of the Principles of the Delhi Declaration among International Biosecurity Agreements and Initiatives, (2.8) The Research Gap, and (2.9) Summary.

The justifications for choosing subtopics (2.2-2.7) for this literature review are as follows. Subtopic (2.2) has been chosen as it is imperative to understand the various forms of biosecurity in existence and their respective international instruments. Biosecurity needs to be situated within the realm of security studies, as in subtopic (2.3), because as the term security suggests, there are different security implications being invoked, all depending on the form of biosecurity being addressed. As to subtopic (2.4), there is a need to understand the extent to which scholars in the biosecurity sphere have interconnected these international instruments, merely within the same or across sectors,

as a means of gauging the level of awareness on how to link disparate biosecurity sectors. With regard to subtopic (2.5), a critical review that identifies weaknesses in suggestions by previous studies concerning the means to merge biosecurity sectors is needed to justify the use of principles from the Delhi Declaration, which has its own strength considering that states have signed and ratified these international biosecurity agreements. As to subtopic (2.6), the rationale here is to gauge the limited extent to which scholars have viewed sustainable development as a means of connecting disparate biosecurity sectors and their respective international instruments within or across sectors. This study will identify such a gap before attempting to fill it. Concerning subtopic (2.7), the review is intended to assess the extent and context to/in which the principles of the Delhi Declaration have been applied among international biosecurity instruments identified in this study to make up for the aspects that are yet to be addressed. Based on a thorough review in subtopics (2.2-2.7), this study will then outline a research gap in subtopic (2.8) concerning areas this study intends to cover. The summary, provided in subtopic (2.9), will show how the literature has informed the researcher's understanding of the issues, as well as being helpful in the development of this study's conceptual framework.

In conducting this literature review, multiple sources of information were utilised such as books, book chapters, scholarly journals, dissertations, conference and working papers, as well as other periodicals. These sources were obtained from academic databases such as Westlaw, Lexis-Nexis, Ebsco, Emerald, Heinonline, and from Google Scholar. There was no delimiting timeframe for these materials on biosecurity, the principles of International Sustainable Development Law (ISDL), and the respective international biosecurity instruments, as this could have precluded materials crucial for this study. Subsequently, Section 2.2 will introduce the various biosecurity sectors and their associated international instruments.

2.2 Biosecurity Sectors and Associated International Agreements and Initiatives

International agreements and initiatives, linked to biosecurity, have all been divided into sectors dependent on biosecurity's definition and scope. Graaf and Khoury (2010, p. 10) as well as Rhodes (2010, p. 164) can attest to the fact that biosecurity at the international level is segregated, which they attribute to related international agreements and initiatives being developed during different periods of time for historical reasons, and were thus formed as distinct issue areas that differ in membership. Moreover, Graaf and Khoury (2010, p. 10) emphasise the impossibility of bringing together these international agreements and initiatives because "[a]lthough a measure of consolidation at [the] international level would in theory be preferable, in practice this is not easy as existing treaties, organisations and programmes were concluded in different for after substantial negotiations followed by long adherence processes". While this may be the case, present biosecurity problems that have had spill-over effects into other sectors require reconciliation among related international agreements and initiatives.

Increasingly, current biosecurity problems are multi-dimensional in nature and span across many areas, be it the environment, trade, health, social and economic development, security, and arms control. Rhodes (2008b) reiterates that international regulations on biosecurity can no longer be confined within the sectors of arms and disease control or laboratory biosecurity but have significant interactions with trade and the environment. This requires that international agreements and initiatives be managed by their respective international organisations to consolidate efforts towards integration and cooperation in order to effectively address any biosecurity problem that encroaches into other sectors.

Indeed, the term biosecurity itself has multiple meanings. Rappert (2009, pp. 7-15) indicates that the definition of biosecurity has evolved over time to refer to biosecurity in the laboratory, biosecurity covering the intentional misuse of biotechnological

knowledge, biological agents, equipment and means of delivery (missile, bomb or other methods) for bioterrorism, as well as biosecurity associated with public health and diseases that occur naturally or deliberately inflicted. Rappert's notion of biosecurity with an evolving meaning is actually derived from various international organisations and their respective mandates which have offered their own definition of the term in terms of relevant international agreements and initiatives.

As indicated in Chapter 1, the Food and Agriculture Organisation of the United Nations (FAO's) version of biosecurity refers to it as agricultural biosecurity. The scope of agricultural biosecurity encompasses "food safety, zoonoses, the introduction of animal and plant diseases and pests, the introduction and release of [genetically modified organisms (GMOs)] and their products, and the introduction and management of invasive alien species" (FAO, 2007, p. 3). Furthermore, the FAO has extended biosecurity risk management to also cover the economic and social impacts wrought by pests, diseases, GMOs, invasive alien species, zoonoses and food security (FAO, 2007, p. 7). For the purpose of this study, the FAO's definition of biosecurity is understood as agricultural biosecurity which constitutes but one biosecurity sector.

In the category of agricultural biosecurity, scholars such as Graaf and Khoury (2010, pp. 7-13), Manzella and Vapnek (2007, p. 6), as well as Outhwaite (2010, pp. 211-215) have identified the Convention on Biological Diversity (CBD), the Cartagena Protocol on Biosafety (CPB), the Sanitary and Phytosanitary Agreement (SPS), the Technical Barriers to Trade Agreement (TBT), the International Plant Protection Convention (IPPC), some initiatives of the Codex Alimentarius Commission of the FAO and World Health Organisation (WHO), and the World Organisation for Animal Health (OIE) as constitutive of the international regulation on this version of biosecurity. Additionally, Manzella and Vapnek (2007, pp. 29-30) as well as Outhwaite (2010, p. 213) have also listed other additional international agreements and initiatives as constitutive of

agricultural biosecurity but will not be analysed in this study as they are beyond its scope.[1] The FAO's agricultural biosecurity definition is the earliest ever used (Baker, 2009, pp. 122-123). Still, the FAO's understanding of agricultural biosecurity fails to highlight any disease-harming humans, plants and animals that are man-made, and any intended to cause harm through bioterrorism or biological warfare (Centres for Disease Control, 2015).[2]

The WHO's version of biosecurity is known as laboratory biosecurity. Laboratory biosecurity controls valuable biological materials (VBMs), which is defined by the WHO as "[b]iological materials that require […] administrative oversight, control, accountability, and specific protective and monitoring measures in laboratories to protect their economic and historical (archival) value, and /or the population from their potential to cause harm" (WHO, 2006, p. v). VBMs cover pathogens, toxins, non-pathogenic organisms, vaccine strains, foods, GMOs, cell components, genetic elements and extra-terrestrial samples (WHO, 2006, p. v).

Notably, this definition of laboratory biosecurity differs from that of the FAO in emphasising measures to prevent stolen pathogens from being deliberately misused for bioterrorism. This WHO's understanding of laboratory biosecurity is intended to address the underlying cause of preventive measures, namely to prevent diseases from spreading to humans, plants or animals if and when pathogens are allowed to escape. In this study, the WHO's laboratory biosecurity initiative will be analysed in terms of the CPB and

[1] Other relevant international agreements listed include the Rotterdam Convention on Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, The Convention on Persistent Organic Pollutants, the FAO International Code of Conduct on the Use and Distribution of Pesticides, the FAO International Code of Conduct on Responsible Fisheries, the Protocol to the Antarctic Treaty on Environmental Protection, the Ramsar Convention on Wetlands, the Bonn Convention on the Conservation of Migratory Species of Wild Animals, the Global Programme of Action for the Protection of the Marine Environment from Land-Based Activities, the United Nations Framework Convention on Climate Change, and the United Nations Convention on the Law of the Sea.

[2] The Centres for Disease Control (CDC) (2015) in the United States defines bioterrorism as the "deliberate release of viruses, bacteria, or other germs (agents) used to cause illness or death to people, animals or plants". Contrastingly, biological warfare refers to the "wartime use of biological weapons".

BWC with a view to identifying whether these international agreements can together cooperate and coordinate their work.

The third form of biosecurity, known as the biosecurity of biotechnology, was provided by the United States National Academy of Sciences (USNAS), as mentioned in Chapter 1. This version of biosecurity addresses the misuse of biological agents, toxins, equipment utilised for these pathogens, and scientific techniques such as genetic engineering or synthetic biology for perpetuating bioterrorism and biological warfare. Resolution 1540 of the United Nations Security Council (UNSC) (S.C. Res. 1540, 2004) addressing export controls of biological agents, toxins and equipment, the Geneva Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare (1925) (hereinafter 1925 Geneva Protocol), and the Convention on the Prohibition of the Development, Protection and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction (in short: Biological Weapons Convention or BWC, 1972) are all international agreements and initiatives linked with this form of biosecurity (Al-Rodhan, Nazaruk, Finaud & Mackby, 2008, pp. 82-88). For the purpose of this study, the BWC has been chosen to represent the biosecurity of biotechnology in testing whether this international agreement would be able to form a cooperative relationship with both the CPB and the WHO's laboratory biosecurity initiative. The need to consolidate various biosecurity international agreements and initiatives is also justified because biosecurity has a bigger impact on security, as it is a highly charged term with different meanings and components that are interrelated, as will be explained in the next section.

2.3 Situating Biosecurity in the Broader Realm of Security Studies

The meaning of security is highly subjective, hence the different interpretations of the term. One form of security, known as human security, is concerned with the security and

wellbeing of individuals, and consists of different dimensions (United Nations Development Programme [UNDP], 1994, p. 6). According to the UNDP (1994, p. 25), one of the components of human security concerns economic security, understood as individuals being assured of basic income from productive and remunerative work or from a public safety net. This means securing employment to assure one's livelihood. The second component of human security refers to food security, defined as "a situation that exists when all people, at all times, have physical, social and economic access to sufficient, safe and nutritious foods that meets their dietary needs and food preferences for a healthy life" (FAO, 1996). According to Halvas and Salman (2011, p. 7), food safety that is compromised also affects food security. This is because the food supply chain that can be accidentally or purposely contaminated by pathogens as a premeditated act will affect the supply of food to the population, as they may have fears of consuming unsafe food that can lead to diseases which could even compromise international trade. Halvas and Salman (2011, p. 7) have indicated that food security which is endangered by terrorists' threat to intentionally contaminate the food supply chain is known as agroterrorism. Health security, the third pillar of human security, is concerned with the spread of diseases, naturally occurring or man-made, that not only affect human health but the environment, too (UNDP, 1994, p. 27). Environmental security, another aspect of human security, has been referred by the United Nations Environment Programme (UNEP) to "the area of research and practice that addresses the linkages among the environment, natural resources, conflict and peacebuilding" (UNEP, 2009, p. 7).

Besides, human security covers a plethora of other issues such as transnational terrorism and the misuse of weapons of mass destruction (WMDs) covering nuclear, chemical and biological weapons, be it for bioterrorism or biological warfare. Having set the parameters of the composition of human security, the varied forms of biosecurity will be reflected on in terms of the different dimensions of human security.

Tanentzap, Bazley, Williams, and Hoogensen (2009, pp. 100-102) have argued that the human security framework is ideally suited for researching the social and economic impacts of invasive non-indigenous plants, an aspect of agricultural biosecurity highlighted by the FAO concerning invasive alien species (FAO, 2007, p. 3). Kuhlau and Hart (2010, p. 176), in their elaboration over pathogens being misused either for biological warfare or bioterrorism (to cause diseases), highlight that this raises the health security aspect of human security. The emphasis by Kuhlau and Hart (2010) on bioterrorism and biological warfare indeed relates to the biosecurity of biotechnology. Biosecurity though is not limited to health security, as indicated by Kuhlau and Hart (2010). This study asserts that biosecurity will have implications for both environmental and economic security. Barnett (2010, p. 129) raises the danger that the population surrounding the Aral Sea may be exposed to widespread diseases arising from water and airborne pollution. This is attributed to genetically modified biological agents that were once released into the environment on Vozrozhdeniye Island, a testing ground of the former Soviet Union for biological weapons that is still causing damage to the environment (Micklin, 2004, p. 107; Nuclear Threat Initiative [NTI], 2011). Damage has been irreversible as the decontamination process on the ground takes time, depriving people of any economic activity such as ploughing the land or any such gainful employment that can trigger economic security. As rightly indicated by Barnett (2010, p. 131), military activities such as those of the former Soviet Union certainly caused pollution, raising environmental security concerns in connection with biological warfare, an aspect of the biosecurity as biotechnology. Food security also applies in the context of agricultural biosecurity when a biological agent is used to contaminate the food supply chain, as will be illustrated by the German *Escherichia coli* case (see Chapter 4), depriving people of a clean supply of food. This is a food safety issue addressed by the FAO in its agricultural biosecurity definition.

Not only is human security involved, but the traditional view of security that obliges the state to defend its territory from external military threats and attacks through military power is still relevant to biosecurity (Nasu, 2011, p. 16). This traditional notion of state security is still relevant to biological warfare, whereby states may develop biological weapons to be used against other states militarily if they envisage a potential threat from other states. Therefore, when broken down, the different aspects of biosecurity can be captured by different components of human security and that of traditional security involving states' territorial integrity and their right to defend it militarily.

2.4 Awareness of Connecting International Agreements and Initiatives across Biosecurity Sectors

At the international level, the cooperative and integrative efforts into bringing international biosecurity agreements and initiatives to complement each other in reality have not been matched by calls for an expanded biosecurity scope. Indeed, Graaf and Khoury (2010, p. 10), Litaay (2011, pp. 26-27), Manzella and Vapnek (2007, pp. 29-30), Outhwaite (2010, p. 209), and Stannard, Graaff, Randell, Lallas and Kenmore (2004, p. 399) have all recognised that biosecurity needs to be approached in an integrative manner to overcome overlaps that would waste resources in implementation, but yet still refer to integration within the confines of agricultural biosecurity among international agreements and initiatives within agriculture, trade and the environment. This is reflected in their call for cooperation among international instruments that reflect the FAO's agricultural biosecurity initiatives, namely the CBD, SPS, TBT, CPB, IPPC, and OIE initiatives (Graaf & Khoury, 2010; Manzella & Vapnek, 2007; Outhwaite, 2010; Stannard et al. 2004).

Increasingly, there is awareness among scholars of the linkages among international agreements and initiatives that bridge the boundaries across different biosecurity sectors. Graaf and Khoury (2010, p. 10) and Outhwaite (2010, p. 213), for instance, in scant

passing mention the BWC (without further elaboration) concerning its connection to other agricultural biosecurity agreements and initiatives. On the other hand, Manzella and Vapnek (2007, p. 31), in their elaboration of numerous international agricultural biosecurity agreements and initiatives, reckon that the BWC's relevance to biological weapons affects targeted plants and crops. Sture, Whitby, and Perkins (2013, pp. 296-305), for their part, relate the WHO's laboratory biosecurity guidance manual to the IHR 2005, BWC and UN Resolution 1540 within the confines of the biosecurity of biotechnology. Gronvall and Rozo (2015, pp. 12-24) have also referred to the CPB, IHR 2005, BWC and UN Resolution 1540 in drawing connection among international agreements and initiatives in the sectors of agricultural biosecurity and the biosecurity of biotechnology. The German Ethics Council (2014, pp. 88-93), for its part, seems to establish links among international agreements and initiatives between agricultural biosecurity and the biosecurity of biotechnology, as reflected in its reference to the BWC, CBD and CPB. Vöneky (2015, p. 122), too, refers to the BWC and CPB as international agreements relevant to the biosecurity of biotechnology and agricultural biosecurity.

While scholars have increasingly become aware of the connection between these two different biosecurity sectors, there are also signs of recognition of the linkages among international agreements and initiatives across laboratory biosecurity, agricultural biosecurity, and the biosecurity of biotechnology. Kallings (2012, p. 32) has provided a very comprehensive list of international agreements and initiatives on biosecurity spanning across three sectors, namely: the 1925 Geneva Protocol, the BWC, UN Resolution 1540, the CPB, the IPPC, the WHO's biosecurity guideline and other international initiatives. While there is growing recognition among scholars of the linkages among international agreements and initiatives that encroach upon the three biosecurity sectors, there have been few efforts to analyse in far greater detail how the

similarities and differences in these various international instruments can complement each other's work.

Few scholars have attempted to analyse in much greater depth the commonalities, differences, and ways in which the feasibility of the BWC can represent the biosecurity of biotechnology as being synergistic with the CPB within the realm of agricultural biosecurity. Anuradha (1999), Keele (2003, p. 125), Mauro (2001, pp. 119-122), Parker and Pate (2005, pp. 166-173) as well as Pearson (2000) have all indicated that the BWC and CPB share commonalities and can complement each other's work. Scholars such as Adell (2008, p. 8) and Stannard et al. (2004, p. 400) assert that the CPB is primarily concerned with agricultural biosecurity regarding GMOs as being invasive alien species and pests, thereby working closely with the IPPC. This raises the issue of whether the CPB can also consider biological warfare and bioterrorism as linked with the biosecurity of biotechnology. If genetic modification is used for developing biological weapons that are subsequently tested and released into the environment, this may trigger provisions from the CPB in the event that there are no other international agreements to monitor the testing of pharmaceutical products that could have an impact on the environment. Therefore, a gap exists as to whether the CPB can address the environmental contamination from GMOs derived from pharmaceutical products such as vaccine testing meant for biological warfare or bioterrorism as well as biopharming.

Moreover, some scholars have highlighted commonalities and potential collaboration between the CPB and BWC. Anuradha (1999, p. 132) and Pearson (2000, p. 29) have stressed that the Advanced Informed Agreement (AIA) in the CPB can be usefully applied to the BWC, as importing states will be notified in advance of the biological agents to be imported within their borders through a common list of biological agents shared

between both agreements (CPB art. 7, 2000).[3] Likewise, Anuradha (1999, p. 133), Mauro (2001, p. 122) and Pearson (2011, p. 8) have all advocated for Article 20 of the CPB addressing information exchange and the setting of a Biosafety Clearing House (BCH) to be used as a role model for Article X of the BWC so as to facilitate scientific, technical, environmental and legal information concerning a country's experience, capacity building project and funding opportunities — as both provisions are similar. Anuradha (1999, pp. 132-133) also recommends a common risk assessment process, and similar criteria for determining whether an end user has the capability and technology for the safe handling, use, transport and the release of transferred biological materials between both agreements.

Additionally, Anuradha (1999, p. 132) recommends that both the CPB and BWC issue end user certificates as evidence of permission for the usage of biological agents and with a common pool of experts available to advise on biological agents used. Both Anuradha (1999, p. 132) and Mauro (2001, p. 122) have asserted that the BWC and CPB could share commonalities with regard to compliance, liability and redress. Moreover, Anuradha (1999, p. 133) further proposes a common mechanism of inspectors and sanctions as well as similar dispute resolution mechanisms for both agreements. Mauro (2001, p. 122), too, highlights other areas to be explored between the BWC and CPB, like sharing the same socio-economic implications, confirmation, capacity building and technical-scientific methods for the recognition and monitoring of agents. Despite potential areas of commonalities and collaboration between the CPB and BWC, as proposed by these scholars, no thorough investigation has indicated whether the international organisations monitoring these international agreements have started collaborating in identifying areas

[3] See Article 7 of the *Cartagena Protocol on Biosafety*. The Advanced Informed Agreement (AIA) of the CPB is contained under Article 7. This requires the exporting country to inform the importing country in writing prior to the first shipment of international transboundary movement of GMOs for the intentional introduction into the environment. Accompanying the AIA are the risk assessments of GMOs through scientific techniques that would evaluate the possible adverse effects of GMOs on the conservation and sustainable use of biological diversity, taking into account the risks to human health.

in which they complement each other's work. Therefore, there is an existing gap, and hence the need for this study to analyse whether in reality the international organisations of both these agreements have started to collaborate in areas of commonalities and differences, and whether there are objections or support from state parties.

In enabling biosecurity international agreements and initiatives to have their scope of work converged, in-build provisions promoting cooperation among other international agreements and organisations are crucial. These in-build provisions within international agreements referring to the specialisation of other agreements are known as "self-referencing" whereby "[a] regulation may refer to others […] to avoid duplication or to make it clear that a particular issue is covered elsewhere in the set" (Rhodes, 2010, p. 134). For instance, Rhodes (2010, p. 136) explains that the CPB refers to other agreements and initiatives such as the IPPC, Codex Alimentarius Commission, the OIE, SPS and TBT. Rhodes (2010, p. 178), in her study of thirty-seven biotechnology international agreements and initiatives, found that some of these agreements contain "self-referencing" to other international agreements, indicating some internal awareness of these connections. Rhodes (2010, p. 176) also highlights that subsequent meeting documents to these international agreements and initiatives on biotechnology also showed self-referencing but this was not incorporated or amended among the international biotechnology agreements themselves.

Besides, Rhodes (2010, pp. 140-141) considers the "complementary provisions" as a catalyst to forming interlinkages and cooperation with other biosecurity international agreements and initiatives. By "complementary provisions", Rhodes (2010, p. 66) refers to conventions and protocols that complement one another whereby "each extending protection to a different subject matter for the same aims". To illustrate her point, Rhodes (2010, p. 141) refers to Article 2 of the IHR 2005, which is intended "to prevent, protect against, control and provide a public health response […] and which avoid unnecessary

interference with international traffic and trade" (IHR 2005, art. 2, 2005). In the example provided by Rhodes, she seeks to illustrate that a health regulation can be complementary to trade. Rhodes' (2010, p. 66) understanding of "complementary provisions" is similar to the principle of integration of ISDL, which not only focuses on the specialisation of an international agreement but also seeks to integrate other areas beyond its scope.

Rhodes (2010, p. 125) also found that there is some external awareness of the connection among disparate international biotechnology instruments through what she calls "common identity". "Common identity", in this instance, is referred by Rhodes to international organisations, the public, media, governments, other groups and organisations that are aware of the connection among these international biotechnology agreements and initiatives (Rhodes, 2010, p. 125). Rhodes' (2010, p. 178) overall conclusion in her study is that the international regulatory framework for biotechnology is still very much fragmented, as there is little awareness of the connections among them.

As shown in this subsection of the literature review, it is true that there is some form of "common identity" (Rhodes, 2010, p. 125), whereby there is external awareness among scholars of the linkages among varying international biosecurity agreements and initiatives. Whether there is internal awareness among international organisations and states so as to connect these various international biosecurity agreements and initiatives in terms of complementing each other's work, as illustrated by subsequent documents to these international agreements and initiatives, is contestable. Therefore, there is a lacuna in this area that requires not just examining the relevant international biosecurity agreements and initiatives to this study but also subsequent documents known as "soft law" (Ahrens, 2007, p. 84; Dekker, 2001, p. 60).[4] These will indicate whether

[4] See Ahrnens (2007, p. 84). Ahrnens defined soft law as rules that are not legally binding, as soft law does not belong to any traditionally accepted sources of international law but are political or moral commitments still having an influence on a state's behaviour. Some examples of soft law documents include declarations, resolutions by international organisations, guidelines, political or economic standards, and voluntary codes of conduct. The vagueness of soft law permits a wider range of action as it is not binding, which sets the direction for the development of the law.

international organisations and states are aware of the connectivity of international instruments across biosecurity sectors.

2.5 Previous Means of Linking International Biosecurity Agreements and Initiatives across Sectors

There have been attempts by scholars to link international biosecurity agreements and initiatives together across sectors; however, the means proposed by scholars do have weaknesses. Al-Rodhan et al. (2008, p. 191) linked the international agreements and initiatives representing various areas of biosecurity through theories of multilateralism, global governance, institutional liberalism, and global public policy networks within the scope of international relations. Al-Rodhan et al. (2008, p. 207) advocates for a new global biosecurity governance that is effective, and one not only involving states and international organisations through institutional liberalism at the international level, but there has to be the involvement by a multiplicity of actors including non-state actors, be it Non-Governmental Organisations (NGOs), Multinational Corporations (MNCs), or other relevant parties to the formation of global policy networks. Al-Rodhan et al. (2008, p. 207) not only refer to the CPB, BWC, IHR 2005, the WHO laboratory biosecurity initiative but include other multitude of initiatives at the regional level. An overarching biosecurity definition reflecting the different biosecurity sectors has been proposed by Al-Rodhan et al. (2008, p. 28), as provided below.[5]

Noticeably, the biosecurity definition proposed by Al-Rodhan et al. (2008, p. 28) has failed to address biological warfare by states. This is despite the fact that Al-Rodhan et al. (2008, pp. 82-84) had referred to the BWC and the 1925 Geneva Protocol, both agreements associated with biological warfare. It is certainly curious that Al-Rodhan et

[5] Al-Rodhan et al. (2008, p. 28) defines biosecurity as "a wide conceptual framework that integrates various aspects of both biosafety and biosecurity, and that thus reflects diverse sides of the biological security problem, ranging from the safety of all living organisms, protection from biological harm (diseases, pests, or bioterrorism), and risk management practices in defence against any biological threat, to preventing or eliminating the effects of intentional or unintentional misuse of the life sciences and technology".

al. (2008) have chosen to exempt biological warfare from their overarching biosecurity definition when they initially mentioned the two said agreements earlier.

While Al-Rodhan et al. (2008, pp. 82-84) clearly acknowledge bioterrorism in their biosecurity definition, biological warfare must still be included, as previously there were states such as the former Soviet Union that secretly utilised biological agents for biological warfare (Bolton, 2002). By neglecting biological warfare, it is as though this scourge is no longer important at present. A cue from the former Soviet Union's case of biological warfare shows that while attempts at destroying biological weapons have been made, there is still a spill-over effect for bioterrorism, namely, the attempts by terrorists to acquire them against the background of unguarded and lax security of former Soviet facilities (Tucker, Khamrakulov & Karimova, 2013). This indicates that biological warfare and bioterrorism are inexorably linked, a fact that still needs to be emphasised. Overall, the scholarly work of Al-Rodhan et al. (2008) is one major attempt at designing a specific model framework that brings together all international biosecurity agreements, initiatives and related parties to collaborate, including non-state actors. Al-Rodhan et al. (2008, p. 197) have also stressed in their model of global biosecurity governance the importance of including ethical principles in decision making, as well as transparency, equity and inclusiveness which are also of relevance. Most importantly, Al-Rodhan et al. (2008, pp. 137-141) have stressed that global efforts to combat bioterrorism by barring developing states access to biological agents, equipment, knowledge and processes can impede their own bio-development, which is utilising biotechnology to advance local development. As biosecurity is multidisciplinary, spanning across various sectors, Al-Rodhan et al. (2008, p. 229) highlight the need to analyse international policy instruments to identify cross-jurisdictional gaps and identify solutions that can help promote better global biosecurity governance.

Be that as it may, there are deficiencies with the proposal by Al-Rodhan et al. (2008) about uniting these various international biosecurity agreements and initiatives through multilateralism, global governance, institutional liberalism and global policy networks. These are merely theoretical and not necessarily mandatory, which would oblige states to put them into practice.

Mariani (2007, pp. 219-222), too, has argued that an "epistemic community" can be adopted within the context of linking GMOs and infectious diseases. For Mariani (2007, pp. 219-222), the connectivity between the CPB and IHR 2005 can be made through an "epistemic community", which is defined as a network of professionals with recognised knowledge and skills from different disciplines having shared causal beliefs that allow them from their analysis to foresee the connectivity between policy and outcomes, and from there to advise policy makers (Haas, 1992, p. 2). Mariani (2007, p. 219) foresees the "epistemic community" as a backdrop to a binding regime of treaties that promotes exchange of information among diverging expert views for the sake of reaching a consensus on issues and providing inputs to binding treaty regimes. By relying on "epistemic communities" that have already negotiated a compromise behind the scene, it is envisaged that policy makers among states will be in a better position to understand cross-sectorial matters in bringing the diverging biotechnology agreements to complement each other's specialisation, based on advice from these experts. Nevertheless, there is no guarantee that policy makers representing states during international negotiations will fully abide by the advice of these "epistemic communities", as this is left in the end to the discretion of policy makers.

Another solution was proposed by Baum and Wilson (2013, pp. 8-9), which was to have a universal treaty that covers all aspects of bioengineering, be it genetic engineering of GMO crops or creating deadly organisms. This is because existing international agreements such as the CPB and BWC are area-specific and are unable to deal with all

the risks of modern dual-use bioengineering (Baum & Wilson, 2013, p. 7). Another proposal was also put forth by Tucker (2002, p. 4), which was to have a Biosecurity Convention but one that would be limited in its scope so as to prevent diversion of biological agents for biological warfare and bioterrorism, with a view to complementing the work of the BWC. However, Tucker (2002, p. 4) does not envisage such a Biosecurity Convention to cover GMOs and biosafety, mainly to avoid a conflict of interest with the CPB.

While the proposal to draft new international agreements may be appealing, Murphy (2001, p. 136) and Rhodes (2010, p. 171) contend that this may be inappropriate for the following reasons. Murphy (2001, p. 136) highlights that states will suffer from "institution fatigue" and "treaty congestion" for spending too much time and resources on negotiations that could lead to the proliferation of more international organisations. Rhodes (2010, p. 171) disagrees with the creation of a single treaty because states with diverging views may not reach a compromise when there are many issues to cover. Rhodes (2010, p. 171) also raised a single treaty as unfeasible in terms of bringing different sectors together because this may very well encroach upon areas of existing treaties while negotiations tend to take a long time. Rhodes (2010, p. 171) favours existing treaties that are specialised in their own area because they are broader in focus and able to handle issues in-depth, while the withdrawal of existing international agreements will leave a void in terms of control within a specific area. This is not to say that some states may not sign or ratify a new comprehensive international agreement when their participation would really matter. Furthermore, it takes time for a new international agreement to come into force, depending on the majority needed for enforcement. Therefore, this option of forming a new international agreement to combine various diverging areas is not feasible for the reasons mentioned.

Nor is the proposal by Al-Rhodan et al. (2008) to combine multilateralism, global governance and global policy networks or Mariani's (2007, pp. 219-222) idea of "epistemic communities" because these are non-binding initiatives dependent on states' voluntary actions. This study proposes that the discipline of international law can offer a binding alternative by virtue of states being parties to international biosecurity agreements, hence bound to implement them once they have signed and ratified these international agreements.

2.6 Sustainable Development as an Integrator of Biosecurity Sectors

The integrative role of sustainable development and biosecurity has been recognised by Stannard et al. (2004) in enabling various international agreements on agriculture, trade, and the environment to complement each other. Stannard et al. (2004, p. 400) have emphasised the connection between the IPPC and invasive alien species as well as GMOs within the scope of the CBD and CPB, thereby linking agreements on agriculture and the environment within the ambit of agricultural biosecurity. Stannard et al. (2004, p. 425) also emphasised that biosecurity-related institutions have extended their scope beyond agricultural production to encroach upon public health and the environment. Stannard et al. (2004, p. 394) view the interaction among these different international biosecurity agreements as a way of policy integration, in line with sustainable development. Notably, the integration that Stannard et al. (2004, p. 399) refer to is limited to the agricultural biosecurity sector and has not been extended to the BWC within the biosecurity of biotechnology sector. Building from Stannard et al.'s (2004, p. 399) proposition that sustainable development can play an integrative role policy-wise in merging different international biosecurity agreements, this should be extended cross-sectorially to combine international instruments within agriculture biosecurity, laboratory biosecurity, and the biosecurity of biotechnology.

Rhodes (2007, pp. 24-32; 2008b), too, has also connected the international regulation for biosecurity and sustainability whereby she identifies the principles of sustainable development from documents such as the World Commission on Environment and Development (WCED) Report, better known as *Our Common Future*, the Rio Declaration on Environment and Development (Rio Declaration), Agenda 21, the Johannesburg Plan of Implementation from the 2002 World Summit on Sustainable Development (WSSD), and the Millennium Development Goals (MDG) of the United Nations (UN). The key principles that Rhodes have identified from these documents include the linkage between the environment and development as being integral, poverty and inequality as fundamental problems, the need for technology transfer and financial resources especially among developing states if they are to achieve some level of sustainable development (Rhodes, 2007, pp. 24-32). Rhodes (2007, pp. 26-27) has also identified other relevant principles from the said documents, such as common but differentiated responsibilities, distinguishing developed and developing states in their contribution and rectification measures to heal environmental damages, special and differential treatment for developing states, the precautionary approach in its application to the environment, and the linkage between health and development.

The principles of sustainable development that Rhodes (2007, pp. 32-36) identifies are then reflected among chosen biosecurity agreements such as the CPB, BWC, and IHR 2005 — all of which are relevant to this study. Rhodes (2007, pp. 36-38) then underlines how the CPB has incorporated sustainable development directly within its preamble as a goal to be achieved. While the BWC and IHR 2005 do not explicitly incorporate sustainable development in their texts, Rhodes (2007, p. 32) insists that these international agreements do contain provisions on scientific and technological development indicating capacity building and biotechnology knowledge transfer to developing states that are supportive of sustainable development. Rhodes (2007, p. 32) also indicates that biological

weapons are a threat to sustainable development because of their negative effects on health, the environment and development. Most importantly, Rhodes (2008b) highlights the need to connect the different sectors of biosecurity in the areas of biological warfare, disease control, and laboratory biosecurity, as they interact with the rules of trade and the environment. Rhodes (2008b) stresses the integration of different international biosecurity agreements bridging the sectorial approach by implying that international organisations and states must be aware of this connection and cooperate among themselves in the pursuit of sustainability. Another crucial point Rhodes (2007, p. 31) made is the lack of political will and commitment, especially among powerful states, towards achieving a sustainable development approach to biosecurity. Knowing that the BWC and IHR 2005 do not contain provisions that explicitly subscribe to sustainable development somehow opens a door to exploring whether other UN and WHO documents refer to these international agreements in a way that embraces sustainable development.

Indeed, the notion of identifying key principles of sustainable development is at least not something new within the realm of international environmental law. Subsequent to the United Nations Conference on Environment and Development (UNCED), the United Nations Division for Sustainable Development (in complying with the requests by states at the Second Session of the United Nations Commission on Sustainable Development that was held in 1994) produced the Report of the Expert Group Meeting on Identification of Principles of International Law for Sustainable Development (Goepel, 2010, pp. 1694-1718). This Report contained nineteen principles and concepts related to the international law of sustainable development taken from the Rio Declaration, Agenda 21, and other environmental agreements. In turn, the ILA Committee on the Legal Aspects of Sustainable Development decided to build upon the above Report and issued the New Delhi ILA Declaration on Principles of International Law relating to Sustainable Development as a resolution of the 70th Conference of the ILA held in New Delhi, India,

from 2-6 April, 2002 (ILA, 2002). Segger and Khalfan (2004a, p. 103) have defined ISDL as "the area of intersection between three fields of international economic, environmental and social laws". The Delhi Declaration contained seven principles pertaining to international sustainable development law that for the most part were already addressed in the Brudtland Report, the Rio Declaration, and in international environmental treaties. Further explanation on these seven principles of the Delhi Declaration will be provided in Chapter 5. It goes without saying that this study clearly builds upon Rhodes' study of sustainability principles, with the only difference being the use of the seven principles from the Delhi Declaration of ISDL to connect the diverging international biosecurity agreements and initiatives with the same goal of achieving sustainable development.

2.7 Current Application of Principles of the Delhi Declaration among International Biosecurity Agreements and Initiatives

This subsection will explore the extent to which principles of international law from the Delhi Declaration have been reflected in the CPB, BWC, IHR 2005, and WHO's laboratory biosecurity and biopharming initiatives (or wherever applicable) within the confines of their specialisation without encroaching on areas addressed by other international instruments.

2.7.1 Cartagena Protocol on Biosafety

The CPB is examined for provisions that facilitate a collaborative relationship with other agreements based on the principle of integration in ISDL. Segger and Khalfan (2004a, pp. 103-104) consider the CPB to be a highly integrative new regime of ISDL because its provisions equally address the environment, as well as economic and social matters, in line with its preamble's reference to sustainable development.[6] This means that the CPB, while strictly not focused on the environment, contains provisions that

[6] See the preamble of the Cartagena Protocol on Biosafety (2000) which addresses sustainable development as follows:
Recognizing that trade and environment agreements should be mutually supportive with a view to achieving sustainable development.

overlap with international trade, social development and health matters. Garforth, Yirfu and Fuji (2013, pp. 19-34), for instance, consider Article 15 and Annex III of the CPB covering risk assessment and Article 16 concerning risk management which identifies, evaluates, regulates, manages and controls possible adverse effects of GMOs on biological diversity covering the environmental component of the CPB. Garforth, Yirfu and Fuji, (2013, pp. 29-30), Jodoin (2005, p. 29), and Welch (2013, p. 149) also indicate that Article 26 of the CPB (addressing the socio-economic considerations of GMOs) illustrates the integration of sustainable development's economic pillar. Additionally, Segger, Welch and Frison (2013, p. 7) highlight the CPB's preamble which mentions trade and environmental agreements needing to be mutually supportive of each other in order to achieve sustainable development. Jaffe (2013, pp. 54-59) also refers to other provisions within the CPB including Article 2(4) that considers the Parties' other obligations under international law and Article 2(5) whereby Parties are to consider instruments and work undertaken in other forums, in particular human health. Besides these relevant provisions in the CPB already highlighted by scholars, there is also the need to further explore other relevant provisions which can facilitate cooperation with other international biosecurity agreements, mentioned in this study.

The relevant literature has also dealt with other principles of ISDL that have been identified among the CPB provisions. Segger et al. (2013, p. 10) have identified the principle of common but differentiated responsibilities within Article 22 of the CPB addressing capacity building and Article 28 on financial mechanism and resources. Hill (2013, p. 76) identifies the principle of precautionary approach to human health, natural resources and ecosystems within Article 10(6) and Article 11(8) of the CPB covering GMOs for food, feed and processing. Additionally, Segger et al. (2013, pp. 13-14) have referred to the principle of good governance in Article 34 addressing compliance, and Article 26 of the CPB covering the impact of socio-economic considerations of GMOs

within the context of the principle of equity and eradication of poverty. Besides, Segger et al. (2013, p. 12) as well as Skarlatakis and Kinderlerer (2013, p. 119) have cited Article 23 of the CPB, covering public participation and access to information, as being in line with the principle of public participation, access to information, and justice. The principle of sustainable use of natural resources has been singled out by Segger et al. (2013, p. 8) in terms of Article 1 of the CPB. This indicates that all seven principles of ISDL have been identified within the articles of the CPB.

While these principles of ISDL within the CPB have been interpreted in light of biosafety of GMOs in terms of agriculture, there is a need to shed light in this study on the very same principles as applied to the CPB but from the angle of bioterrorism and biological warfare. Vöneky (2015, pp. 122-123) refers to Article 25 of the CPB covering illegal transboundary movement of GMOs as being relevant to the context of biological agents being transferred across borders in light of bioterrorism. In view of the limited scholarly literature that have analysed the CPB provisions in light of bioterrorism and biological warfare, it goes without saying that an issue of such importance deserves a more in-depth look, a task that is left to this study.

While scholars have identified areas of commonalities between the CPB and BWC which can facilitate integration, there is a lack of interconnectedness in the regulatory efforts for GMOs and infectious diseases as represented by the IHR 2005 in its relation to the CPB, as highlighted by Mariani (2007). Mariani (2007, p. 209) highlights the scant attention paid to GMOs in the context of infectious diseases because the CPB does not address human health in much depth. Mariani (2007, p. xii) argues that the regulation of GMOs at the international level has barely included discussions of public health concerns, in particular the focus on infectious diseases. Mariani (2007, p. xiv) highlights the bias of international regulations on GMOs as being overly focused on international trade and

biological diversity but neglect the interaction between the side effects of GMOs and public health and the environment.[7]

Notably, Mariani (2007) refers to two international agreements, the CPB and IHR 2005, which are also relevant to this study's attempt at unification of fragmented biosecurity sectors. Mariani (2007, p. xiv)[8] has suggested that an epistemic community can integrate the segmented areas of GMOs between the CPB and IHR 2005. Mariani's (2007, p. 221) scholarly work is rare in terms of recognising the CPB's coordinating efforts with the IHR 2005, since the CPB does not specialise in addressing the impact of GMOs, as infectious diseases which are referred to by the WHO. Although Mariani makes a connection between the CPB and IHR 2005 as a health environment interface, there is no analysis in connection with the BWC that is also concerned with the deliberate spread of diseases due to bioterrorism and biological warfare. Therefore, there is room made in this study for exploring, in the event of a deliberate release of biological agents, whether the CPB can adequately address this matter or it ought to be within the purview of the WHO.

Moreover, Nexon (2011, p. 5) also reminds that the CPB primarily addresses biosafety. Given that the CPB (2000) also addresses the contained use of GMOs in Article 6(2) thereby making laboratory biosecurity relevant, there is also a need for the CBD Secretariat to establish connection with the WHO because the CPB must also consider security measures for laboratories. This leaves us with a gap in terms of identifying which principle(s) within the Delhi Declaration of ISDL will enable the CPB and BWC to collaborate with respect to laboratory biosecurity albeit under the purview of the latter.

[7] See Mariani's (2007) elaboration, also on page 212.
[8] See Mariani's (2007) work, especially on page 221.

2.7.2 Biological Weapons Convention

As for the BWC, a gap there exists in ascertaining whether this international arms control agreement can make sustainable development one of its objectives within the ISDL framework. Tladi (2007, p. 107) and Weiss (2000, p. 348) have both mentioned that arms control law can equally subscribe to sustainable development, in addition to the need for integration. Given that ISDL principles of the Delhi Declaration have never been applied to the BWC as a whole, this exercise should be implemented to gauge the extent to which the BWC is capable of attaining sustainable development as an objective. This is in line with one United Nations General Assembly (UNGA) Resolution on the Observance of Environmental Norms in the Drafting and Implementation of Agreements on Disarmament and Arms Control (2013, p. 1), which urges states that are parties to the BWC to consider all relevant environmental norms and to ensure that scientific and technological progress within the realm of international security, disarmament and other related spheres is not detrimental to the environment but rather contribute to sustainable development. Moreover, the application of international law principles from the Delhi Declaration need not be applied solely to international environmental law agreements but should also be applied to other international agreements in the other branches of international law. The justification for this is based upon Article 31(3) (c) of the Vienna Convention on the Law of Treaties (VCLT, 1969) reiterating the need for a treaty to be interpreted in light "of any relevant rules of international law applicable between the [P]arties." This shows that the different branches of international law, be it international environmental law, international trade law or international social law, should not function disparately on their own but should permit referencing among them so as not to be "self-contained islands of international law, de-linked from other branches of international law" (Pauwelyn, 2004, pp. 903-927). Therefore, there is a need for this study to elaborate on the BWC within the context of the seven ISDL principles but from the angle of the

biosecurity of biotechnology. By indicating that the BWC provisions and the subsequent Intersessional Process (ISP) meeting documents do contain elements supportive of sustainable development as indicated by Rhodes (2007) earlier, this study will be able to dispute the notion that ISDL is to be restricted to international environment, trade and social law. Such a finding will also contribute towards linking international arms control law and sustainable development law, which has been implied by Tladi (2007, p. 107) and Weiss (2000, p. 348), and yet remains underexplored.

As for the nexus between the IHR 2005 and BWC, scholars such as Enemark (2005a, p. 485; 2005b, p. 107; 2010, p. 489), Fidler and Gostin (2008), and Millet (2010, p. 37) reckon that the BWC forms a closer relation with the WHO, since the BWC's scope of work equally overlaps with the outbreak and means of controlling infectious diseases, whether naturally or deliberately through biological warfare or bioterrorism as per Article X (BWC, 1972). Enemark (2005a, p. 485) and Millet (2010, p. 37) are of the opinion that the BWC has established links with the WHO for effective disease surveillance and detection, as health security is outside the specialisation of the BWC. Besides, Nexon (2011, p. 5) highlights the alliance of the BWC with the WHO in the realm of laboratory biosecurity, another specialised area of the WHO. Based on this review, the BWC seems to work more collaboratively with other international organisations like the WHO. There is a lacuna though concerning the extent to which the BWC has been able to forge links with the CPB in exchanging knowledge about each other's specialisation and mutually benefiting from one another. This needs further analysis which this study will undertake.

2.7.3 International Health Regulations 2005, the World Health Organisation's Laboratory Biosecurity and Pharmaceutical Initiatives

According to Prabhu (2004, p. 323), academics and scholars have begun to analyse the relevance of the international health law to sustainable development law. Prabhu (2004, p. 324), in scant passing, mentions the relevance of International Health Regulations

(IHR) for monitoring infectious diseases before its major revision in 2005. At present, IHR 2005 encompasses a broader range of diseases, both infectious and non-infectious, apart from yellow fever, plague and cholera, including those caused by biological warfare and bioterrorism, all of which are relevant to the discussion of biosecurity in this study (Fidler, 2005, p. 355). Prabhu (2004, p. 329) has highlighted the principle of integration and its relationship to human rights, as well as social, economic and environmental objectives that are relevant to the right to health in connection with trade and environmental regimes. Building on Prabhu's proposition, there is a need to utilise the principle of integration in linking international biosecurity agreements and initiatives identified in this study, helping to combine fragmented biosecurity sectors in a holistic manner, as this is a grey area yet one that can significantly contribute to the understanding of international health law and sustainable development law.

Among scholars, a reflection of the principle of integration from the Delhi Declaration within the IHR 2005 shows its integrative nature. Fidler (2005, p. 367) identifies Article 3(1) and Article 32 of IHR 2005, addressing the respect of dignity, human rights and fundamental freedoms of persons with regard to travellers, as covering international social law which is a component of the principle of integration in ISDL. Article 17(d) of the IHR 2005 which stresses that health measures taken must not be more restrictive of international traffic and trade, also indicates consideration for the international trade law besides the health law (Fidler, 205, p. 383). Fidler (2005, p. 364) also highlights that IHR 2005 refers to other international organisations through Article 14, which can facilitate collaboration with other international agreements. Additionally, this study will identify other relevant provisions that can promote integration with other international agreements. Since one of the WHO's resolutions stresses Health and Sustainable Development (WHO, 2002b), it is only fitting that IHR 2005 be evaluated against other

principles of ISDL so as to gauge the extent to which this agreement can make sustainable development its objective in light of the biosecurity of GMOs.

Besides the principle of integration being embedded in the IHR 2005, other principles of ISDL has similarly found a place within this agreement. Fidler (2004, pp. 799-804) and Gostin (2004, p. 2626) have referred to the principle of good governance being relevant through the incorporation of non-governmental sources for disease surveillance as reflected in Article 9 of the IHR 2005, while the same provision has been interpreted by Abbot and Gartner (2012, p. 3) as contributing towards the principle of public participation and access to information and justice. Other scholars such as Fidler (2003, p. 2) and Reader (2006, p. 525) have connected the principle of the duty of states to ensure the sustainable use of natural resources within the context of states failing to notify the WHO and other states of outbreak of diseases within their territory that can spread to the jurisdiction of others, causing harm to health let alone environmental contamination that triggers state responsibility. Notably, the various principles identified within the IHR 2005 by the said scholars have been piecemeal at best and incomplete in light of the seven principles of ISDL. Therefore, there is a need for this study to analyse the remaining principles of ISDL within the IHR 2005 in the context of biosecurity and diseases, as well as possible linkage to the CPB and BWC.

A potential collaboration between the WHO and CPB in the context of laboratory biosecurity has not been given much emphasis, too. Nexon (2011) asserts that the CPB is not mainly concerned with laboratory biosafety but that biosafety within the CPB is understood differently as "safety procedures aimed at regulating, managing or controlling the risks associated with the use and release of living modified organisms (LMOs) resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health" (CBD Secretariat, 2012d). This does not mean that

laboratory biosafety and laboratory biosecurity is totally irrelevant to the CPB since Article 6 (b) (CPB, 2000) addresses the contained use of GMOs. Therefore, there is another potential underexplored area of collaboration between the WHO and CPB within the context of laboratory biosecurity that needs further exploration in this study.

Further collaboration between the WHO and CPB concerning pharmaceuticals is covered by Article 5 of the CPB (2000). MacKenzie et al. (2003, pp. 56-57) highlights the collaboration between the CPB and WHO for pharmaceuticals since this does not fall directly within the scope of the CPB's work. MacKenzie et al. (2003, pp. 56-57) explains that pharmaceuticals were incorporated into the CPB because developing states were concerned about genetically modified plants and animals being used to produce pharmaceutical substances for vaccines or other prophylactics through biopharming and its potential for misuse. While MacKenzie et al. (2003, p. 55) are convinced that genetically modified plants and animals used to produce these pharmaceutical substances will still be regulated by the CPB, there exists a lacuna concerning which specific guidelines of the WHO will monitor the processing of these substances to ensure safety and consistency when consumed by humans. Thus, there is a need to determine which WHO guidelines would be appropriate for monitoring the biopharming of plants and animals to ensure the safety and consistency of these substances for human consumption. Having identified gaps in the literature, the next subsection details those gaps as part of the justification for conducting this study.

2.8 The Research Gap

Some of the gaps identified are summarised and indicated below:

(a) While the literature is unanimous that the CPB has been analysed based on all the principles of the Delhi Declaration, these have been conducted in light of GMOs in agriculture with regard to agricultural biosecurity. The CPB provisions need to be

analysed against the principles of the Delhi Declaration in the context of biological warfare and bioterrorism. Possible linkages with the BWC also need to be identified given the scant nature of the literature concerning the relationship between both agreements.

(b) The literature also showed a gap concerning which principle from the Delhi Declaration can be linked with the CPB in conjunction with WHO's IHR 2005, laboratory biosecurity and biopharming initiatives in the area of health — hence the need for a study of this kind to be conducted.

(c) The literature also revealed an underexplored area relating to whether the BWC can likewise make sustainable development an objective through the application of principles of the Delhi Declaration with a view towards enriching the area of international arms control law and ISDL. In this regard, identification of which principle from the Delhi Declaration can function as a catalyst for such ties to the CPB, IHR 2005, and WHO's laboratory biosecurity initiative is needed.

(d) The review of the literature indicated that biosecurity has been approached from the perspective of segregated sectors. There has been an attempt to offer a holistic definition of biosecurity covering all three sectors which was suggested by a group of scholars, but there is also a need to offer an alternative definition of biosecurity that brings together the three definitions, in line with the understanding that the adoption of ISDL principles will unite disparate biosecurity sectors, as well as their respective international agreements and initiatives.

2.9 Summary

Biosecurity problems know no boundaries and can encroach upon multiple sectors simultaneously. This conjures up the need for international organisations and states to consider merging international biosecurity agreements and initiatives into one that is holistic rather than sectorial within and among such international instruments. Based on

the literature review, sustainable development holds the prospect of fusing together international biosecurity agreements and initiatives from different sectors. This has provided the basis for exploring the extent to which the principles of ISDL in the Delhi Declaration are reflected among selected international biosecurity agreements and initiatives specific to this study, because there is obviously a gap in this area that calls further exploration in subsequent Chapters 6-8.

2.10 Conceptual Framework

The critical review of the literature and insight from the researcher's own experience have allowed for a conceptual framework to be developed that will assist in guiding the research process and methodological design, and the manner in which the information gathered for this study is used. This conceptual framework provides a structure for reporting the study's findings, analysis, interpretation, and synthesis. In such a manner, the conceptual framework may be considered a working tool.

The conceptual framework above has been guided by the research questions posed in this study. The first research question seeks to explore the scope, limitations, relevant recommendations, and risk management practices needed in harmonising various biosecurity sectors and their respective international instruments. Figure 2.1 refers to the CPB (environmental agreement) under the agricultural biosecurity sector. The BWC (an arms control agreement) and IHR 2005 (a health agreement) are both within the biosecurity of biotechnology sector. WHO's laboratory biosecurity guidance falls within the laboratory biosecurity sector. WHO's biopharming initiative falls under the health area, and not within the confines of any biosecurity sector.

The second research question seeks to identify the principles of international law in the Delhi Declaration. As indicated in Figure 2.1, all seven principles of the Delhi Declaration are listed but their meaning will be further deliberated in detail in Chapter 5,

as these principles differ in meaning depending on the context in which they are used among international law agreements.

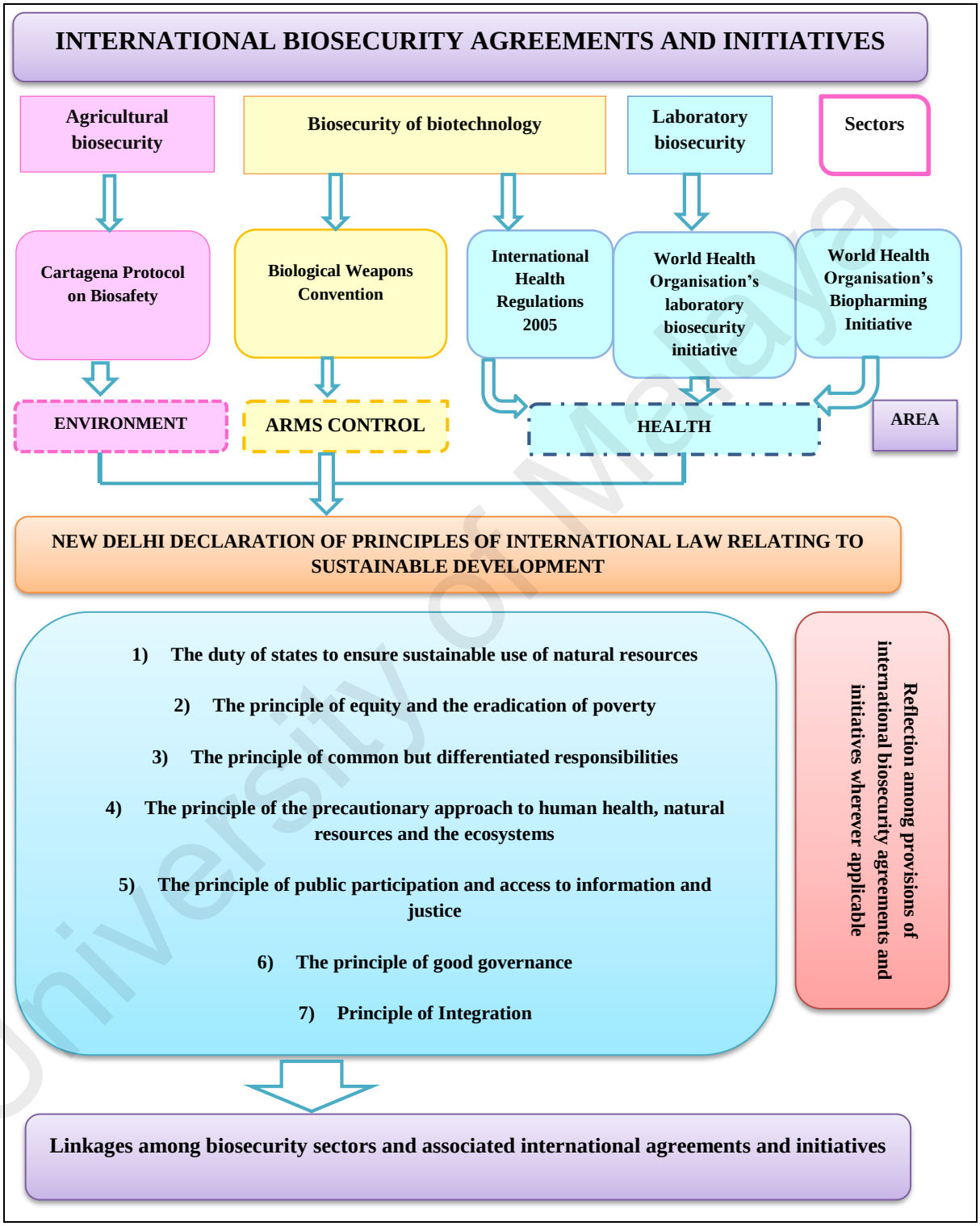

Figure 2.1: A conceptual framework linking biosecurity sectors, associated agreements and initiatives.

These principles are used as auxiliary tools to assist in gauging whether their presence among selected international biosecurity agreements and initiatives (wherever applicable) can help transform the biosecurity sectorial problem to one that is more integrated as a catalyst for cooperation. This is in tandem with the third research question, which is intended to ascertain how principles of international law in the Delhi Declaration are being reflected among the international biosecurity agreements and initiatives chosen for this study.

The reason for choosing these principles from the Delhi Declaration of ISDL stems from the accommodating nature and bridging function of sustainable development itself. Sustainable development, as defined in the Brudtland Report, refers to "development that meets the needs of the present without compromising the ability of future generations to meet their own needs" (WCED, 1987, p. 87). Sustainable development consists of three components, namely economic development, social development, and environmental protection — all of which are "interdependent and mutually reinforcing components of sustainable development" (World Summit for Social Development, 1995, para. 6). In this way, sustainable development does not function as a separate sector that merely focuses on environmental protection but it is multidisciplinary in nature, as reflected by its two other components, so as to build bridges of reconciliation among them.

Since biosecurity consists of an assortment of international agreements and initiatives reflecting a sectorial approach, the route to a coherent biosecurity management at the international level lies with the adoption of principles from the Delhi Declaration of ISDL in order to be able to correlate these international instruments.

2.11 Conclusion

The literature review has provided an insight into the extent to which biosecurity sectors and their associated international instruments are interconnected with one another. There is a strong prevalence of international biosecurity instruments being linked to one another within sectors but concerning the relationship of these international instruments across sectors, only a weak link exists. This is further compounded by the review's revelation of little awareness about the durability of utilising sustainable development as a means of connecting biosecurity sectors and their associated international instruments; after all, sustainable development is multifaceted. While the literature pertaining to the CPB and IHR 2005 indicated that principles of ISDL have been applied either completely or partially depending on context, the case of the BWC shows that principles of the Delhi Declaration have been devoid of application despite scholars who argue that these principles can be applied to international arms control agreements such as the BWC. Although the principles of ISDL have been applied by scholars to the CPB, this has not been done in the context of biological warfare or bioterrorism, even though the same principles have been applied albeit partially to the IHR 2005. The implication, therefore, is for this study to reflect and apply the principles of ISDL from the Delhi Declaration to the CPB within the context of bioterrorism and biological warfare, and even more so in terms of the BWC and IHR 2005. Be that as it may, this study's attempt to fill the apparent gaps in research could lead to a fresh even innovative contribution which can only enrich the vital areas of ISDL, international arms control, and international health law.

CHAPTER 3: RESEARCH METHODOLOGY

3.1 Introduction

The purpose of this study is to determine whether principles of international law from the New Delhi Declaration of Principles of International Law Relating to Sustainable Development (hereinafter Delhi Declaration; International Law Association [ILA], 2002) hold the solution to linking together different biosecurity sectors and their respective international agreements and initiatives within the context of genetically modified organisms (GMOs) for a coherent management among international organisations. The researcher is persuaded that the reflection of International Sustainable Development Law (ISDL) principles among chosen biosecurity international instruments can be the catalyst to forming interlinkages among them and their respective sectors for the effective governance of biosecurity at the international level. To achieve this lofty aim, this study poses three research questions, namely: (i) What are the scope, limitations, relevant recommendations and risk management practices that would be needed to harmonise the various biosecurity sectors and their respective international instruments? (ii) What principles of international law can be gleaned from the New Delhi Declaration of Principles of International Law Relating to Sustainable Development? (iii) How are the principles of international law in the Delhi Declaration of ISDL being reflected in the selected international biosecurity agreements and initiatives?

This chapter will now describe this study's methodology by discussing the research design in relation to the following subtopics: (i) epistemological position, (ii) research methodologies, and (iii) research methods. This chapter will end with a few brief concluding remarks.

3.2 The Research Design

3.2.1 The Epistemological Position

The epistemological position in this study is interpretivism grounded within qualitative research. Interpretivism is defined as "[t]he study of social phenomena [requiring] an understanding of the social worlds that people inhabit, which they have already interpreted by the meanings they produce and reproduce as a necessary part of their everyday activities together" (Blaikie, 2004, p. 509). Interpretivism therefore requires a researcher to interpret elements within such study that involve human interest. Diverse approaches are associated with interpretivism but of particular interest to this study is hermeneutics.

Hermeneutics is concerned with the interpretation of texts to illicit meaning (Wernet, 2014, p. 234). Within the realm of law, legal hermeneutics has emerged as a science of interpretation concerning the application of legal rules from the foundations of philosophical hermeneutics (Merezhko, 2014, p. 4). The procedure for interpreting text in legal hermeneutics covers understanding, interpretation, and reference to both the legal text and context (Merezhko, 2014, p. 4). The relevance of hermeneutics to this study relates to the interpretation of provisions within the selected international biosecurity agreements, especially in terms of locating the principles from the Delhi Declaration of ISDL in Chapters 6 to 8. Indeed, Merezkho (2014, p. 8) agrees that legal hermeneutics is relevant to the interpretation of international treaties, hence its relevance to this study.

3.2.2 Research Methodologies

This study has used a combination of doctrinal research approach and socio-legal research methods to address the research questions posed in this study. These combinations provide greater reliability, vigour, breadth, richness and depth to analysis than a single methodological approach to a problem.

Both methodologies used in this study are elaborated in detail below.

(a) ***A doctrinal research approach***

Vibhute and Aynalem (2009, p. 71) assert that doctrinal research "involves a rigorous systematic exposition, analysis and critical evaluation of legal rules, principles or doctrines and their interrelationship." Besides, doctrinal research is also concerned with a "critical review of legislation and of decisional processes and their underlying policy" (Vibhute & Aynalem, 2009, p. 26). Therefore, doctrinal research denotes "research in law" or "research in black-letter of law", as it asks what the law is on a particular issue (Singhal & Malik, 2012, p. 252). Doctrinal research is largely qualitative because it involves synthesising the law, applying the law to the facts and contexts which is a highly subjective process (Hutchinson & Duncan, 2012, p. 116). The relevance of doctrinal research applies in particular to Chapters 5-8 on the elaboration of the Delhi Declaration principles and their application to the Cartagena Protocol on Biosafety (CPB), Biological Weapons Convention (BWC), and the International Health Regulations 2005 (IHR 2005). The relevance of the doctrinal research approach, particularly to Chapter 5, is that it identifies sustainable development and its status in international law, whether it be the principle itself, rule or doctrine, by analysing statutory instruments, international case laws, legal treaties, commentaries, textbooks, and legal periodicals that have taken place at its formative stage.

Doctrinal research has also been compounded throughout Chapters 4-8 in terms of case laws concerning bioterrorism and laboratory biosecurity providing relevant judicial opinions that serve as models from the United States (US) and the United Kingdom (UK).

While primary documents form the basis of doctrinal research, Singhal and Malik (2012, p. 253) as well as Vihbute and Aynalem (2009, p. 75) have equally emphasised the secondary resources. This provides credibility to the information relied upon in this

study rather than solely depending on a document analysis of case laws. Vihbute and Aynalem (2009, p. 75) emphasise that a researcher working on a new theme must rely on law textbooks, cases, materials, and legal journals in acquainting with the basic principles or subject under investigation. Secondary resources are useful in elucidating concepts, principles, and standards within international conventions, legislation, and case laws because the law has been interpreted (Singhal & Malik, 2012, p. 253). This will enable researchers to form their own opinion and ensure it does not completely digress from those of other scholars. The doctrinal research approach undertaken in this study indeed confirms the following aims: (i) study relevant case laws in order to find the law, (ii) aim at achieving consistency and certainty of the law, and (iii) to some extent, highlight the purpose and policy of the law that exists (Singhal & Malik, 2012, p. 73).

(b) ***A Socio-legal approach***

This study also adopts a socio-legal approach because of its multidisciplinary nature. There is no exact definition of such a socio-legal research because it has been understood in various ways. Socio-legal research refers to a "wide-ranging and varied area of research activity" that permits a diversity of methods and perspectives to be used — a description provided by the UK's Economic and Social Research Council (Cowney & Bradney, 2013, p. 35). Cownie and Bradney (2013, p. 51) emphasised that socio-legal research draws from many disciplines but it also refers to various methods of research drawn from the social sciences. The justification for using the socio-legal approach has to do with this study being multidisciplinary in nature, combining biosecurity, an area of science, security and arms control, health, environmental studies, and law.

Indeed, Faulkner, Lange and Lawless (2012, p. 7) have also indicated such linkages between the socio-legal research approach with Science and Technology Studies (STS) involving risky technology such as genetic engineering, coupled with the political

dimension to decision making. Likewise, Bose and Meulen (2014) have also used a socio-legal research approach to analyse the impact of introducing genetically modified brinjal and cotton to a small tribal group in India, thus linking biotechnology in the sciences with the law.

In particular, how the principles of the Delhi Declaration, e.g. the principle of public participation, access to information and justice, and the principle of equity and the eradication of poverty, are reflected among relevant international biosecurity instruments would seem to point to the social and political values of society influencing the contents of these documents.

The socio-legal research approach is also used because of the adoption of the social sciences research methods. In collecting the relevant information for this study, documents have been a key part. As to the methods of this study, a textual and content analysis, derived from the social sciences, has been used — to be further elaborated below.

3.2.3 Research Methods

(a) ***Sources of Information***

i) *Documents and Secondary Resources*

This study relied on documents as primary resources. Olson (2010, pp. 319-320) underlines that documents are crucial in providing a record of human activity in written or visual forms, even physical materials. Some of the documents for this study include that of public records readily available for public use in written form or through the internet in relevant databases such as court documents, judicial reports, government policy documents, case laws (nationally, regionally, and internationally) and other sources (Olson, 2010, pp. 319-320).

Indeed, Singhal and Malik (2012, p. 253) have also indicated that when doctrinal research is undertaken in international law, additional materials referred to include treaties, declarations, resolutions and other numerous United Nations (UN) and international organisations' documents. Therefore, doctrinal research is highly reliant on a document analysis which may be defined as "a systematic procedure for reviewing or evaluating documents – both printed and electronic (computer-based and Internet-transmitted) material" (Bowen, 2009, p. 27).

The case laws referred to throughout Chapters 4-8 were meant to obtain the latest judiciary opinions about sustainable development, bioterrorism and laboratory biosecurity practices in the US and the UK. Most of these case laws on sustainable development were obtained from the websites of the International Court of Justice (ICJ), the Permanent Court of Arbitration (PCA), the International Tribunal for the Law of the Sea (ITLOS), the World Trade Organisation (WTO), and judicial opinions from India and the Philippines. Vihbute and Aynalem (2009, p. 75) stress the need to obtain the most updated statutes and case laws so as to ensure an updated judicial opinion on any particular subject matter, since a mere reliance on secondary literature is backdated.

Reliance on documents also raises the issue of authenticity. Most of the case laws and documents from different bodies of the UN have either been obtained from the international organisations' websites or credible databases such as Lexis-Nexis Universe and Westlaw at the University of Malaya (UM) and National University of Malaysia (UKM). As these are considered reliable websites, these documents are assumed to be authentic in their original form.

This study also relied on secondary resources such as books, book chapters, journal articles, conference papers, working papers, newspapers, magazine articles, and other information from relevant international and Non-Governmental Organisation (NGO)

websites that provide an overview of ISDL, the different sectors of biosecurity, and related international agreements and initiatives.

3.2.4 Methods of Analysis

As explained below, both a textual and content analyses have been used throughout this study.

(a) ***Textual Analysis***

This study also relied on a textual analysis, which may be defined as "a method of analysing the contents of documents [using] qualitative procedures for assessing the significance of particular ideas or meanings in the document" (Scott, 2006, p. 298). A textual analysis is grounded within the interpretivist tradition, linked to hermeneutics (Scott, 2006, p. 298; Wharton, 2006, pp. 80-82). The use of textual analysis is not intended to obtain a correct interpretation of a document but rather to identify the possible and likely meaning of a given text, and hence subjective (Lockyer, 2008, p. 865).

The textual analysis is used in this study to analyse the relevant case laws, provisions of international biosecurity agreements that reflect the principles of ISDL and subsequent documents derived from them, and other international organisations' documents examined in Chapters 4-8. This conforms with the doctrinal research approach, associated with interpretivism, with a view to eliciting the hidden and outright meaning of case laws and international agreements and their relevance to this study (Banakar & Travers, 2005).

The approach of locating principles of international law among international agreements has previously been taken up by scholars. Pallemaerts (1995-1996, pp. 623-676) located the principles from the Rio Declaration in relation to sustainable development among the non-legally binding Authoritative Statement of Principles for a Global Consensus on the Management, Conservation and Sustainable Development of

All Types of Forests, the Convention on Biological Diversity (CBD), and the United Nations Framework Convention for Climate Change (UNFCCC). Frison (2006, pp. 155-174) also used each of the principles from the Delhi Declaration as themes to analyse whether any of these principles are embedded within the International Treaty on Plant Genetic Resources in Food and Agriculture (ITPGRFA). And so, this study follows the precedent set by other scholars in adopting a textual analysis to locate the principles of ISDL among selected international biosecurity agreements and initiatives.

(b) ***The Content Analysis***

A content analysis has simultaneously been applied throughout Chapters 4-9 of this study. A content analysis refers to "the process of organising information into categories related to the central questions of the research" (Frison, 2006, pp. 155-174). A content analysis entails skimming through relevant research materials by means of a superficial examination whereby meaningful and relevant passages of a text or other data are identified (Frison, 2006). The researcher then identifies the pertinent information relevant to her research, separating it from the irrelevant by means of the relevant themes (Frison, 2006).

3.2.5 Limitations

Using documentation and textual analysis in this study would seem bias, especially if a single source of information and the researcher's own interpretation of such a source are solely relied upon. To overcome this limitation, other secondary resources have also been referred to in order to correlate the researcher's interpretation of an issue with that of other scholars. This coheres with triangulation, whereby a few sources of information are used to strengthen the validity of the study findings (Yin, 2003, pp. 97-98).

Besides, this study acknowledges the limitation of generalisability, typical of a qualitative study. It must be stressed that transferability is the goal of this study,

concerned with the richness of description and detailed information that gauge whether knowledge can be addressed for its applicability and be applied in other contexts (Bloomberg, 2012, p. 127). The few international biosecurity agreements and initiatives selected for this study do not permit generalisability on the usefulness of the ISDL principles but only transferability.

Another limitation encountered in this study was the inability of the researcher to conduct interviews among representatives of the CBD Secretariat, Implementation Support Unit (ISU) of the BWC, and World Health Organisation (WHO). Reasons for this include the budgeting constraint on the researcher to travel abroad for such interviews. Neither would long distance interviews conducted through emails be feasible as this would not have provided first-hand knowledge, as is the case with a face to face interview. Moreover, in replying to email interviews, respondents may take some time answering the questions. Nevertheless, such interviews among relevant international organisations would have provided an insight into jurisdictional boundaries, as these organisations and their mandates tend to impede cooperation among them. These interviews could also provide first-hand insight into how these international organisations could find effective ways to collaborate while mindful not to overstep each other's mandate.

To overcome this constraint though, the researcher examined documents pertaining to the Counter Terrorism Implementation Task Force (CTITF) of the UN for use as a model of consolidation. This is because the CTITF has brought together various UN international organisations and agencies to collaborate with one another through working groups in addressing various aspects of terrorism. If this has worked for CTITF, it can also bring together international biosecurity organisations.

3.3 Conclusion

This chapter had outlined in detail this study's research methodology. While this study is qualitative, it combines a doctrinal legal approach and socio-legal research approach. The justification for a doctrinal legal research approach was based on interpretivism being used for case laws, international biosecurity agreements, and interpreting other soft law documents. As for the socio-legal approach, the rationale for choosing this research method is that this study is multidisciplinary in nature, combining the areas of science, law, security, and environmental studies. Moreover, socio-legal research involves the methods of social science for analysing data such as a document, textual and content analysis for both primary and secondary resources. Indeed, the combination of legal research approach together with that of the social sciences and numerous resources lends credibility to the data in accordance with triangulation, thereby enriching this study's findings.

CHAPTER 4: THE DIFFERENT BIOSECURITY SECTORS, SCOPE AND LIMITATIONS

4.1 Introduction

Previously, in Chapter 1, the three forms of biosecurity that currently exist were briefly mentioned. This chapter thoroughly explored the scope and limitations and suggested relevant recommendations and risk management practices to harmonise various biosecurity sectors and their respective international instruments in fulfilling the first objective of this study. This chapter introduced the biosecurity of biotechnology, laboratory biosecurity and agricultural biosecurity, their coverage and limitations. This was then followed by a recommendation for a comprehensive definition of biosecurity and a coordinating mechanism at the United Nations (UN) level that will unite the relevant international organisations and agencies among the three biosecurity sectors to cooperate together as a means of integration. Subsequently, this was followed by the conclusion.

4.2 The Biosecurity of Biotechnology and its Coverage

As indicated in Chapter 1, biosecurity has been defined by the United States National Academy of Sciences (USNAS) as the "security against the inadvertent, inappropriate, or intentional malicious or malevolent use of potentially dangerous biological agents or biotechnology, including the development, production, stockpiling, or use of biological weapons as well as natural outbreaks of newly emergent and epidemic diseases" (N.R.C. Committee, 2006, p. 32). This form of biosecurity will be referred to as the biosecurity of biotechnology, distinct from other forms of biosecurity addressed in this study. As evident from USNAS's definition of biosecurity, the development of biological weapons is one concerned with biological warfare, as it is similar to Article I of the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxic Weapons and on Their Destruction, in short, the Biological Weapons Convention (BWC),[1] and also bioterrorism. This form of biosecurity also relates

[1] Article I of the BWC reads as:

to infectious diseases, an outcome of using biological weapons. The misuse of biological agents,[2] their means of delivery (missiles and bombs) and the knowledge for creating biological weapons also form part of the biosecurity of biotechnology. Thus, the following subsections provide an overview on biological warfare, bioterrorism and dual use matters relating to the misuse of biological agents, technology and knowledge for malevolent intentions. This is accomplished in the context of genetic engineering.

Genetic engineering is a process understood as "using recombinant [Deoxyribonucleic Acid (DNA)] techniques and related methods to move one or several genes from one organism to another, to rearrange one or several genes within a cell, or to alter gene-controlled processes" among unrelated species, bringing about profound implications for biosecurity (Organisation for Economic Cooperation and Development [OECD], 2009). The product from genetic engineering is called genetically modified organisms (GMOs), which are "organisms wherein the genetic material (DNA) has been artificially altered, usually by replacing some of the host organism's gene with those of another related or unrelated species" (OECD, 2009). Additionally, GMOs do not naturally occur in nature and are not produced through conventional cross-breeding nor mutagenesis, as these old methods predate the discovery of recombinant DNA (rDNA) techniques since 1973 (World Health Organisation [WHO], 2006, p. iv).

Each State Party to this Convention undertakes never in any circumstances to develop, produce, stockpile or otherwise acquire or retain:
(1) Microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes.

[2] See the Occupational Safety and Health Administration's (OSHA's) definition of biological agents, which covers bacteria, viruses, fungi, other microorganisms and their associated toxins. Biological agents can adversely affect human health through relatively mild, allergic reactions to serious medical conditions or even cause death.

4.2.1 Biological Warfare

4.2.1.1 The Former Soviet Union

The advancement of genetic engineering in the 1970s was utilised by the former Soviet Union to develop biological weapons meant for biological warfare. Biological warfare refers to "the wartime use of biological weapons" (OECD, 2009). While the Soviet Union succeeded in creating biological weapons by employing genetic engineering, it never had the opportunity to openly test these weapons in biological warfare with its enemies. However, if there were any previous doubts, the Soviet Union's case provides sufficient proof that a country succeeded in using genetic engineering to create biological weapons

One of the earliest known cases that applied genetic engineering for biological warfare to modify microorganisms with new characteristics was the Biopreparat programme of the former Soviet Union (Ainscough, 2002, p. 3; Gilsdorf & Zilinskas, 2005, p. 1160). Biopreparat, a huge military programme disguised as civilian cover, was intended to develop and weaponised biological agents or pathogens as biological weapons (Koblentz, 2009, p. 19). In 1973, President Brezhnev formed the "Enzyme" programme to revitalise the biological weapons programme by introducing genetic engineering to produce genetically modified pathogens (Ainscough, 2002, p. 5). The Soviet Union not only experimented with anthrax and tularaemia, but with the most contagious lethal bacteria, plague, as well as viruses such as smallpox, all known for their lethal attributes (Ainscough, 2002, p. 3). In the journal *Vaccine*, it was reported in 1997 that the Soviet Union had changed the immunological properties of anthrax, rendering existing vaccines and detection methods ineffective through the development of newly genetically engineered types (Pomerantsev, Staritsin, Mockov & Marinin, 1997). The Soviet Union researchers subsequently produced a new vaccine to be used effectively with a genetically altered strain of anthrax (Pomerantsev et al., 1997). If proof was needed that genetic

engineering could render any vaccine ineffective, here was evidence from the Soviet Union's action.

Apart from the anthrax case, the Soviet Union succeeded in using genetic engineering to conceive plague and tularaemia to make them resistant to antibiotics and to withstand temperature extremes (Ainscough, 2002, p. 4). The Soviet Union intended that these biological agents be distributed through means of delivery using spray tanks, cluster bombs and Intercontinental Ballistic Missiles (ICBMs) (Ainscough, 2002, p. 4). Moreover, the Soviet Union also perfected the technique of aerosolisation for its use with weapons. Thus, the Soviet Union had the necessary capabilities to develop biological weapons on a large scale.

Aerosolisation was regarded as an encumbrance in weaponising biological weapons. Biological agents had to be of a minute size of 1-5 micrometres in diameter to be easily inhaled into the respiratory tract (Cole, 2011, p. 43; Koblentz, 2009, p. 15). Other difficulties include biological agents losing their virulence or toxicity during transportation to another destination, and the problem of clogging that disabled the aerosol emission. Additional factors hindering the success of aerosolisation include the biological agents' exposure to "humidity, desiccation, oxidation, air pollution, heat, shock and ultraviolet light" that may obstruct their effectiveness (Cole, 2011, p. 43). Meteorological conditions when dispensing the biological agent, the wind speed direction, terrain and atmospheric stability, also influence the aerosolisation process (Koblentz, 2009, p. 16).

The hurdles affecting aerosolisation caused the Soviet Union scientists to spend 30 years in solving the survival of fragile microbes under major atmospheric pressure changes and temperature extremes during missile flight (Ainscough, 2002, p. 4). These setbacks were overcome by fitting biological weapons with rockets that were astronaut

cabin-like protective systems (Ainscough, 2002, p. 4). The hardiest strains were also chosen to withstand the destruction of these microorganisms and Soviet scientists calculated the redundant quantity needed to withstand this stress (Ainscough, 2002, p. 4). Ample funding, "equivalent to tens of millions of United States (US) dollars" as an annual budget, throughout the 1980s (Ainscough, 2002, p. 3) and a large deployment of 60,000 workers at eighteen biological weapon facilities also ensured the success of the Soviet's biological weapons programme. This is indeed a crucial distinction, differentiating large-scale biological warfare preparation through extensive state sponsorship, financially, facility-wise and time allocation.

The Soviet Union also succeeded in creating chimera viruses by inserting genes from one virus into another. For instance, they inserted the DNA from Venezuelan Equine Encephalitis (VEE) virus into the vaccinia virus, a genetic structure similar to the smallpox virus (Ainscough, 2002, p. 7; Gilsdorf & Zilinskas, 2005, p. 1160). Likewise, in 1991, other chimeras of VEE, Ebola and the Marburg genes were also inserted into smallpox genes (Ainscough, 2002). This indicated that, throughout the 1980s and 1990s, the Soviet Union was successful in utilising genetic engineering to alter the characteristics of microorganisms in making them more virulent, lethal, resistant to antibiotics and evading vaccines.

Even though Soviet scientists succeeded, these newly created GMOs could simultaneously exhibit pleomorphic effects, which are emerging weaknesses to environmental stresses (Zilinskas, 1999, p. 11). Thus, the pleomorphic effects had to be removed, requiring a new cycle of experiments, development and field-testing to maintain the desired characteristics of biological agents or they could not be effectively used for biological warfare.

While the Soviets never had the occasion to apply their genetically modified biological agents in open biological warfare, there were some minor incidences that showed the potential of genetically modified strains. In 1979, an accidental release of anthrax spores occurred at a biological weapons facility in Sverdlovsk (currently known as Yekaterinburg, Russia) causing the death of 66 people (Ainscough, 2002, p. 7). A DNA sequencing study conducted in 1998 on 11 victims showed the presence of four distinct genetic variants of bacillus anthracis (Ainscough, 2002, p. 7). This indicated the possibility that the Soviets had possibly employed genetic engineering for anthrax, as there were four variants, whereas, a natural outbreak would likely have only one strain of anthrax (Ainscough, 2002, p. 7).

Another minor incident involved the release of genetically engineered smallpox in an open air test on Vozrozhdeniye Island in 1971, the Soviet's testing ground at the Aral Sea (Tucker & Zilinskas, 2002b, p. 1). The release of the airborne smallpox virus particles through aerosolisation drifted south of the island to infect a female ichthyologist doing an ecological survey of the Aral Sea on a vessel; this disease was then spread to others (Tucker & Zilinskas, 2002b, p. 1). Dr. Zelicoff, a biological warfare expert at Sandia National Laboratories in the US, deduced that the smallpox virus had been genetically modified to make it more virulent so that it would continue to remain infectious after travelling downwind for nine miles from Vozrozhdeniye Island (Tucker & Zilinskas, 2002b, p. 1). Regardless whether further evidence will ever surface to show the potency of the Soviet's genetically modified strains of pathogens, the fact remains that this technology had been utilised for the purpose of creating biological weapons.

The dissolution of the Soviet Union in 1991 triggered fears that unemployed scientists (possessing knowledge to genetically engineer microorganisms or unpaid by successor states of the Soviet Union) might be tempted to disseminate the relevant knowledge to

states with biological weapons proliferation or to terrorists and insurgents (Ainscough, 2002; Cole, 2011, p. 35; Leitenberg, 2005, pp. 19-20). Such fears, though, have been unfounded, because "[n]o Soviet or Russian [biological weapons (BW)] scientists are known by the US intelligence community to have gone to North Korea or Iraq" (Leitenberg, 2005, p. 20). There have been a few Russian scientists who went to Iran, but they are not those who worked with smallpox at institutes in the Soviet Union (Leitenberg, 2005, p. 20). Thus, it is doubted that any knowledge acquired by former Soviet Union scientists has passed into the hands of rogue states.

4.2.1.2 The United States (US)

As a countermeasure to the Soviet Union's effort, the US (in its biodefense initiative) embarked on replicating the former's experiments to develop its own anthrax vaccine. This initiative intended to overpower the Soviet Union's genetically engineered anthrax (Koblentz, 2009, p. 71). Apart from this, the US constructed a small biological agent production facility for the production of anthrax and tested replicates of the Soviet-designed biological bomblets (Koblentz, 2009, p. 71). Thus, the US army increased its expenditure for defensive biological research after realising that the Soviet Union had an active biological weapons programme involving genetic engineering (Koblentz, 2009, pp. 69-70). Indeed, this race in developing biological weapons led to the formation of BWC (1972). The BWC aimed to stop biological weapons development, especially between the Soviet Union and the US, but was not a deterrent to the former to still pursue biological weapons.

Apart from the US's effort, as mentioned above, the US Naval Research Laboratory recently used genetic engineering to degrade weapons, such as destroying hydrocarbons, plastics, natural and synthetic rubber, metals and composite materials (Sunshine Project, 2002). These genetically engineered microorganisms produce biopolymers called

polyhydroxyalkanates which cause machinery failure (Sunshine Project 2002). In such a manner, metal parts, coatings, lubricants of weapons, aircrafts and replacement parts can be damaged if they encounter polyhydroxyalkanates on their surface (Sunshine Project, 2002). It was said that such an effort would "clearly have [the] potential for development as a means of warfare or for hostile use against material crucial for normal civilian life" (United Nations Office at Geneva [UNOG], 2001). However, the US asserted its biological weapons initiative was one of defence.

4.2.1.3 Iraq

A genetic engineering programme was launched by Iraq in 1990 to create an antibiotic resistant strain of anthrax and came to a halt in 1991 during the Gulf War (Koblentz, 2009, p. 176). Yet again, following the US invasion of Iraq in 2003, Iraq was evasive as to whether it had embarked on a biological weapons programme using genetic engineering (Koblentz, 2009, p. 20).

Based on the examples from the Soviet Union, the US and Iraq, there is evidence indicating that biosecurity, with the misuse of knowledge of genetic engineering, had been used to develop biological weapons for biological warfare.

4.2.2 Bioterrorism

This sub-section investigates whether there is any substantial evidence indicating that terrorist groups will be able to employ genetic engineering to develop biological weapons. This triggers bioterrorism to be defined as the "deliberate release of viruses, bacteria, or other germs (agents) used to cause illness or death to people, animals or plants" (Centres for Disease Control and Prevention [CDC], 2015). In December 2011, Hillary Rodham Clinton, the US Secretary of State, in a policy statement at the Biological Weapons Convention Review of the United Nations in Geneva, Switzerland, highlighted that a

bioweapon can easily be created by terror groups to develop and spread new diseases (Jordans, 2011, p. 1). Clinton also asserted that "[a] crude but effective terrorist weapon can be made using a small sample of any number of widely available pathogens, inexpensive equipment, and college level chemistry and biology" (Jordans, 2011, p. 1). In stressing the grave threat posed by terrorists in developing a biological weapon, Clinton cited that Al-Qaeda has urged "brothers with degrees in microbiology or chemistry […] to develop […a] weapon of mass destruction" (Jordans, 2011, p.1). In this regard, this sub-section sought to explore whether there is any validity to Clinton's claim or if this was pure exaggeration.

4.2.2.1 Terrorist Capabilities for Bioterrorism

Terrorist intentions of developing biological weapons all depend on the capabilities they possess. The unsuccessful attempt by Aum Shinrikyo, a cult group in Tokyo back in 1995 that failed to cultivate a virulent strain of anthrax (*bacillus anthracis*) from the wild, is an example of an unsuccessful attempt (Koblentz, 2009, p. 213). Seicho Endo, the leader of the biological weapons programme, merely managed to obtain an anthrax strain used for animals (Koblentz, 2009, p. 213). In creating a biological weapon and ensuring its effectiveness, some features to be considered include the choice of a "particular pathogen used, its growth conditions, the age of the culture and the methods of preparing and preserving it"; this determines whether the pathogen survives dissemination (Cole, 2011, p. 43). It is highly likely that a terrorist group would choose a bacteria or toxin to develop a biological weapon since it is easier to cultivate than a virus. This explains Aum Shinrikyo's choice of anthrax, as it is a bacterium assumed to be easily cultivated as a biological weapon, but, without a virulent strain, this had not been possible.

Moreover, Aum Shinrikyo's attempt to utilise aerosolisation to disseminate the very low quality liquid slurry of anthrax failed. The liquid slurry contained debris and

vegetative cells, clogging the crude aerosol device launched from a rooftop sprayer, with a low concentration of spores that broke down and leaked; moreover, its particles were not the optimum size of 1-5 microns for aerosolisation (Koblentz, 2009, p. 213). This confirms that a terrorist group need not resort to sophisticated aerosolisation as in the Soviet Union's case, for a large-scale attack. Terrorists only need to use a crude form of aerosol or converted industrial equipment to accomplish their purpose (Cole, 2011, p. 15; Shea & Gottron, 2004, p. 13). This reflects the dual use dilemma, as it is hard to distinguish whether the equipment will be used for genuine biotechnology research or for malevolent purposes.[3] Terrorists are unable to master an efficient aerosolisation system, since it requires technological sophistication beyond their reach. A requirement of practical engineering skills, patience, effort, luck and a long period of time is needed to ensure the success of aerosolisation. This explains why Aum Shinrikyo resorted to the sarin gas attacks in Tokyo (Koblentz, 2009, p. 213).

Likewise, Al-Qaeda never went beyond trying to obtain a virulent strain of anthrax, which it failed to do, to graduate to a weaponisation stage of aerosolisation through the initiative of Yazid Suffat, a Malaysian biochemist seeking to lend his expertise (Koblentz, 2009, pp. 221-224). The anthrax project initiated by Suffat was at the initial stages of operation and came to a halt when the US invaded Afghanistan in 2001 (Koblentz, 2009, p. 221). In this regard, terrorist groups are highly unlikely to apply genetic engineering to create biological weapons because of the sophistications of the technology, requiring large financial resources and modern laboratory facilities (Cole, 2011, p. 46; Koblentz, 2009, p. 215). Despite this, Aum Shinrikyo still tried to acquire knowledge in genetic engineering through obtaining sophisticated designer software, enabling the re-engineering of molecular structures of chemicals and microorganisms; however, this

[3] Refer to the *OECD, International Futures Programme: Bioeconomy Glossary*. The OECD defines the dual use as "certain material, information, and technology that are useful in both military and civilian spheres [but] increasingly being used to refer not only to military and civilian purposes, but also to criminal and terrorist activities."

quest also failed (Cole, 2011). As of now, one scholar doubts "the development of genetically modified [biological weapons (BW)] by a terrorist group [that] remains a theoretical threat only" because, as highlighted, most of the terrorist groups have encountered difficulties using natural pathogens and aerosolisation to develop biological weapons (Cole, 2011, p. 46). Given the impediments faced by these terrorist groups, this scholar feels that "it is highly unlikely that they [terrorist groups] would choose an even more difficult technological option", such as genetic engineering, for their black deeds (Cole, 2011, p. 46). Similarly, based on the past experiences of terrorist groups, other scholars, such as Leitenberg (2005, p. 99) and Koblentz (2009, p. 215), are of the same view.

Spending long periods of time and a lack of scientific expertise to create biological weapons successfully are factors obstructing bioterrorism. Endo, in the Aum Shinrikyo cult, was not a microbiologist and did not have the expertise to work with bacteria, but did have limited experience with virology and veterinary medicine (Koblentz, 2009, p. 213). While Aum Shinrikyo had a team of other skilled scientists, ample funding and equipment to develop a biological weapon in the form of anthrax, this did not ensure the success of their group's dark project (Koblentz, 2009, p. 213).

Moreover, intrinsic knowledge concerning a hands-on experience of actually transforming a biological agent into a biological weapon is crucial for developing a biological weapon. Thus, seasoned practitioners well-versed in the "tricks of the trade" could be one of the right ingredients for developing a biological weapon (Cole, 2011, p. 35). Experienced practitioners in the team could then disseminate their knowledge to other scientists by training them or by word-of-mouth to multiply the level of expertise.

A terrorist group's dissemination of a biological agent could be through the means of contaminated food or through the water supply. For food contamination at a food

processing plant, the biological agents could be killed by quality control procedures that are able to detect its presence. If a biological agent is to be introduced in a restaurant, it has to be done after cooking, because heat could kill the pathogen. This explains the case of the Rajneeshpuram cult dispensing *Salmonella typhimurium* at salad bars in Oregon, US, back in 1984 (Cole, 2011, p. 55). Poisoning the water supply requires a large amount of biological agents, sufficient to the level of the water in the reservoir or the effect will be diluted. Chlorine or ultraviolet rays from sunlight can also destroy biological agents. Yard foggers and crop dusters are also a means of dispersal that can be adapted to function as an aerosol. So far, only Al-Qaeda has shown an interest in crop dusters, since this terrorist group never reached the stage of perfecting aerosolisation (Koblentz, 2009, p. 223). Therefore, scholars predict that commercially available devices to produce a crude biological weapon or food contamination would be the most likely means for a terrorist group to effectively spread a biological weapon to civilians at large in the near future (Cole, 2011, p. 215; Koblentz, 2009, p. 226).

Terrorists may also resort to more rudimentary means to accomplish their goals. If a terrorist group has volunteer scientists or technicians who are willing to get themselves infected with a biological agent and to spread it at a public place or on a plane, the distribution will be high, causing an epidemic (Cole, 2011, p. 54). This does not require a lot of financing and technological sophistication, but it is an effective means for dispersing a biological agent to cause mass causalities. Religious groups, such as Al-Qaeda, with extreme fundamental Islamic beliefs which perceive self-sacrifice as a sacramental act, may resort to such means in dispersing a biological weapon.

Terrorists' motivations for using a biological weapon are for the following reasons. Utilising a biological weapon can serve to intimidate and create anxiety among the public and mistrust in a government’s ability to protect national security (Cole, 2011, p. 68).

Media coverage garnered to spread a terrorist group's propaganda may also prompt them to resort to biological weapons rather than conventional weapons (Cole, 2011, p. 66).

Based on the above, it will, indeed, be difficult to gauge whether terrorist groups will resort to biological weapons to achieve their aims. It is certainly not easy for any country's intelligence to estimate the form of biological agents that terrorist groups might use, nor the means of dissemination, because most terrorist groups operate in secrecy. In the case of Al-Qaeda, the Central Intelligence Agency (CIA) of the US had, by chance, found some key pieces of paper during the US invasion of Afghanistan in 2001 that suggested Al-Qaeda was working on anthrax (Koblentz, 2009, p. 225). Likewise, the case of the Rajneeshpuram cult, wherein a dissident dissatisfied with its group leaked information to the US authorities that the cult was responsible for disseminating *Salmonella typhimurium* in the salad bars of Oregon in 1984 (Koblentz, 2009, p. 226). Without these chance discoveries, it would be have been unlikely for the US police or intelligence to discover whether these terrorist groups were developing biological weapons.

Biotechnological development, over time, may change terrorist capabilities of manufacturing biological weapons. Cole (2011, p. 46) mentioned that "[o]ver time, […] these considerations might change as the biotechnology industry becomes more sophisticated and scientific knowledge disseminates." Koblentz (2009, p. 227) also foresaw that "advances in the life sciences are not only generating new knowledge and techniques that can be misused for hostile purposes, [but] they may be reducing the level of expertise required to utilise previously developed techniques." Therefore, intelligence gathering is crucial, as this can enable authorities to gauge the extent to which terrorists possess the necessary equipment and biotechnological knowledge to launch a bioterrorism attack and to take precautionary measures to mitigate such a possibility. In

preparation for bioterrorism, it is crucial for states to learn to use detection devices to detect biological weapons, especially in public places.

In the aftermath of 11 September, 2001 (9/11) and the attack of the World Trade Centre (WTC) by Al-Qaeda members, detectors were introduced in thirty cities throughout the US by the Biowatch programme (Shea & Gottron, 2004, p. 39). These detectors functioned to identify catastrophic releases of biological weapons rather than those in small quantities. This system detected *Francisella tularensis* as a naturally occurring bacterium in Houston, Texas back in October 2003 (Shea & Gottron, 2004, p. 39). The challenge lies in whether the detectors (ultimately) will be able to distinguish between a naturally occurring pathogen or one that has been genetically modified to have altered attributes.

There is also the need to acquire microbial forensics knowledge to trace the biological agents used in a bioterrorism attack and the perpetrator responsible for the misdeed. Indeed, it is also worth noting that, in the case of bioterrorism, Resolution 1540 of the United Nations Security Council (UNSC) (S.C. Res. 1540, 2004) is the international instrument that monitors non-state actors' actions, namely, terrorists, in their quest to obtain biological agents, equipment and the means of delivery to develop biological weapons. This is in view of the fact that the BWC only monitors states' quest in developing biological weapons.

4.2.3 Dual Use Matters

4.2.3.1 Misuse of Facilities and Equipment

In tracing whether laboratories will be used for biological warfare or bioterrorism, it was highlighted in this sub-section that inspectors wanting to detect the misuse of

facilities will face constraints, because it is hard to distinguish between true civilian purposes and that of malicious intent. This raises the dual use dilemma indicated earlier.

Referring back to the Soviet Union's Biopreparat programme, most of the forty research and production facilities were actually designated to conduct civilian research, but, at the same time, posed as a subterfuge for military biological weapons production (Atlas & Dando, 2006, p. 278). Another example includes the Soviet Union's anti-plague research institutes and field monitoring stations which, while having legitimate health functions, were also supplying agents for biological weapons development (Atlas & Dando, 2006, p. 278). At the Institute of Applied Microbiology at Obolensk, for instance, it was found to have contained an "explosive containment chamber, extensive physical security and biosecurity measures, and a large scale fermentation capacity", pointing towards the development of biological weapons rather than legitimate civilian microbiology research activities being conducted (Atlas & Dando, 2006, p. 278). It was only through human intelligence and informants who divulged the biological weapons development taking place at the said Institute that the unsavoury activities that took place were unmasked. By pretending that a research institute or production facility has legitimate biotechnology civilian activities, this would avert any curiosity or suspicion towards that organisation.

Moreover, scientists and staff from a civilian biotechnology research institute or production facility can easily obtain disease strains from foreign biological resource centres or universities abroad, which may be impossible if it was a military laboratory. Disguising as a legitimate biotechnology research institute will also permit scientists to attend international conferences and network with the world scientific community to exchange tips about the finer intricacies in conducting genetic engineering experiments without raising any suspicion as would happen if they were military laboratory personnel.

Additionally, distinguishing whether a civilian biotechnology institute or production facility has a legitimate or illegal purpose can be complicated because of the similarities in the equipment used. Fermenters, tissue-cell cultures and egg incubators found in pharmaceutical, dairy and brewery industries can similarly be used to produce biological warfare agents (Koblentz, 2009, p. 66). In purifying liquid slurries of bacteria for biological warfare, the Soviet Union scientists used centrifuges that are similarly used at civilian dairy equipment plants (Koblentz, 2009, p. 66). The Soviet Union and Iraq, prior to the Gulf War in 1991, also resorted to using machines to fill munitions with biological agents that were commercially available for civilian use (Koblentz, 2009, p. 66). It was also found that Iraq, in the 1980s, used available civilian equipment, sourced locally, and also imported agricultural sprayers for aerosolisation to disseminate biological agents (Koblentz, 2009, p. 66). Moreover, Iraq once wanted to purchase fermenters from a Swiss company for its biological agents production meant for biological warfare at its Al-Hakam facility, and falsified documents in stating it was for civilian use in its Al Latifyah facility (Atlas & Dando, 2006, p. 279). Subsequently, the US and its allies managed to get the Swiss government to deny an export license to the Swiss company wanting to export fermenters to Iraq (Atlas & Dando, 2006, p. 279). Since the equipment used for producing biological warfare agents is similar to that used for civilian legitimate activities, this makes it difficult for any inspector to detect any development of biological agents for biological warfare. This is, unless they already have vast experience.

In addition, an overlap between defensive and offensive activities makes it hard to distinguish a legitimate activity; again creating the dual use dilemma. As a point of illustration, the US, throughout 1990-91, wanted to stockpile botulinum toxin, but the process in producing such a vaccine was similar to producing the poisonous toxin itself (Koblentz, 2009, p. 68). In this case, the US had to grow large amounts of the toxin, which made it appear that it was producing more biological warfare agents. Only when the

botulinum toxin was treated with formalin to inactivate it, but preserving its immunogenic properties, did it finally become a vaccine. It is for this reason that, when a state proposes to create a facility producing vaccines, this would arouse suspicion because of the dual use function of similarly producing biological warfare agents at the same time.

In this regard, Malaysia received adverse publicity when it once wanted to produce its own vaccine through its Ministry of Health's company, Ninebio Sdn. Bhd. At one point in time, Ninebio Sdn. Bhd., in cooperation with Emergent BioSolutions from the US, were set to produce a vaccine for anthrax called Biothrax in preparation for a bioterrorist attack ("Emergent", 2008; "Planned Malaysian", 2010). Apart from developing the anthrax vaccine, Malaysia wanted to produce other vaccines, starting in 2013, for Severe Acute Respiratory Syndrome (SARS) and Japanese Encephalitis (JE), also spurring research in identifying cures for biological agents that could be used for terrorist activities ("Emergent", 2008; "Planned Malaysian", 2010). This venture was a way of avoiding stringent US restrictions in undertaking any biodefence work, such as producing vaccines in the aftermath of the terrorist attacks of 9/11. Professor Francis Boyle, a well-known international law professor at the University of Illinois, remarked that "[i]t seems to me that this could be a very dangerous end-run by [Emergent Biosolutions] and its government funders around the numerous legislative restrictions […] put in place since 9/11 making it difficult to research, develop and test bioweapons domestically" in the US ("Emergent", 2008; "Planned Malaysian", 2010). Malaysia's case of wanting to develop its own vaccine facility raised concern as to whether it was able to secure such a facility from being the target of terrorists to steal biological agents. This would require good practices of laboratory biosecurity.

Based on the elaboration made, it is possible that any genetic engineering activity to produce biological weapons may be disguised as legitimate civilian uses because of the

similarity of the equipment used for both activities. Additionally, both defensive and offensive activities undergo the same processes in creating biological agents, making it hard to distinguish which is the legitimate purpose.

4.2.3.2 The Misuse of Biotechnological Knowledge

Increasingly, an emphasis on ethics by the WHO regarding the good conduct for research has been given more prominence. This is because it is feared that experimental steps, along with the knowledge generated, have the potential to be misused for malevolent intentions of bioterrorism. Therefore, the WHO has recommended that member states establish a research oversight mechanism consisting of a committee with different expertise in science to oversee, approve or reject the form of experiments that scientists can conduct, based on ethical considerations already formulated (WHO, 2010, p. 12). Some of the considerations outlining the classes of experiments to be reviewed include:

i) Experiments rendering any vaccine ineffective;

ii) Experiments that involve antibiotic resistance;

iii) Experiments encouraging the virulence of pathogens or making a non-pathogen virulent;

iv) Experiments encouraging the transmissibility of pathogens;

v) Experiments altering the host range of a pathogen;

vi) Experiments that cause an evasion of diagnostic or detection modalities and;

vii) Experiments leading to the weaponisation of a biological agent or toxin (Committee of Research Standards and Practices to Prevent the Destructive Application of Biotechnology, 2004).

This emphasis by the WHO is not unwarranted, as scientists have conducted controversial experiments. The bid to eradicate wild mice in Australia in 2002 was made by utilising genetic engineering to insert an immunosuppressant and egg protein gene into the mousepox virus genome so that the modified virus would sterilise mice (Smithson, 2010). This caused the mousepox vaccine to be ineffective among inoculated mice, as they still succumbed to the ailment (Smithson, 2010). This raised a pertinent issue in that the scientists involved in this experiment were given permission to go ahead even though it caused the mousepox vaccine for wild mice to be ineffective, as in point (i) above.

Another crucial issue is that the genetic engineering methods for mousepox could similarly be used by terrorists to increase the lethality of smallpox, as they come from a similar family genre (Smithson, 2010). Terrorists could use the results in creating a biological weapon, thereby violating point (vii), as above. This case also shows an interplay of the dual use dilemma since the Australian scientists actually embarked on this experiment for the good of humankind in trying to eradicate wild mice; yet, simultaneously, their research results could be misused.

Given the above scenario, any scientific evaluation committee is always in a dilemma in deciding whether the benefits of an experiment would outweigh the negative consequences to permit scientists to conduct the experiment. Ethical consideration become important in this context, as it involves judgement and values to decide whether an experiment should go ahead. It is for this reason that the WHO, under the biorisk management framework, emphasises that scientists will have to weigh the future implications of their work, not only for the benefit of the scientific community, but for

the security implications that their research will be misused by unscrupulous characters (WHO, 2010).

Aside from the above, censoring scientific articles among journal publications that may assist terrorists in the development of a biological weapon utilising genetic engineering must also be considered. In the US, its National Security Advisory Board for Biosecurity (NSABB) permitted the publication in scientific journals detailing the experimental steps to create the deadly bird flu, H5N1 strain, by two scientists from the University of Wisconsin-Madison and the Erasmus Medical Centre in the Netherlands, utilising the genetic engineering technique (Finkelmeyer, 2012; Greenfieldboyce, 2012). While the US and the Netherlands initially rejected the request by both scientists to publish in scientific journals, the WHO opined that the results should be published as it is "important for public health efforts to prepare for a possible future pandemic" (Greenfieldboyce, 2012, p. 29). In this instance, the WHO thought the medical benefits derived for the good of public health would outweigh the likelihood of terrorists applying the steps of the experiment to recreate bird flu as a biological weapon, since, at present, terrorists still lack the technological capability to master genetic engineering (Cole, 2011, p. 46; Koblentz, 2009, pp. 214-215). Upon review by the NSABB, it permitted the research for bird flu for publication, but with certain steps of the experiment and results to be censored (Greenfieldboyce, 2012, p. 2). Other scientists worldwide wanting to know the sensitive details of the experiment, had to utilise "some sort of secure communication process" (Greenfieldboyce, 2012, p. 2).

Additionally, the WHO has pushed for prestigious peer reviewed journals, well known internationally, to practise responsible publication in screening articles that may contain steps and results that can be misused for the creation of biological weapons (WHO, 2010, pp. 14-15). Therefore, editors, reviewers and authors will need to be aware about the dual use concern of a particular research publication and adopt the ethics of responsible

publication. Journals such as *Nature*, *Science* and the *New England Journal of Medicine* have also adopted a responsible publication policy, requiring authors to modify their articles concerning Dual Use Research of Concern (DURC) that may be misused, or to reject an article outright if it is too controversial (WHO, 2010, p. 15). Already in Malaysia, the complete sequencing of the Nipah virus, made available online through internet academic databases, could possibly provide the necessary steps for terrorists to use this virus (that is easily found in nature) as a biological weapon (Sai, 2003, p. 117).

As for a suitable oversight mechanism, Institutional Biosafety Committees (IBCs) within universities and research institutes provide the closest suitable candidates to evaluate whether any DURC involving biological agents can be approved before commencing, monitoring an experiment in progress and reviewing the methodology and results of the experiment to decide whether some or all of its parts should be censored for publication fearing misuse for bioterrorism. If IBCs lack expertise in the area of biosecurity, security studies, microbiology, virology, immunology and other areas dealing with biological agents within Biosafety Level 3 (BSL-3) and 4 (BSL-4), experts should be recruited from these areas to complement the existing role of IBCs.

Indeed, the Institutional Review Boards (IRBs) and ethics review committees among universities and research institutes are unsuitable for reviewing a DURC. IRBs and ethics review committees must not review a DURC, because their focus is to protect human research subjects and not be involved in the contentious long-term policy implications of research best left to legislation and administrative policy-making (Resnik, 2010, p. 3). Moreover, IRBs and ethics review committees are unsuitable to review DURC because they are already too overburdened with numerous issues beyond their mandate to consider such as reflecting whether investigators of experiments have a conflict of interest, if their research involves outside sponsors and funding, and health information privacy rules (Relman, 2013, p. 2; Resnik, 2010, p. 3). Expertise only from medicine, pharmacology,

public health, epidemiology, psychology, biostatics, theology (ethics), law and business that constitute the IRBs and ethics review committees are inadequate to evaluate DURC, as they lack expertise from biosafety, biosecurity and national security issues (Resnik, 2010, p. 3). If IRBs and ethics review committees are given the task to review DURC, their lack of expertise and clear guidance will only cause delays in approval, leading to legal liability (Relman, 2013, p. 2). Therefore, IBCs may be suited to review DURCs, albeit with the inclusion of suitable expertise together with the necessary training, education and financial resources to take on an additional task.

Evidence indicating that scientific academic literature can be misused for malevolent purposes has been illustrated in the case of Al-Qaeda. Access to declassified documents in 2004 concerning the activities of Al-Qaeda in Afghanistan illustrated a computer link to the famous journal, *Science* (Leitenberg, 2005, p. 29). There were eleven books and twenty-one professional journal papers backdated to the 1950s and 1960s, all associated with pathogens and biological weapons (Leitenberg, 2005, p. 29). Moreover, a reference to a work titled *The Problems of Chemical and Biological Warfare* from the Stockholm International Peace Research Institute (SIPRI) and the 1969 UN study on chemical and biological weapons were found as references for Al-Qaeda members to create biological weapons (Leitenberg, 2005, p. 30). It is indeed a reality then, that there is a threat for scientific article publications depicting the process and results of scientific experiments to be misused by terrorists. Similarly, in 2004, it was found that Jemaah Islamiyah, a subsidiary terrorist group associated with Al-Qaeda in Southeast Asia, had developed a manual demonstrating the means of creating a biological weapon, as discovered in the Philippines, showing the rudimentary means of achieving their objective ("Asian countries", 2004).

Increasingly, background checks regarding the recruitment of potential foreign students into a receiving country's universities have been emphasised. This is because it

is feared that terrorists, disguised as students, will try to acquire the relevant knowledge through various science courses in the quest to develop biological weapons. In 2008, the United Kingdom (UK) reported that one hundred potential terrorists posing as postgraduate students tried to enrol in science courses to obtain materials and expertise from laboratories of universities and research institutions in their bid to create biological weapons (Towsend, 2008, p. 1). The UK's Foreign Commonwealth Office conducted background checks based on information from its intelligence, using a new vetting scheme, that led to the rejection of these foreign students (Towsend, 2008, p. 1). Under its Academic Technology Approval Scheme, the UK rejected students from states of concern such as Iran and Pakistan (Towsend, 2008). This initiative was implemented "to stop the spread of knowledge and skills that could be used in the proliferation of weapons of mass destruction and their means of delivery" (Towsend, 2008, p. 1). The UK was particularly concerned that extremist groups targeted students by offering to fund courses for them in exchange for their expertise (Towsend, 2008, p. 2). The infiltration of the UK laboratories in hospitals, universities and private firms holding dangerous select agents like Ebola, polio and avian flu would certainly be a reservoir for foreign students with the intent of not only gaining knowledge to create biological weapons, but possibly to smuggle biological agents of value from these laboratories (Towsend, 2008).

Since the UK decided to screen foreign students taking science courses in its country, one lawsuit, *AE v Secretary of State for the Home Department* (2008) (hereinafter known as '*AE*'), was brought against UK authorities. In this case, AE was denied from pursuing A-level courses in subjects of chemistry and human biology out of "national security concerns relating to access of materials and opportunities to develop understanding and knowledge in areas that could be used for terrorist-related activities" (*AE*, 2008, p. 2). This was in view that AE, in the past, had "received terrorist training and had taken part in terrorist activities [and] that he was involved in providing support for the jihadist

insurgency in Iraq" (*AE*, 2008, p. 2). Experts' testimony in gauging whether AE could acquire the necessary skills indicated "skills acquired in the course would be useful in developing bacterial matter because such dangerous bacteria could be obtained from certain farm animals and that there was a risk of obtaining it from abroad" (*AE*, 2008, p. 8). As the human biology course in which AE wanted to enrol emphasised practical work, he would have been very familiar with laboratory equipment and biological substances to provide enough "confidence and skills to safely and effectively follow instructions on the production of chemical devices and toxins" (*AE*, 2008, p. 7). The judgment from this case prevented AE from enrolling in human biology on the grounds that he would be "in a substantially stronger position to produce or to assist in the growth of such pathogens [... as] he would have been told how to handle and produce such pathogens" (*AE*, 2008, p. 8). One expert, John Wood, from the National Institute for Biological Standards and Control in the UK, remarked that "[a]ny scientist would say it's important that we know who is working in our laboratories and also why they are working there" (Towsend, 2008, p. 2).

As evidence shows that background screening of foreign students wanting to enrol in science courses should not be taken lightly by any state, proof that Al-Qaeda recruited a postgraduate student in microbiology was further elaborated. A Pakistani microbiologist with a doctoral degree (PhD) was given the task by Al-Qaeda of obtaining pathogenic culture of anthrax because he understood professional procedures in purchasing pathogen cultures (Leitenberg, 2005, pp. 29-30). He also tried to obtain a vaccine that would protect Al-Qaeda personnel handling and developing anthrax as a biological weapon (Leitenberg, 2005, p. 30).

Likewise, the Pakistani microbiologist, Malaysia's own Yazid Suffat, was a biochemistry graduate from the University of Sacramento, California, who once served Malaysia's Ministry of Defence as a scientific technician and was then recruited by Al-

Qaeda (Leitenberg, 2005, pp. 32-33). This shows that Al-Qaeda was wisely trying to recruit individuals with the necessary expertise in biology to create a biological weapon. Although Suffat failed to obtain a virulent strain of anthrax (Leitenberg, 2005, pp. 33-34), it is only a matter of time before Al-Qaeda is able to recruit the right combination of people to succeed in its aim of creating a biological weapon. Given Al-Qaeda's dispersed network, making it difficult for any state's police and intelligence to really know their whereabouts and activities, it will certainly be hard to track whether they are planning another attempt at creating a biological weapon.

Thus, while both biological warfare and bioterrorism, as well as dual use matters, form the crux of biosecurity in biotechnology, these are the only issues that fall within the scope of this particular biosecurity sector. Unfortunately, the biosecurity of biotechnology has its limitations in failing to address the environmental impacts wrought from the release of biological agents, and further fails to address the security of biological agents within laboratories. This is because it is a specific sector, and its limitation in being unable to address other biosecurity matters that are addressed by other sectors.

4.3 Laboratory Biosecurity and its Features

This section will primarily be concerned with laboratory biosecurity in its connection with genetic engineering. Laboratory biosecurity is defined by the WHO as "the protection, control and accountability for valuable biological materials (VBMs) within laboratories, in order to prevent their unauthorised access, loss, theft, misuse, diversion or intentional release" (WHO, 2006).

Prior to this, a distinction must be made between laboratory biosecurity and biosafety. The WHO refers to biosafety as "the containment principles, technologies and practices that are implemented to prevent the unintentional exposure to pathogens and toxins, or their accidental release" (WHO, 2006). One key difference between both terminologies

is that "biosecurity measures are intended to prevent deliberate diversion of deadly pathogens for malicious purposes, [while] biosafety measures are intended to prevent accidental infections of researchers or releases of pathogens from a research facility that could endanger public health or the environment" (Tucker, 2003, p. 12).

Biosafety emphasises containment measures, laboratory practices and techniques, and safety equipment, as well as facility design and construction. On the other hand, laboratory biosecurity is intended to prevent a biological agent from being stolen, lost, misused, diverted or intentionally released from a laboratory or biological resource centre (BRC).

To illustrate that genetic engineering may be a breach of laboratory biosecurity, a case at the Lawrence Livermore National Laboratory (LLNL) in the US is used as an example. Tri-Valley Cares, a Non-Governmental Organisation (NGO), together with other plaintiffs, had filed a lawsuit at the Northern District of California when it was found that, in 2005, the LLNL had conducted a contagious experiment using "recombinant Deoxyribonucleic Acid (rDNA)" technology or genetic engineering to modify *Yersinia pestis* (plague) to become antibiotic resistant (*Tri-Valley Cares v. United States Department of Energy*, 2010) (hereinafter *Tri-Valley Cares*). The experiment to change plague to become antibiotic resistant definitely did not get a risk assessment approval from the US Department of Health and Human Services (HHS) and the LLNL was ordered by the Centres of Disease Control (CDC) to destroy the samples in order to keep its certificate of registration permitting the possession, use and transfer of select agents and toxins (*Tri-Valley Cares*, 2010, pp. 7-8). It was unclear whether LLNL conducted the research of genetically modified plague for defensive purposes in trying to test the resistance and create a stronger vaccine, or whether this was meant for hostile purposes; creating the dual use dilemma. In this instance, the first form of biosecurity concerning the usage of genetic engineering for benevolent or malevolent purposes was applied, as

shown in Figure 4.1, within the biosecurity of the biotechnology sector. However, laboratory biosecurity also applies, since the experiment in genetically modified plague occurred in a highly contagious laboratory, showing an overlap with the biosecurity of biotechnology, as in Figure 4.1. This case also showed a clear violation of biosafety procedures when, normally, in conducting a highly dangerous experiment approval should be obtained from the designated risk assessment committee recommending measures to mitigate hazards.

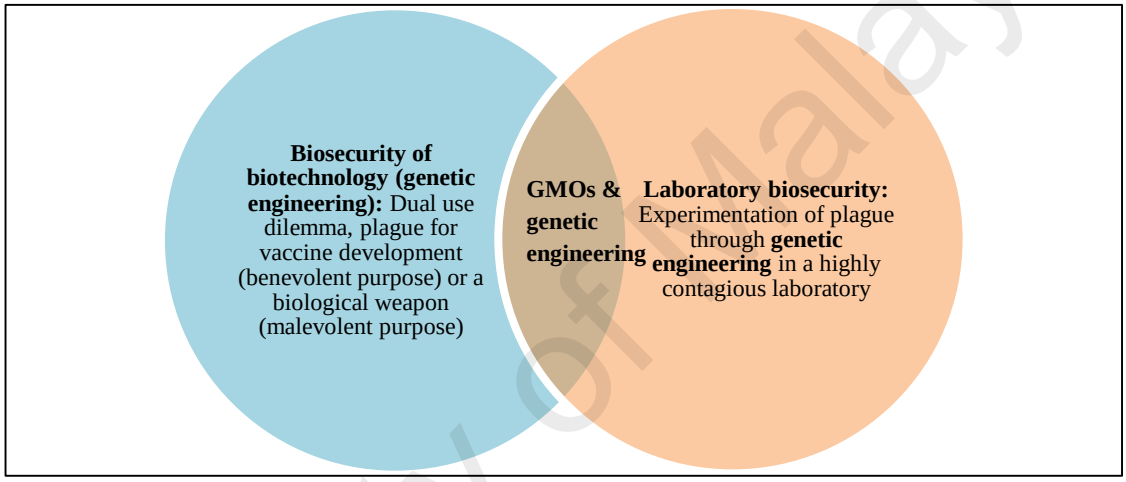

Figure 4.1: An overlap of the biosecurity of biotechnology with laboratory biosecurity in the case of plague

Apart from conducting a highly risky experiment, the LLNL violated other biosecurity measures. The WHO had asserted that laboratory accidents normally occur when there is "inappropriate accountability [and] incomplete record keeping" (WHO, 2006, p. 2). LLNL did not have a "robust, automated inventory system for select agents" (WHO, 2006, p. 17). Without a systematic record-keeping structure regarding which authorised party can handle a select agent, it is likely for an item to get lost or stolen, as it is unaccounted for. On June 9, 2007, LLNL was given a warning that it permitted "an unauthorised individual access to more than 4,000 vials of anthrax to allow the individual 'to package and ship the vials'" (*Tri-Valley Cares*, 2010, p. 7).

Moreover, LLNL failed to comply with "applicable shipping and packaging laws" when transporting the anthrax (*Tri-Valley Cares*, 2010, p. 7). The incident clearly violated the WHO's recommendation regarding the treatment of select agents as VBMs during the transportation process to ensure the "appropriate authorisation and communication between facilities before, during and after external transport" (WHO, 2006, p. 22). This requires counting the number of select agents before transportation and to ensure that the total is the same, otherwise they could have been lost or stolen during the transportation process. The labelling of the select agents in vials or in any other form for keeping must also be checked to ensure that they truly represent the substance they have been labelled as. LLNL clearly breached the WHO's recommendation for accountability regarding the transportation of anthrax to Virginia because it received a voicemail from its counterpart stating that the shipment was packaged "at random" and there were inventory discrepancies, whereby, some vials were missing and mislabelled samples were present (*Tri-Valley Cares*, 2010, p. 6). Having breached the procedure for transporting anthrax, LLNL was ordered to instigate a "full stand-down" of its select agent work (*Tri-Valley Cares*, 2010, p. 6). Unfortunately, LLNL employees still continued work with the select agents, since their facility manager was not informed about the work stand-down (*Tri-Valley Cares*, 2010, p. 6).

Given that LLNL was handling highly dangerous select agents, such as plague and anthrax, it is no wonder that Tri-Valley Cares and other plaintiffs who were part of the community of Livermore decided to file a lawsuit, as all these agents posed "a new and greater risk to human health and the environment in the Livermore locale" should these agents have escaped the laboratory or be stolen by any party with malicious intent (*Tri-Valley Cares*, 2010, p. 17). In fact, the mislabelling and packaging of anthrax vials in the course of transportation to a laboratory in Florida had caused "two employees and three contract workers at the Florida laboratory" to be exposed to anthrax, requiring them to

undergo medical treatment because their health was threatened (*Tri-Valley Cares*, 2010, p. 6).

Most importantly, the Tri-Valley Cares lawsuit highlighted that the US Department of Energy, and other parties as defendants, failed to thoroughly analyse the different scenarios in which a terrorist attack could occur in breaching the LLNL BSL-3 laboratory, as well as the environmental effects resulting from this violation of the US National Environmental Policy Act (NEPA) (*Tri-Valley Cares*, 2010, p. 16). This breach in containment included likely terrorist acts, such as a suicidal plane crashes, explosions and fire or damage to the laboratory's autoclaves; scenarios wherein the defendants should have proposed means of dealing with such situations (*Tri-Valley Cares*, 2010, p. 15). Moreover, the defendants failed to analyse the possibility of theft and the release of pathogenic material, either by an insider within the facility or a terrorist managing to break through, regardless as to whether this concerned genetically modified organisms or any unidentified organisms having an environmental impact on nearby residences in the city of Livermore (*Tri-Valley Cares*, 2010, pp. 17-18). In this regard, should this have involved the release of genetically modified pathogens by a terrorist into the environment, health officials would have the obstacle of trying to diagnose a disease associated with related symptoms, because altered pathogens may have different "epitopes or sequences used for detection and diagnostics" as it is a mixture of organisms with different characteristics combined together (Petro, Plasse & McNulty, 2003, p. 162). Failure to fastidiously diagnose the appropriate disease would mean a delay in treatment, or a wrong choice of medications and therapeutics prescribed to treat the infected public at large. In such a situation, death may even occur among infected patients if the genetically modified pathogens show prevailing characteristics leading to lethality. For this reason Tri-Valley Cares and other plaintiffs brought this lawsuit against the relevant US authorities because they feared the unpredictable consequences of genetically modified pathogens that were

already lethal enough in the natural environment and would be deadlier if combined with other pathogens. Although all of these laboratory biosecurity concerns were raised by Tri-Valley Cares and other plaintiffs to stop the LLNL operation, the US Federal Appeals Court permitted LLNL to continue its operations as it found that the probable scenario for a potential terrorist to steal and release lethal pathogens would be unlikely to cause significant danger because the feasibility was too remote (Bigongiari, 2012, p. 2).

If the Tri-Valley Cares example is not enough, another example was illustrated in the case of research mice infected with bubonic plague bacteria at a BSL-3 laboratory in Newark, New Jersey, which got lost and were never accounted for (Klotz & Sylvester, 2009, p. 12). Various reasons were given for the loss, such as the mice being stolen, eaten by other laboratory animals or miscounted (Klotz & Sylvester, 2009, p. 128). This left the nearby neighbourhood fearful and angry as the plague could have spread, causing a deadly disease. Assurance by the state health Commissioner of New Jersey in asserting that the escaped mice would have died, because they were already infected, was no consolation at all to the affected community (Klotz & Sylvester, 2009, p. 128).

Further evidence showing a laboratory biosecurity breach in the US concerns the case of Maureen Stevens who sued Battelle Memorial Institute in Fort Detrick for negligence because it "failed to conduct background investigations prior to hiring in individuals who would have access to anthrax" (*United States v. Maureen Stevens*, 2008) (hereinafter *Maureen Stevens*). This resulted in the Institute hiring a scientist allegedly responsible for the mailing of anthrax letters in October 2001 (*Maureen Stevens*, 2008, p. 2). Robert Stevens, Maureen's husband, who opened the tainted letters while serving at American Media Incorporated, Florida, became infected and subsequently died (*Maureen Stevens*, 2008, p. 2). In Maureen's lawsuit, she claimed that the US Government failed to provide adequate security for the handling or shipping of materials, whereby, sometime before October 2001, anthrax was improperly intercepted, either from the United States Army

Medical Research Institute (USAMRIID) or from another research facility to which the materials had been sent (*Maureen Stevens*, 2008, p. 2). This case involved Bruce Irvins, a disgruntled American scientist whose funds to create an anthrax vaccine at the Institute were being cut (Klotz & Sylvester, 2009, p. 111). Dissatisfied, Irvins allegedly mailed the anthrax letters to a number of destinations in the US, wanting to prove that anthrax could be a hazardous biological weapon needing more funding in the creation of more vaccines to fight it. By 2008, the US Federal Bureau of Investigation (FBI) was able to confidently prove that the source of the anthrax spores originated from Irvins' flask, labelled as RMR-1029, which he himself had cultured, leading him to commit suicide for fear of being caught (Klotz & Sylvester, 2009, p. 111).

Irvins had also suffered from a mental illness and alcoholism, making him an unsuitable candidate to work in a scientific laboratory handling highly dangerous pathogens, given his frame of mind (Klotz & Sylvester, 2009, p. 111). Based on the precedent case of Irvins, it was only appropriate that the WHO, in its laboratory security guidance, highlighted the need to ensure that "[t]he professional and bioethical eligibility and suitability for working with [valuable biological material (VBM)] of all personnel who have regular authorised access to sensitive materials" be crucial for a secure laboratory management (WHO, 2006, p. 26). This clearly indicates that an organisation should evaluate a potential employee's state of mind before hiring him for a risky job that involves highly dangerous pathogens. Other breaches found at the Battelle Memorial Institute include the loss of samples of "anthrax bacterium, hanta virus and ebola virus" in 1992, clearly the result of unaccounted breaches in laboratory biosecurity (*Maureen Stevens*, 2008, p. 10).

If a breach of laboratory biosecurity can occur in an advanced state such as the US, with ample funding to have sophisticated secured facilities, this does not auger well for developing states thinking of experimenting with deadly select agents to create vaccines.

Already, it has been remarked that "Asian laboratories are often lax in their biocontainment practices" in citing the case of three laboratory workers being infected with SARS in laboratories in Taiwan, Singapore and Beijing (Klotz & Sylvester, 2009, p. 125).

Moreover, the WHO, in stressing the need to protect VBMs, has emphasised on selecting agents with "historical, medical, epidemiological, commercial or scientific value" (WHO, 2006, p. 14). Past VBMs, whether found naturally or genetically modified, have an intrinsic value and need to be preserved for any future experiments involving a younger generation of scientists. The WHO, therefore, stressed the need to document past select agents to track their movements and availability (WHO, 2006, p. 14). If there is a need to destroy past VBMs, or transfer them to a more secure facility, the necessary protocols must be followed to ensure that they do not fall into destructive hands. Such is the case of genetically modified strains being archived now in Russia, which may be a source of intentional or accidental infectious disease outbreaks if not stored properly with inadequate biosecurity measures, or become the acquired target of terrorist groups (Gilsdorf & Zilinskas, 2005, p. 1161). Presently, Russia, or any of its former satellite states entrusted with the safekeeping of historical pathogens, have the duty to ensure that they have adequate laws in place to address the risk of these GMOs being lost, stolen, misused or deliberately being released into the environment if they fall into the hands of wrongdoers.

Thus, this section demonstrated relevant examples of genetic engineering being applied and breaches of laboratory biosecurity in illustrating the relevance of this form of biosecurity. As indicated, laboratory biosecurity is limited to its application of security measures within the laboratory. If biological agents are being dispersed and released into the environment, laboratory biosecurity has its limitations, as it cannot address the contamination wrought on the environment. This leaves it to the agricultural biosecurity

sector to address the environmental aspect, something which laboratory biosecurity cannot address.

4.4 Agricultural Biosecurity and its Scope

This section covers the aspect of public health in the form of food safety affecting humans in the context of GMOs, a part of agricultural biosecurity highlighted by the Food and Agricultural Organisation of the United Nations (FAO). Agricultural biosecurity covers a "wide-ranging aspect of public health and protection of the environment" (FAO, 2007, p. 3). Indeed, the Cartagena Protocol on Biosafety (CPB) deals with GMOs released into the environment to affect biological diversity within the agricultural biosecurity sector, as indicated in Chapter 1.

The importance of public health has not been underestimated, especially by the WHO, since "[p]oor practices in agriculture or food production can favour biosecurity threats, and directly have an impact on public health or threaten food security" (International Food Safety Authorities Network [INFOSAN], 2010, p. 3). It is highlighted that the focus of discussion on agricultural biosecurity in this section was limited to diseases affecting humans. Agroterrorism, meaning "the deliberate introduction of an animal or plant disease with the goal of generating fear, causing economic losses, and/or undermining stability", will only be given attention to the extent to which it affects humans (Monke, 2004, p.1).

Having defined the parameters for the discussion on agricultural biosecurity, an example of one recent case of genetic engineering bringing about food safety concerns and diseases to humans is the outbreak of *Escherichia coli (E.coli)* 0104: H4 contaminating sprouts in Hamburg, Germany, which began in May 2011 and was alleged to have come from fenugreek seeds in Egypt ("E.coli outbreak: EU", 2011). However, subsequent tests conducted in October 2011 and involving technical experts from the

WHO and European Union (EU) showed a negative presence of the *E.coli* bacteria among Egyptian fenugreek seeds ("E.coli outbreak: EU", 2011). The real source of the food contamination was not found. Scientists from Germany did indicate that the *E.coli* was a new strain attributed to "the emergence of an apparent [Enterohemorrhagic strain bacterium *Escherichia coli*] (EHEC) and [Entero Aggregative *Escherichia coli*] (EAggEC) hybrid in the form of *E.coli* 0104: H4" ("Shiga Toxin", 2011, p. 5). It was suspected that the contamination occurred during seed cultivation through a sewage spill or during the transfer of the sprouting seed bed, as no animal reservoirs were identified ("Shiga Toxin", 2011). This showed a form of environmental contamination. In this instance, the contamination of *E. coli* was supposedly a natural outbreak caused by a natural mutagenesis between the different hybrids of *E. coli.*

Before scientists attributed the outbreak to natural causes, a link to genetic engineering was sparked because the various strains of *E. coli* were combined with DNA sequences from the plague bacteria. Dr. Helge Karch, Director of the Robert Koch Institute (RKI) for *E.coli*, indicated that the gene sequencing showed it was chimera, a combination of different genetic materials joining various strains of *E.coli* and DNA sequences from the plague, making this new strain highly pathogenic (Hackenborch, Shafy & Thadeusz, 2011). It was highly unusual to find DNA sequences from the plague bacteria in *E.coli*, and the Centre for the Protection of National Infrastructure in the UK warned that "it would not be beyond al-Qaida to launch a food-based attack" (Hall, 2011, p. 3). The said Centre also warned manufacturers and retailers in the country about possible agroterrorism attacks leading to a large outbreak of food poisoning ("E. coli outbreak could", 2011, p. 3). Klaus-Dieter Zastrow, the chief doctor for hygiene at Germany's Vivantes Hospital, Berlin, also remarked that "it is quite possible there's a crazy person out there who thinks: I'll kill a few people or make 10,000 ill" (Hall, 2011, p. 3). Both the said Centre and Dr. Zastrow suspected that terrorists had genetically engineered the

E.coli to include DNA sequences from the plague in order to produce a new pathogen displaying unusual characteristics. Shea and Gottron (2004, p. 38) indicated that "incidence of catastrophic, anonymous attacks is projected to increase, as terrorist groups organise around issues that have less local, concrete political goals, but […] more ideologically driven." If this was the case, the *E. coli* incident in Germany may have been an anonymous terrorist attack wherein the perpetrators wanted to be undetected. This should not be completely discounted, as Dr. Zastrow added, "[i]t is a negligent mistake not to investigate in that direction" (Hall, 2011, p. 3).

From the viewpoint of this study, Dr. Zastrow's remark should not be dismissed lightly. He raised a very important policy matter regarding the failure of German authorities to look beyond the *E. coli* incident as a health outbreak, but as one which may have had security implications of bioterrorism. This would have involved the German police and its intelligence. Therefore, the approach taken by the German authorities was criticised because they were not broadminded enough to look at the incident beyond a health perspective, given the unusual characteristics displayed by the biological agent.

Regarding the outbreak, this may be an indicator that it may have been genetically modified. Gilsdorf and Zilinskas (2005, p. 1162) stated that, "[i]llness caused by bioengineered microbes, […] may be characterised by signs and symptoms that are not usually associated with a single agent, such as signs and symptoms that are unusual given the causative agent that was isolated by culture or detected by other diagnostic tests [or] a cluster of symptoms that do not fit the expected clinical picture." This makes it impossible for physicians and scientists to truly recognise the original form of a biological agent that has undergone genetic engineering changes. Pathogens which have undergone genetic changes may have "an unexpected age distribution of cases, such as childhood illnesses appearing in adults who are considered to be immune" (Gilsdorf & Zilinskas, 2005, p. 1162). This was precisely the phenomenon that was

encountered in the *E.coli* case in Germany, whereby Rolf Sthal, the head from the Third Medical Clinic and Polyclinic at the University Medical Centre Hamburg-Eppendorf (UKE), remarked "[w]e weren't even thinking of EHEC at first […] because it normally affects children", rather than young healthy women which were mostly affected in this case (Hackenborch et al., 2011, p. 3). Stahl was also quoted to have said, "[w]e are dealing with a completely new clinical picture", implying that the epidemiologic characteristics of a pathogen were altered (Hackenborch et al., 2011, p. 3). This clearly showed that the doctor was encountering problems to diagnose the form of disease from which the patients were suffering because the symptoms displayed did not conform to the norm of suspected EHEC. Furthermore, the *E. coli* also presented unusual characteristics of being resistant to multiple classes of antibiotics (Turner, 2011). This seems to confirm the different characterisation of signs and symptoms of a genetically modified microbe which has "an unexpectedly poor response to standard treatment" (Gilsdorf & Zilinskas, 2005, p. 1162).

Given that the *E.coli* outbreak demonstrated some highly unusual characteristics, that should have given some clues to the German officials, but they never even bothered to look into the possibility that this might be an act of bioterrorism involving genetic engineering. Such an incident occurred because there is a tendency to view a biosecurity issue purely from the angle of one particular biosecurity sector without thinking of the possibility that it is a bigger problem stretching across other biosecurity sectors. Therefore, there is a more valid reason to propose the merging of the three separate biosecurity sectors together, because this will provide an avenue to authorities to approach biosecurity from a different perspective. In other words, there is not a single solution to a biosecurity issue, as there could be many solutions depending on from which angle biosecurity is being looked at by the different biosecurity sectors.

This study also asserted that authorities and policymakers cannot take for granted that, whenever a food contamination occurs, it is all attributed to a natural outbreak. It could be that the food contamination incident may be caused by terrorists as an act of bioterrorism. A case in point concerns the contamination by *Salmonella Typhimurium* at the salad bars of a chain of restaurants in Oregon, US, in 1984 by the Rajneeshpuram cult (Koblentz, 2009, p. 203). The US State Health Department and the CDC initially thought the outbreak was from the unsanitary practices of workers serving at restaurants. It eventually surfaced that the cult was responsible when a disgruntled member leaked information to the US authorities (Koblentz, 2009, pp. 203-204). This clearly illustrated that a food contamination incident should not be treated as a routine outbreak caused by human error, but to look at it from the biosecurity angle of bioterrorism. It may be then, that the *E. coli* outbreak in Germany of 2011 could be a repetition of the *Salmonella* incident in the US, but the truth will never surface because the German authorities did not investigate in the direction of bioterrorism.

Based on the setbacks highlighted, this study has further delved into the need for an integrated form of biosecurity merging the three disparate sectors; namely, the biosecurity of biotechnology, laboratory biosecurity and agricultural biosecurity. This is because agricultural biosecurity is limited in its ability to only deal with matters of food safety, GMOs, pests, diseases and invasive alien species, but not laboratory biosecurity or issues pertaining to the biosecurity of biotechnology sector. By specialising within its own area of work, this becomes agricultural biosecurity's limitation, because it cannot deal with a biosecurity issue, as in the German *E. coli* case, that spans across other sectors.

A summary of the different biosecurity sectors and their limitations is provided in Table 4.1 based on the previous elaboration of these sectors.

Table 4.1: Biosecurity sectors and their limitations

Biosecurity Sectors	Scope	Limitations
Biosecurity of Biotechnology	• Bioterrorism • Biological warfare • Dual use matters	• Environmental matters of biosecurity not covered • Excludes laboratory biosecurity covered.
Laboratory Biosecurity	• Specific to biological agents and equipment in laboratories	• Excludes biological warfare and bioterrorism • Environmental matters of biosecurity not
Agricultural Biosecurity	• GMOs, pests, diseases, invasive alien species, zoonoses • Relates to environmental matters and biodiversity	• Excludes bioterrorism and biological warfare • Laboratory biosecurity excluded

4.5 The Need for a Comprehensive Form and Coordinator of Biosecurity at the International Level

Using the German *E. coli* incident as a benchmark, this section proposes the need of combining the disparate biosecurity sectors to be complementary to each other, because they each can offer their own perspective, especially among related governmental agencies, in treating a biosecurity problem in a holistic manner.

Initially, it was assumed that all three forms of biosecurity were isolated and existing on their own, since there was no interaction among them, as shown in Figure 4.2. In depicting the German case of biosecurity as isolated (see Figure 4.2), this means the food safety issue affecting public health is merely treated as an agricultural biosecurity matter with the involvement of a few agencies, such as the RKI at the Münster University Hospital and other German health officials, without the involvement of the police or intelligence guarding national security (Hackenborch et al., 2011, p. 4; Hall, 2011, p. 3).

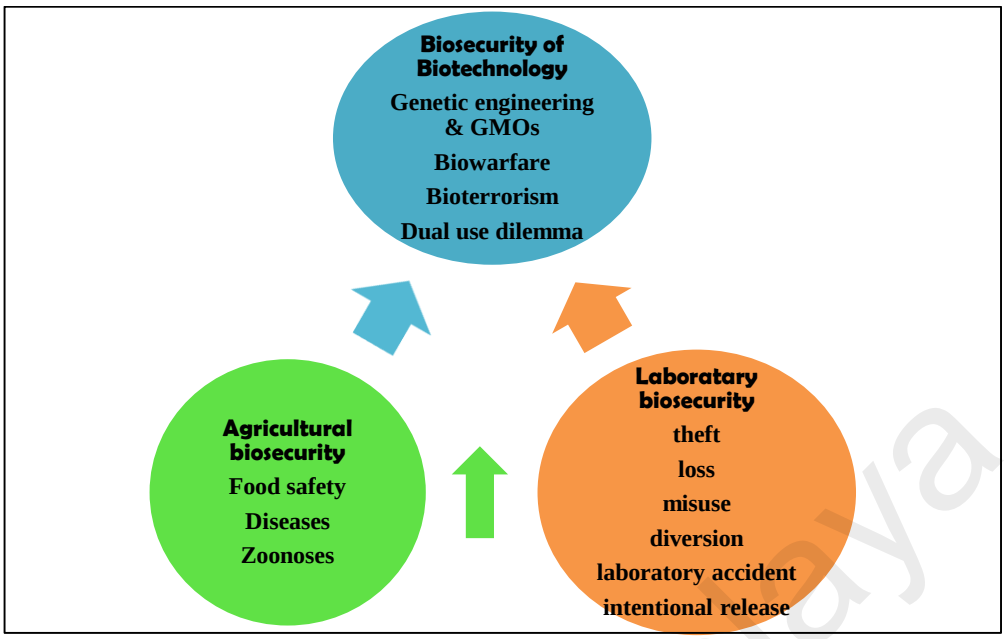

Figure 4.2: Three different forms of biosecurity as isolated sectors to merge together

The arrows in Figure 4.2 depict the need for all three sectors to come together, since their scope of work would eventually intersect with one another.

If Germany had taken a more comprehensive approach beyond agricultural biosecurity, this would have included other sectors, such as the biosecurity for biotechnology involving bioterrorism, in view that the *E. coli* could have been deliberately genetically modified to contain fragments of plague DNA. This would have required the German police and its intelligence, with their own expertise, to investigate if they suspected an act of bioterrorism. If the *E. coli* had been assumed to be modified in a crude laboratory by any terrorists, laboratory biosecurity would be another sector involved. This would bring all three biosecurity sectors and respective agencies to cooperate together so as to have their scope of work intersect among one another, as in Figure 4.3. This would also require the German agencies involved to be broadminded and willing to hear the other agencies' point of view from a different perspective, without sticking to their own steadfast ways. This means a compromise and the willingness of

each to surrender a bit of their turf, even though the scope of work among German agencies within one biosecurity sector may sometimes encroach into another. As stated by Fidler and Gostin (2008, p. 2), "integrating security and public health requires changing entrenched perspectives and practices and building new, sustainable governance approaches."

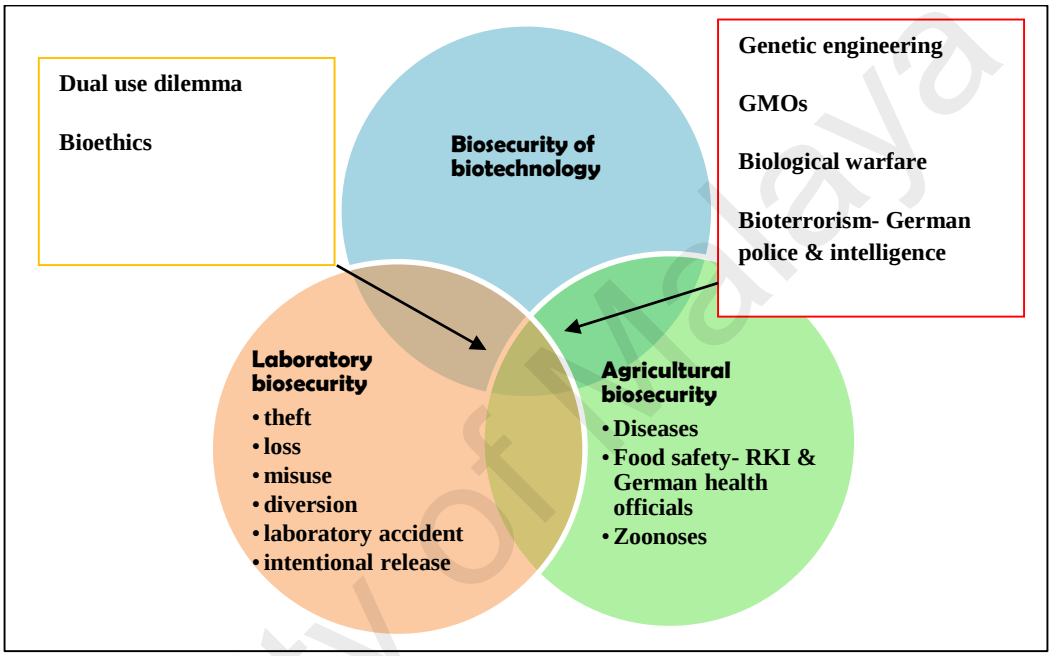

Figure 4.3: The merger of all three biosecurity sectors involving Germany's case of *E. coli*

Similarly, Malaysia's Nipah virus outbreak from September 1998 to May 1999 (while clearly a case of agricultural biosecurity involving zoonoses) could have been a case of the biosecurity of biotechnology (Committee on Prevention of Proliferation of Biological Weapons in States Beyond the Former Soviet Union, 2009, p. 138). The Committee on Prevention and Proliferation of Biological Weapons in States Beyond the Former Soviet Union, from the US indicated that there "were also initial accusations that the Nipah outbreak occurred as a result of US bioweapons experiments" (2009, p. 138). If this had been the case, the Malaysian authorities had viewed the Nipah virus outbreak as one beyond an agricultural biosecurity matter, involving the testing of a biological weapon leading to the misuse of biotechnology for malevolent purposes. This would have also

covered two sectors of biosecurity for the Nipah outbreak; namely, agricultural biosecurity and the biosecurity of biotechnology.

The above discussion indicates the preference for an extended scope of biosecurity beyond each isolated sector. Such a position runs the risk of being criticised, since biosecurity is too broad and vague, overwhelming policymakers regarding the various threats to be addressed and the overlapping and conflicting solutions to resolve them (Koblentz, 2009, p. 108). Another criticism levelled against an overarching concept of biosecurity is the hindrance of policymakers to prioritise which sectors of biosecurity are more crucial and deserving of the necessary budget, leading to a sub-optimal priority of whichever is the "lowest-common-denominator" (Koblentz, 2009, p. 108).

Despite these highlighted criticisms, this study has defended the position for a broad scope of biosecurity for the following reasons. First, treating each biosecurity sector as a fragmented field of its own only serves to overly focus on one sector. This neglects the fact that the concerns of one sector of biosecurity may actually intersect with another sector, requiring the cooperation of agencies across sectors. This may be vital in resolving a complicated biosecurity issue.

Secondly, a broad approach to biosecurity will be able to identify all the relevant actors affected; this concerns the various state and non-state actors from different disciplines who are readily available to respond appropriately in an emergency requiring a spontaneous reaction or risk further danger affecting various parties. For all the reasons cited above, this study still posits for a broad scope of biosecurity combining all biosecurity sectors that are currently existing individually on their own.

For starters, an integrated definition of biosecurity at the international level reflecting the combination of sectors is anticipated to change the mind-set of the administrators of international organisations overseeing international agreements and non-binding

initiatives and member states. A holistic definition of biosecurity can shed light on the interrelatedness among sectors and invoke the need to cooperate among international organisations in bringing the disparate biosecurity sectors together. This is one partial solution in resolving the issue of disparate biosecurity sectors, to be followed by a need of forming a coordinating mechanism at the UN level, one able to unite various biosecurity international organisations and agencies together as the means of integration.

The suggested coordinating mechanism within the ambit of the UN is anticipated to bring biosecurity international organisations and agencies together, such as the Implementation Support Unit (ISU) of the BWC, in managing biological warfare and, to an extent, addressing bioterrorism, the WHO, which addresses laboratory biosecurity and biosafety, the Convention on Biological Diversity (CBD) Secretariat managing the administration of the CPB along with the United Nations Environment Programme (UNEP). The envisioned coordinating mechanism must be headed by an appointed coordinator to oversee the day-to-day work of these various international organisations and agencies to ensure that no duplication of their work occurs.

A cue can be taken from the Counter Terrorism Implementation Task Force (CTITF) formed in June 2005 and which manages 38 entities from the UN and other agencies, acting as coordinator for the coherence of counter-terrorism efforts (Rosand, 2009, p. 1). The CTITF office, housed within the Department of Political Affairs (DPA) of the UN, provides a wide system support for the implementation of the UN Global Counter-Terrorism Strategy to member states as a holistic entity able to advise states as to which international organisations or agencies within its purview can provide assistance on a terrorism issue, based on these organisations' mandate (United Nations Counter-Terrorism Centre [UNCTC], 2016). Cockayne, Millar, Cortright and Romaniuk (2011, p. 11) have praised the formation of working groups within the CTITF because this provides an informal bridge between UN entities, bringing them to collaborate closely "without

being hampered by the limitations of their own mandates and governance." Cockayne et al. (2011, p. 11) indicated this as "highly innovative and produced some important positive results." This is because the working groups provide a zone of comfort for these UN entities to collaborate on a common theme of terrorism. The CTITF Working Group on preventing and responding to weapons of mass destruction (WMDs), for instance, already involved the ISU of the BWC and the WHO in the Inter-Agency Coordination in the Event of a Terrorist Attack Using Chemical or Biological Weapons and Materials in a meeting of May 2011 (Paturej, 2011, p. 5) and a Workshop on Effective Inter-Agency Interoperability and Coordinated Communication in case of Chemical and/or Biological Attacks (UNOG, 2015, p. 7) in February 2015. Even a representative of the CTITF attended the BWC's Meeting of Experts in August 2015 and presented the scope of work of the CTITF among BWC member states (Santori, 2015, p. 1). Additionally, the WHO is a CTITF member (WHO, 2012, p. 3), while the ISU of the BWC is not.

It is envisioned that the biosecurity coordinating mechanism to be created could already refer to the created structure of CTITF entities as a point of reference on the CTITF website. This biosecurity coordinating mechanism will simply utilise existing UN international organisations and agencies that can contribute to biosecurity, broadly based on their specialisation learning from the CTITF. Since both the ISU of the BWC and WHO are involved with the CTITF in addressing bioterrorism, an aspect of biosecurity covered by USNAS mentioned in Chapter 1, this leaves the need to incorporate the CBD Secretariat and UNEP to address the environmental consequences of terrorism, known as eco-terrorism.[4] In Europe, UNEP, through its Environmental and Security (ENVISEC) initiative, has collaborated together with the United Nations Development Programme (UNDP), the Organisation for Security and Cooperation in Europe (OSCE), UN

[4] See Brunel's (2011) definition of eco-terrorism. She indicates that eco-terrorism can include both the use of the environment as a destructive tool (through release of biological agents) and also attacks against the environment through contamination of water, agricultural crops and natural resources.

Economic Commission for Europe (UNECE) and the North Atlantic Treaty Organisation (NATO) through its Science for Peace and Security (SPS) Programme in addressing eco-terrorism, being a new challenge to security (Beten, 2009, p. 9; Kingham & Bernstein, 2006, p. 3; Mullaart, 2006, p. 43). UNEP's incorporation into the biosecurity sphere of agencies will be beneficial to address the void whereby the CTITF has not envisioned in covering eco-terrorism since terrorist release of biological weapons has negative repercussions for the environment. Through a proposed coordinating mechanism of the UN managing various agencies, and with a broad new definition of biosecurity, it is envisioned this can usher in a more integrated practice of biosecurity than being segregated sectors. Through the coordinating mechanism for biosecurity also leading various international organisations to adopt and create an awareness of the International Sustainable Development Law (ISDL) principles from the Delhi Declaration mentioned in Chapter 1, this can further assist the integration of biosecurity at the international level, as those principles are used as a benchmark for integration.

4.6 Conclusion

As indicated in this chapter, the implication of genetic engineering, or GMOs, on biosecurity all depends on the form and meaning of biosecurity, as there are three different definitions treated as segregated sectors. It was argued in this chapter that all three biosecurity sectors (namely, the biosecurity of biotechnology, laboratory biosecurity and agricultural biosecurity), while specialised, are unable to address complex biosecurity issues spanning across sectors; as illustrated from the German *E. coli* case. As a partial solution, this study recommended for a holistic definition of biosecurity to be entrenched among international organisations and agencies to change their mind-set from the existing segregated approach to one of convergence. Creating a coordinating mechanism at the UN level to unite existing international organisations and agencies among the three sectors followed by the need to instil the practice of integrating ISDL principles among

the related international instruments which these organisations manage will spur the path for integration. Therefore, the following chapter seeks to decipher these ISDL principles, as these must be understood just before they can be a form of benchmark for the means of integration.

CHAPTER 5: INTERNATIONAL SUSTAINABLE DEVELOPMENT LAW (ISDL)

5.1 Introduction

In Chapter 4, it was proposed that different sectors of biosecurity ought to complement one another in view of the fact that specialisation limits their ability to address any biosecurity matter that encroaches across sectors, as illustrated by the German *Escherichia Coli (E. Coli)* case. In bringing the biosecurity sectors and associated international agreements and initiatives together, this chapter will introduce the International Sustainable Development Law (ISDL), which is based on the 2002 New Delhi Declaration of Principles of International Law Relating to Sustainable Development (hereinafter Delhi Declaration; International Law Association [ILA], 2002), as a means of bringing together various biosecurity sectors and associated international agreements and initiatives. Thus, this chapter intends to fulfil the second objective of this study which is to identify the principles of international law from the Delhi Declaration of ISDL.

To achieve this objective, a brief history of the evolution of sustainable development is sketched, followed by a clarification of its definition and components, before elaborating on the various principles of the Delhi Declaration. Measures to implement ISDL, and the legal status of sustainable development, are also covered before drawing the chapter to a conclusion.

5.2 The Evolution and History of Sustainable Development

This section begins with a brief historical overview of how sustainable development first came to light. To this end, the sub-sections will be organised according to the key events that contributed to the present-day crystallisation of sustainable development.

5.2.1 The End of the 19th Century and Towards Stockholm

This sub-section introduces the beginnings of international environmental law, for the advent of sustainable development is closely tied to this branch of international law. The link between economic activity and its negative ramifications for the environment has always been a concern of international environmental law, beginning with the *Behring Sea Fur Seals Arbitration* (Government Printing Office [GPO], 1898, p. 935) involving the United States (US) with an interest in conserving the common natural resources beyond its borders and the United Kingdom (UK) who was pursuing its own economic interest. Another arbitral decision in *Trail Smelter* (GPO, 1941) reflected similar conflicting goals of pursuing economic activity versus preserving the environment – when an overwhelming amount of sulphur dioxide from a smelter of lead and zinc in Trail, British Columbia, Canada had caused transboundary pollution in areas under US jurisdiction.

The *Trail Smelter* Tribunal held Canada responsible for the transboundary environmental harm in the form of air pollution, as a smelter in British Columbia was the actual perpetrator, triggering the law of state responsibility for actions of non-state actors within a state's own borders (GPO, 1941).[1] In the advisory opinion for *Legality of the Threat or Use of Nuclear Weapons* (1996, p. 226) (hereinafter *Nuclear Weapons*), the International Court of Justice (ICJ) reaffirmed the decision from *Trail Smelter* that "[t]he existence of the general obligation of states to ensure that activities within their jurisdiction and control respect the environment of other States or areas beyond national control is now part of the corpus of international law relating to the environment".

[1] In the decision of the *Trail Smelter Arbitration*, reported on 11 March, 1941 between the United States and Canada, it was mentioned:

[u]nder the principles of international law, as well as of the law of the United States, no state has the right to use or permit the use of its territory in such a manner as to cause injury or fumes in or to the territory of another or the properties or persons therein, when the cause is of serious consequence and the injury is established by clear and convincing evidence.

In the post-World War II period (1945 - 1960s), many developing states emerged with their new-found independence from colonial powers in the regions of Africa, Latin America, South Asia, and Southeast Asia (Vogler, 2007, p. 431). Inequities in trade and development and the need to liberate developing states from the shackles of poverty required foreign aid and the transfer of technology. This led to developing states forming the Group of Seventy-Seven (G77) on 15 June 1964 and the formation of the United Nations Conference on Trade and Development (UNCTAD) (Vogler, 2007, p. 431). The formation of the G77 enabled developing states to push for their economic development agenda and address the structural inequities existing in the international system at the time (Vogler, 2007, p. 432).

Throughout the 1960s and 1970s, it became apparent that pursuing economic activities without considering their environmental repercussions had led to environmental degradation (Almeida, 1972). *Silent Spring*, a book written by Rachel Carson in 1962, suggested that usage of agricultural pesticides at catastrophic levels was endangering animal species and harming human health (Armstrong, Farell & Lambert, 2007, p. 260; International Institute for Sustainable Development [IISD], 1997, p. 2). By 1971, the International Institute for Environment and Development (IIED) was established in the UK to identify ways in which economic development could proceed without destroying the environment resource base (IISD, 1997, p. 3).

Subsequently, in June 1971, a meeting of the United Nations Conference on the Human Environment (UNCHE) Preparatory Committee (Prep Com) was held in the Swiss village of Founex (IISD, 1997, p. 3), which clarified the discrepancy in developing states' emphasis on economic development and foreign aid to alleviate poverty while environmental issues were treated as "relatively marginal" (Almeida, 1972, p. 15). Hence, the need for another conference which took place in Stockholm in 1972.

5.2.2 The 1972 Stockholm Conference

Emerging from UNCHE in Stockholm was the Declaration of the United Nations Conference on the Human Environment (UNCHE, 1972) (hereinafter Stockholm Declaration) with twenty-six principles. Although the Stockholm Conference did not explicitly mention sustainable development as an emerging concept, the said Declaration had laid the foundation for it.

For instance, the need to strike a balance between economic development and environmental protection was indicated in Principle 13 of the Stockholm Declaration, which mentions that "[s]tates should adopt an integrated and coordinated approach to their development planning so as to ensure that development is compatible with the need to protect and improve the environment for the benefit of their population". The term "integrated" (UNCHE, 1972) emphasises the blending between development and environmental concerns as complementary in nature.

Another pertinent point from the Stockholm Declaration is its emphasis on preserving the environment for present and future generations as reflected in its preamble: "[t]o defend and improve the human environment for present and future generations has become an imperative goal of mankind" (UNCHE, 1972, p. 3). Likewise, Principle 1 of the Stockholm Declaration also emphasises the need for environmental conservation for the benefit of present and future generations.[2] From the above, it is obvious that preserving the environment is crucial not only for present generations as reflected in intragenerational equity but also for future generations through intergenerational equity.

[2] The exact wording of Principle 1 from the Stockholm Declaration reads as follows:

Man has the fundamental right to freedom, equality and adequate conditions of life, in an environment of a quality that permits a life of dignity and well-being, and he bears a solemn responsibility to protect and improve the environment for present and future generations.

Most importantly, the 1972 Stockholm Conference led to the formation of the United Nations Environment Programme (UNEP) as an overseer of international environmental concerns among states (Vogler, 2007, p. 433). Thus, environmental consciousness was the spark that led to a study of possible connection between development and the environment, culminating with the World Commission on Environment and Development (WCED) Report in 1987, and its famously quoted definition of sustainable development (WCED, 1987).

5.2.3 The World Commission on Environment and Development (WCED) Report

The growing interest in exploring the intersection between environmental protection and economic development eventually led to the establishment of the WCED, headed by Norway's former Prime Minister, Gro Harlem Brudtland, which resulted from a United Nations (UN) General Assembly Resolution 38/161 ("Process", 1983). Subsequently, this led to the 1987 WCED Report, more commonly known as Our Common Future Report (WCED, 1987). In the WCED Report, sustainable development is defined as "development that meets the needs of the present without compromising the ability of future generations to meet their own needs" (WCED, 1987, p. 87). As defined by the WCED Report, "needs" are the requirements for "food, clothing, shelter" and "jobs" that fulfil the "essential needs of the world's poor" (WCED, 1987, p. 87). Throughout the WCED Report, poverty alleviation was emphasised in terms of meeting the basic needs of people (as per definition of sustainable development). The WCED Report also highlighted that environmental problems are integral to development activities: "[e]nvironment and development are not separate challenges; they are inexorably linked" (WCED, 1987, p. 81).

At the time of the WCED Report's publication, genetic engineering was viewed as a revolutionary technology because "[g]enetic engineering means that agriculture's Green

Revolution will be superseded by a 'Gene Revolution' " (WCED, 1987, p. 200) towards improving human and animal health. The WCED Report also highlighted this technology's contribution towards new drugs, new therapies and new ways of controlling disease vectors (WCED, 1987, p. 261).

However, the WCED Report failed to highlight the dual nature of genetic engineering – not only for the good of humankind in its contribution towards agriculture and medicine but that a misuse of the same technology could lead to biological warfare and bioterrorism. The WCED Report was also instrumental, in that it required changes at the legal and institutional levels so as to reconcile development and environmental concerns (WCED, 1987, p. 107).[3]

Indeed, the WCED Report proposed changes to the legal framework, namely, to set up a Universal Declaration and Convention on Environmental Protection and Sustainable Development that incorporates the relevant legal principles guiding state behaviour, which subsequently will be expanded into a binding Convention (WCED, 1987, pp. 363-378). This Convention would detail the sovereign rights and reciprocal responsibilities of states to provide new norms of state and interstate behaviour.

It was the Experts Group on Environmental Law of the WCED, which provided advice to the Commission (Munro & Singh, 1987, p. 7), that also produced the Proposed Legal Principles for Environmental Protection and Sustainable Development with its twenty-two principles annexed to Our Common Future Report (WCED, 1987, pp. 392-395). Indeed, the WCED Report set the tone for further debate on this Report at the UN General Assembly (UNGA) in 1989 that soon led to the 1992 UN Conference on Environment and Development (UNCED) (Das, 2013, p. 14).

[3] It is stated in the WCED Report (p. 107) that:
Sustainability requires the enforcement of wider responsibilities for the impacts of decisions. This requires changes in the legal and institutional frameworks that will enforce the common interest. Some necessary changes in the legal framework start from the proposition that an environment adequate for health and well-being is essential for all human beings – including future generations.

5.2.4 The United Nations Conference on Environment and Development (UNCED), Rio de Janeiro, Brazil, 1992

In 1992, the world convened in Rio de Janeiro, Brazil for UNCED, better known as the Rio Conference or Earth Summit (Pallemaerts, 1995-1996). UNCED produced the binding Convention on Biological Diversity (CBD) and the UN Framework Convention on Climate Change (UNFCCC). Apart from these binding documents, there were also soft law instruments which, while non-binding, were political commitment by states to abide by and apply in good faith such as the Rio Declaration on Environment and Development (Rio Declaration), the non-legally binding Authoritative Statement of Principles for a Global Consensus on the Management, Conservation and Sustainable Development of All Types of Forests (Forest Principles), and a plan of action called Agenda 21 ("Report of the United Nations", 1992). Although these soft law documents were non-binding, they do have legal relevance in that states making these declarations must also abide by these soft law instruments in good faith. These states must be willing to agree, in whole or in part, with the terms and conditions let alone disregarding these commitments as it would constitute a violation. Some of these commitments in the soft law documents form the crux of the sustainable development law. For instance, Agenda 21 in Chapter 39 reiterated the need for "further development of international law on sustainable development giving special attention to the delicate balance between environmental and developmental concerns" (Division for Sustainable Development [DSD], 1992b, p. 1). Agenda 21 further stated the "need to clarify and strengthen the relationship between existing international instruments or agreements in the field of environment and relevant social and economic agreements or instruments, taking into account the special needs of developing states" (DSD, 1992b, p. 1).

Moreover, Principle 4 of the Rio Declaration points out that "to achieve sustainable development, environmental protection shall constitute an integral part of the development process and cannot be considered in isolation" ("Report of the United

Nations", 1992, p. 2). Another crucial aspect addressed by the Rio Declaration regarding the interface between environmental protection and trade promotion includes Principle 12 in promoting "a supportive and open international economic system" that leads to economic growth and sustainable development ("Report of the United Nations", 1992, p. 3). This same principle, however, cautions that any trade policy measures formulated for environmental protection must not "constitute a means of arbitrary or unjustifiable discrimination of a disguised restriction on international trade" ("Report of the United Nations", 1992, p. 3).

Subsequent to UNCED, the United Nations Division for Sustainable Development, in compliance with requests by states at the Second Session of the United Nations Commission on Sustainable Development held in 1994, produced the Report of the Expert Group Meeting on Identification of Principles of International Law for Sustainable Development (Goepel, 2010). This Report contained nineteen principles and concepts related to the international law of sustainable development, taken from the Rio Declaration, Agenda 21, and other environmental agreements.

Later, the ILA Committee issued the New Delhi ILA Declaration on Principles of International Law relating to Sustainable Development or what is known as the Delhi Declaration of International Sustainable Development Law (ISDL) as a resolution of the 70th Conference of the ILA held in New Delhi, India from 2-6 April, 2002 (ILA, 2002). The Delhi Declaration contained seven principles pertaining to the international sustainable development law that mostly were already addressed in the WCED Report, the Rio Declaration, and in international environmental treaties. It is the seven principles of the Delhi Declaration that will be deliberated and explained in detail in another section of this chapter. After UNCED and the formulation of the Delhi Declaration, the next milestone for sustainable development was its review conference in the form of the World Summit for Sustainable Development (WSSD).

5.2.5 The 2002 World Summit on Sustainable Development (WSSD), Johannesburg, South Africa

In 2002, the WSSD convened in Johannesburg, South Africa. The WSSD emphasised the need for governments to adhere to "the principles of international law and those enshrined in the Charter of the United Nations" (Commission on Sustainable Development [CSD], 2002, p. 57). The WSSD Plan of Implementation once again reaffirmed the role of governments in "undertaking concrete actions and measures at all levels and to enhancing international cooperation, taking into account the Rio Principles" (CSD, 2002, p. 2). In abiding by the Rio principles, this would "promote the integration of the three components of sustainable development – economic development, social development and environmental protection – as interdependent and mutually reinforcing pillars" (CSD, 2002, p. 2). The WSSD Plan of Implementation also emphasised that "the social dimension of sustainable development should be strengthened, inter alia, by emphasising follow-up to the outcomes of the World Summit for Social Development" (CSD, 2002, p. 56). The WCED Report addressed social development by recognising that the "inability to promote the common interest in sustainable development" is "a product of the relative neglect of economic and social justice within and amongst nations" (WCED, 1987, p. 93). It was not until the 1995 Copenhagen Declaration on Social Development that economic development, social development and environmental protection became clearly stated as "interdependent and mutually reinforcing components of sustainable development" (World Summit for Social Development, 1995).

During the WSSD, the Netherlands raised the appropriateness of the Delhi Declaration as a way to respond to integrating the three components of sustainable development (Goepel, 2010, p. 1698). This is not surprising since Principle 7 of the Delhi Declaration itself promotes the principle of integration and interrelationship, particularly in relation to human rights as well as social, economic and environmental objectives (ILA, 2002, p. 6). It is this Principle 7, the principle of integration, which has given its name to ISDL.

Segger and Khalfan (2004a, p. 103) define ISDL as an "intersection between the three fields of international economic, environmental and social laws". ISDL is seen as a response to Chapter 39 of Agenda 21 mentioned earlier so as "to clarify and strengthen the relationship between existing international instruments or agreements in the field of environment and relevant social and economic agreements" (DSD, 1992b, p. 1).

Thus, the term "sustainable development" has evolved over time since its first appearance in the WCED Report to encompass all the relevant principles under its ambit through the Delhi Declaration and Rio Declaration.

5.2.6 Rio+20 - The United Nations (UN) Conference on Sustainable Development, 20-22 June 2012, Rio de Janeiro, Brazil

The 2012 UN Conference on Sustainable Development, better known as Rio+20, produced a document entitled The Future We Want (the Future) (2012), a form of soft law document with some legal significance. The Intergovernmental High Level Political Forum (the Future, 2012, p. 16), which evolved from the Commission of Sustainable Development (CSD), would provide political leadership, guidance and recommendations for sustainable development. Other duties of the Forum include enhancing and further integrating the three pillars of sustainable development, having regular dialogue, stocktaking and agenda setting, and promoting system-wide coherence to policies concerning sustainable development, not only among UN bodies but also among relevant multilateral financial and trade institutions (the Future, 2012, p. 16). UNEP, too, also underwent a revamp to become one of universal membership through Decision 27/2 adopted on 22 February, 2013 by the Governing Council of the UN Environment Programme (UNGA, 2013).

Apart from this, Rio+20 reaffirmed the principles of the Rio Declaration as the basic foundation for international environmental law, Agenda 21, the Johannesburg Plan of Implementation of the WSSD in 2002, and the Johannesburg Declaration on Sustainable Development (UNGA, 2013, p. 3). Common but differentiated responsibilities (CBDR)

was emphasised by developing states, which outstandingly saw its own paragraph included in the Future (2012, p. 3). Given the historical contribution of developed states towards environmental pollution, they bear more responsibility for environmental protection and should assist their less affluent counterparts through financial aid and transfer of environmentally safe technology for the betterment of the environment. Other features include participants in decision making while acknowledging that democracy, good governance, and the rule of law apply to all levels of governance, including principles embedded within the Delhi Declaration (ILA, 2002, pp. 5-6).

Ironically, too, the Future does not mention anything at all about contamination from weapons as an outcome of biowarfare or bioterrorism. In this regard, the International Committee of the Red Cross (ICRC) highlighted in a presentation the consequences of weapon contamination for sustainable development (ICRC, 2012). Indeed, weapon contamination from warfare or bioterrorism can contaminate soil and water, destroy fauna and flora, and undermine sustainable use of natural resources (ICRC, 2012). While biowarfare was not addressed in the Future, terrorism was mentioned with regard to removing restraints and strengthening support for people in cases of humanitarian emergencies and terrorism (the Future, 2012, p. 5).

Other emerging themes from the Future include the green economy as a vehicle towards achieving sustainable development and poverty eradication in a way that is consistent with international law, respect for state sovereignty over natural resources, and avoiding arbitrariness and unjustifiable discrimination (the Future, 2012, p. 9).

Lastly, Rio +20 proposed certain targeted goals as Sustainable Development Goals (SDGs) in 2015. These are briefly mentioned in the next section.

5.2.7 Sustainable Development Goals (SDGs)

SDGs comprise seventeen goals that are targeted to be reached by 2030 (United Nations [UN], 2016d). Relevant to ISDL is goal 10 which is to reduce inequality within and among states, basically poverty reduction and ensuring that economic growth and its benefits are enjoyed equally by all segments of society (UN, 2016b). Goal 3 of the SDGs, which is to ensure healthy lives and promote wellbeing at all ages, is also relevant in the context of eliminating both communicable and non-communicable diseases, as well as the need for more vaccines for developing states, as indicated in the International Health Regulations 2005 (IHR 2005) of this study (UN, 2016a). Goal 16 of the SDGs, which is to promote just, peaceful and inclusive societies, is also relevant to the principles of ISDL that stress public participation in decision making at both national and international levels (UN, 2016c). Goal 16 of the SDGs also emphasises good governance in terms of accountable and transparent institutions at all levels (UN, 2016c). These SDGs are used as benchmarks, much like the ISDL principles used in this study, in determining whether or not sustainable development can be met.

In summary, all of these international conferences and their document outcomes, whether in the form of soft law or binding agreements since 1972, have instigated the debate over sustainable development and contributing to the legal sphere as ISDL as will be explored in the next section.

5.3 Definition and Elements of Sustainable Development

This section will discuss the definition of sustainable development from an international law perspective. The preamble of the Delhi Declaration indicates that the principles it contains "would be instrumental in pursuing the objective of sustainable development in an effective way" (ILA, 2002, p. 1). The aim of this chapter is to set out the principles of the Delhi Declaration separately from the biosecurity theme. Moreover,

sustainable development's contentious meaning and legal status will need to be clarified beforehand. The application and analysis of the principles of the Delhi Declaration relevant to international agreements on biosecurity will be dealt with in Chapters 6– 8 of this study.

5.3.1 Definition of Sustainable Development

Based on the WCED Report, it was indicated that a definition of sustainable development already exists. This definition is vague according to critics like Jacobs (1999, p. 22) who retorts that "[s]ustainable development is never properly defined, it is protested; everybody seems to think it means something different." Sustainable development in Caring for the Earth (Munro & Holdgate, 1991, p. 9) is defined as "improving the quality of life while living within the caring capacity of supporting ecosystems." Thus, sustainable development comes in all forms and are subjected to all kinds of interpretations. For Jacobs (1999, p. 24), that there are various definitions is its weakness because sustainable development "can only be made 'operational' in policy terms if a single and precise meaning can be agreed upon."

Despite sustainable development's vagueness in the WCED Report (1987), this definition is highly relied upon and quoted in international publications including the Plan of Implementation of the WSSD (CSD, 2002) of 2002 and the Panel Report entitled Resilient People, Resilient Planet: A Future Worth Choosing (United Nations Secretary-General's High-Level Panel on Global Sustainability, 2012) prior to Rio+20 with the necessary recommendations towards attainment of sustainable development. This shows sustainable development's resilience in having survived its critics well into the 21st century. According to Das (2013, p. 21), "[i]ts vagueness in itself enables this definition to be used as a guiding definition of sustainable development in differing circumstances, yet it is not so hopelessly vague that it cannot guide decision making in these various contexts." Thus, while there is discrepancy in the understanding of sustainable

development, all will depend on which aspect(s) will need to be highlighted in any particular area of study. Bearing this in mind, the next section will focus on sustainable development from the angle of law.

5.3.2 Introducing International Sustainable Development Law (ISDL)

In the realm of law, the Separate Opinion of Vice-President Weeramantry in his pronouncement on sustainable development in the famous *Gabčíkovo-Nagymaros Project* (*Hung. v. Slovk.*) (1997) (hereinafter *Gabčíkovo-Nagymaros*) jurisprudence had set a precedence. In reconciling Slovakia's interest in the Gabčíkovo scheme for its development without overlooking Hungary's need for environmental protection, Justice Weeramantry highlighted in his separate opinion that:

> *The Court must hold the balance even between the environmental considerations and the developmental considerations raised by the respective Parties. The principle that enables the Court to do so is the principle of sustainable development* (*Gabčíkovo-Nagymaros*, 1997, p. 88).

As evident from the above, sustainable development reconciles two separate considerations with one another, namely environmental and developmental considerations. As Justice Weeramantry aptly puts it, "[b]oth these vital and developing areas of law require, and indeed assume, the existence of a principle which harmonises both needs" (*Gabčíkovo-Nagymaros*, 1997, p. 88). In further asserting the role that sustainable development plays in international law, Justice Weeramantry states: "[i]t offers an important principle for the resolution of tensions between two established rights. It reaffirms in the area of international law that there must be both development and environmental protection, and that neither of these rights can be neglected" (*Gabčíkovo-Nagymaros*, 1997, p. 95). Indeed, the opinion of Justice Weeramantry coincides with the WCED's understanding of sustainable development whereby both environmental protection and development concerns do not have mutually exclusive concerns.

It can be said that the *Gabčíkovo-Nagymaros* case had set the tone for the birth of ISDL. Segger and Khalfan (2004a, p. 103) have defined ISDL as "the area of intersection between three fields of international economic, environmental and social laws" which merely strengthens Justice Werramantry's earlier opinion that sustainable development reconciles environmental and developmental considerations. The seven principles of the Delhi Declaration, its status and legal relevance, will now be elaborated in-depth because the attainment of sustainable development as an objective relies on the fulfilment of these seven principles – to which we now turn.

5.3.2.1 The Duty of States to Ensure Sustainable Use of Natural Resources

This well-established principle has its roots in the case of *Trail Smelter* where no state has the right to use or permit the use of its territory to cause environmental injury and/or other serious consequences to the territory of another state or properties of person(s) in another state (GPO, 1941). The injury caused to another state or properties of person(s) in another state must be supported by clear and convincing evidence (GPO, 1941). The case of *Nuclear Weapons* (1996, p. 226) reaffirmed the fact that this principle was part of the corpus of international law relating to the environment that became part of customary international law.

This principle has also found a place in Principle 21 of the Stockholm Declaration which prescribes that "[s]tates have, in accordance with the Charter of the [UN] and the principles of international law, the sovereign right to exploit their own natural resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other states or of areas beyond the limits of national jurisdiction" (UNCHE, 1972, p. 5). Twenty years later, Principle 2 of the Rio Declaration more or less repeated Principle 21 of the Stockholm Declaration with one addition, namely, that states have "the sovereign

right to exploit their own [natural resources pursuant to] their own environmental and development policies" ("Report of the United Nations", 1992). The Rio Declaration indicates that not only can states utilise their natural resources in line with their environmental policies but also in line with their development plans. Up until the Rio+20 conference, the newly proposed Green Economy ought to "[r]espect each country's national sovereignty over their natural resources taking into account its national circumstances, objectives, responsibilities, priorities and policy space with regard to the three dimensions of sustainable development" (the Future, 2012, p. 10). This shows that the understanding of this principle is certainly undergoing an evolutive process as the right over natural resources is now being subjected to broader concerns.

Based on the Delhi Declaration, interpretation of the aforesaid principle would be made along the following. Firstly, states have a duty to manage their natural resources within their own territory or jurisdiction in a rational, sustainable and safe way and not cause undue damage to other states beyond their territory and jurisdiction (ILA, 2002, p. 3). Secondly, states must manage their natural resources sustainably for the needs of future generations, curtailing the rate of use of natural resources as indicated by the Delhi Declaration (ILA, 2002, p. 3). Thirdly, the Delhi Declaration calls upon states to protect, preserve and enhance the natural environment, particularly the climate system, biological diversity, as well as fauna and flora for the common good of humankind (ILA, 2002, p. 3). The last part of preserving natural resources for the common heritage of humankind has indeed been quite contentious during the negotiations of the CBD (1992) because developed states in the past may have exploited developing states' resources without sharing the benefit, making the latter hesitant about committing to such a common heritage for humankind (Segger & Khalfan, 2004a, p. 112).

Some examples that show the incorporation of the said principle into treaties are here provided. The right of a state over its natural resources has been reflected by Article 2(3)

of the Ramsar Convention on Wetlands (1971) (hereinafter Ramsar Convention), whereby the inclusion of natural wetland sites in the List of Wetlands must "not prejudice the exclusive rights of […] the party in whose territory the wetland is situated." The same goes for the International Tropical Timber Agreement (ITTA, 1983) in Article 1 which recalled "the sovereignty of producing members over their natural resources." Other examples incorporating the right of states over their natural resources include the preamble to the Basel Convention on the Transboundary Movements of Hazardous Waste and Their Disposal (1989) (hereinafter Basel Convention),[4] the 1992 UNFCCC,[5] and Article 15(1) of the CBD.[6]

As far as the obligation not to damage the environment of other states is concerned, the following treaties have included this obligation. The 1968 African Convention on the Conservation of Nature and Natural Resources (hereinafter African Convention) under Article XVI (1) (b) requires consultation and cooperation among states in the event that development efforts in one state would affect the natural resources of another state. Similarly, Article 6(3) of the 1972 Convention for the Protection of World Cultural and Natural Heritage (hereinafter World Heritage Convention) prohibits parties from taking measures that can damage heritage situated in the territory of other parties.

[4] The preamble of the Basel Convention reads as follows:

Fully recognising that any State has the sovereign right to ban the entry or disposal of foreign hazardous wastes and other wastes in its territory,

Recognising also the increasing desire for the prohibition of transboundary movements of hazardous wastes and their disposal in other States, especially developing countries.

[5] The preamble of the United Nations Framework Convention for Climate Change mentions the following:

Recalling also that States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental and developmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction.

[6] Article 15 (1) of the Convention on Biological Diversity is quoted as follows:

Recognising the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.

The aspect of ensuring that natural resources must be managed in a sustainable and safe way, as mentioned by the Delhi Declaration, has also been reflected in the following treaties. Article 2 of the CBD (1992) stresses the use of components of biological diversity in a manner that does not lead to long-term decline in biodiversity so as to meet the needs and aspirations of present and future generations. Likewise, the ITTA (1983) in Article 1(h) emphasises the "sustainable utilisation and conservation of tropical forests and their genetic resources."

In fulfilling the third aspect of the Delhi Declaration to protect, preserve and enhance natural resources for the common heritage of humankind, certain examples from treaties do merit some acknowledgement. The preamble to the CBD (1992) affirms the conservation of biological diversity as a common concern of humankind, while parties should embark on the conservation of biological diversity for the benefit of present and future generations. As to the UNFCCC (1992), its preamble also acknowledges that "change in the Earth's climate and its adverse effects are a common concern of humankind."

The duty of states to ensure sustainable use of natural resources has also been applied in some international case laws. In *Land Reclamation by Singapore in and around the Straits of Johor (Malay. v. Sing.)* (2003, p. 14) (hereinafter *Johor Straits*), a Diplomatic Note issued by the Malaysian Ministry of Foreign Affairs on 30 April 2002 quoted "the basic duty [of] States not to carry out activities […] that would injure the rights and interests of neighbouring states." Malaysia resorted to this principle of international law because Singapore had repeatedly ignored Malaysia's request for cooperation and consultation regarding Singapore's land reclamation works on Tekong Island, alleged by Malaysia to have affected the marine environment in the Straits of Johor that both countries share (*Johor Straits*, 2003, pp. 19-22). As pinpointed by Segger and Khalfan (2004a, p. 113), the duty of states to ensure that activities within their jurisdiction or

control do not cause significant damage to the environment of other states is one derived from extending the principle of good-neighbourliness requiring cooperation and consultation to resolve a conflict. Indeed, in this dispute Malaysia pointed to Singapore's failure to comply with good neighbourly obligations under the UN Convention on the Law of the Sea (UNCLOS, 1982), which would have been to notify and consult Malaysia about the serious risk of land reclamation affecting the marine environment on Malaysia's side of the Johor Straits, and to initiate a joint consideration of the environmental consequences (*Johor Straits*, 2003, p. 19).

In another case concerning *Responsibilities and Obligations of States Sponsoring Persons and Entities with Respect to Activities in the Sea* (2011, p. 40) (hereinafter *Seabed Mining Opinion*), the International Tribunal for the Law of the Sea (ITLOS), in emphasising a state's responsibility, indicated that states must conduct their activities so as not to cause pollution to the environment of other states, in line with article 194, paragraph 2 of UNCLOS (1982).[7] ITLOS also related the principle under discussion with a precautionary approach.[8]

At least in this case, ITLOS successfully managed to link the law of state responsibility not only with the principle that obliges states to ensure sustainable use of their natural resources but also with the principle of precautionary approach, for it viewed them all as interconnected with one another, since one state's appropriate action leads to that of another.

[7] See the *United Nations Convention on the Law of the Sea.* It is quoted in this instance that:

[s]tates shall take all measures necessary to ensure that activities under their control are so conducted as not to cause damage by pollution to other states and their environment.

[8] See the *Seabed Mining Opinion,* (2011) ITLOS No. 17, at page 40. It is quoted in this case that:
[t]he due diligence obligation of the sponsoring States requires them to take all appropriate measures to prevent damage that might result from the activities of contractors that they sponsor. These obligations apply in situations where scientific evidence concerning the scope and potential negative impact of the activity in question is insufficient but where there are plausible indications of potential risks.

Based on the above, it is clear that the age-old principle of the duty of a state to ensure sustainable use of its natural resources is firmly grounded in binding treaties, soft law documents and international jurisprudence, rendering it truly appropriate to become customary international law, which it deserves.

5.3.2.2 The Principle of Equity and Eradication of Poverty

As discussed in an earlier section in this chapter, the definition of sustainable development in the WCED Report makes a reference to present and future generations (WCED, 1987, p. 87). The principle of equity refers to both intragenerational equity (dealing with the present generation) and intergenerational equity (covering future generations). Some examples include Principle 1 of the Stockholm Declaration: "[m]an has the fundamental right to freedom, equality and adequate conditions of life, in an environment of a quality that permits a life of dignity and well-being and he bears a solemn responsibility to protect and improve the environment for present and future generations" (UNCHE, 1972). Likewise, Principle 3 of the Rio Declaration asserts that "[t]he right to development must be fulfilled so as to equitably meet developmental and environmental needs of present and future generations" ("Report of the United Nations", 1992). Even the Future (2012, p. 1) stresses the need to "renew our commitment to sustainable development and to ensuring the promotion of an economically socially and environmentally sustainable future for our planet and for present and future generations." In exploring the green economy principles after Rio +20 by comparing the Future with the previous Rio Declaration, it showed that an equitable, fair and just society between and within states and between generations had featured prominently in both soft law documents (Allen, 2012, p. 19).

Moreover, intragenerational equity emphasises fairness in the utilisation of resources by the present generation at both domestic and global levels (Segger & Khalfan, 2004a, p. 125). While the present generation are able to utilise earth's resources, they do bear a

solemn responsibility to consider the long-term impact of their activities and ensure those resources are sustained for use by future generations (ILA, 2002, p. 4). Intragenerational equity is also concerned with distributive justice, that is, how resources are distributed within and between societies and whether it is done so equally between developing and developed states (Maggio & Lynch, 1998, p. 1). Intragenerational equity seeks to provide basic human needs as defined in the WCED Report, i.e., food, shelter, health care, and education (Segger & Khalfan, 2004a, p. 125).

In contrast, intergenerational equity calls for fairness in the utilisation of resources among past, present, and future generations (Segger & Khalfan, 2004a, p. 124). This calls for an equilibrium in meeting the consumption demands of the present generation while yet ensuring that adequate resources still remain for future generations.

An examination of treaties incorporating both intra and intergenerational equity leads to the following observation. Article 2 paragraph 6(c) of the Convention on the Protection and Use of Transboundary Watercourses and International Lakes (1992) states that "water resources shall be managed so that the needs of the present generation are met without compromising the ability of future generations to meet their needs." The preamble of the UNFCCC (1992) requires a consideration of "the legitimate priority needs of developing states for the achievement of sustained economic growth and the eradication of poverty" and to "protect the climate system for the benefit of present and future generations, on the basis of equity." Similarly, in its preamble, the CBD (1992) calls for the sharing of benefits equitably – as intra and intergenerational equity.[9]

Other than treaties, reference to the principle discussed can also be found among international case laws. Justice Weeramantry, in his dissenting opinion in the *Request for*

[9] The preamble of the CBD (1992) mentions the following:
Determined to conserve and sustainably use biological diversity for the benefit of present and future generations.

an Examination of the Situation in Accordance with Paragraph 63 of the Court's Judgement of 20 December 1974 in the Nuclear Tests (N.Z. v. Fr.) (1995, p. 341) (hereinafter *Nuclear Tests*), indicated that "[t]he case before the Court raises, as no case ever before the Court has done, the principle of intergenerational equity – an important and rapidly developing principle of contemporary international law." Nevertheless, Justice Weeramantry also expressed his disappointment in the case since the ICJ did not avail itself of the opportunity "to make any pronouncement on this developing field" (*Nuclear Tests*, 1995, p. 342). At least from the standpoint of Justice Weeramantry, intergenerational equity was "building itself into the corpus of international law, or has already done so" but unfortunately the ICJ did not rise to the challenge by declining to elaborate on the principle (*Nuclear Tests*, 1995, p. 342).

Once again, in the case of *Maritime Delimitation in the Area between Greenland and Jan Mayen (Den. v. Nor.)* (1993, pp. 274-277) (hereinafter *Maritime Delimitation*), Justice Weeramantry in his concurring opinion referred to intergenerational equity and specifically to "[…] the concept of wise stewardship [of natural resources…] and their conservation for the benefit of future generations."

One domestic court's decision from the Philippines, *Minors Oposa v. Secretary of the Department of Environment and Natural Resources (DENR)* (1993, p. 185) (hereinafter *Minors Oposa*), makes a similar reference to intergenerational equity. This was a class action suit in which children were allowed to file a case against DENR for giving out permission to government licensees to cut timber (*Minors Oposa*, 1993, p. 185). The Philippines Supreme Court decided that Minors (Plaintiffs) were entitled to the class action suit "for themselves, for others of their generation and for succeeding generations" (*Minors Oposa*, 1993, p. 185).

In the *Pulp Mills on the River Uruguay (Arg. v Uru.)* (2010, p. 180) (hereinafter *Pulp Mills*), the separate opinion of Judge Cançado Trindade also referred to intergenerational equity as "a long-term temporal dimension to international law." In this case, Judge Cançado briefly described intergenerational equity as "the right of each generation to benefit from this natural and cultural heritage [which] is inseparably coupled with the obligation to use this heritage in such a manner that it can be passed on to future generations in no worse condition than it was received from past generations" (*Pulp Mills*, 2010, p. 180). He further prescribes responsibilities to intergenerational equity that "require conserving the diversity and the quality of biological resources, of renewable resources such as forests, water and soils which form an integrated system, as well as of our knowledge of natural and cultural systems" (*Pulp Mills*, 2010, p. 180). This implies not just preserving natural resources for their own sake but also traditional or indigenous knowledge that underpins these resources. Regrettably, in its judgement, the ICJ did not look into the principles of international law and was even unable to make any pronouncement on intergenerational equity so as to contribute to the development of international environmental law (*Pulp Mills*, 2010, p. 180).

As regards its legal status, the said principle is not yet entrenched as customary international law for the reason that there exists uncertainty with regard to the needs of future generations as well as a lack of consensus among states regarding the need to ensure distributional justice especially between developing and developed states (Segger & Khalfan, 2004a, p. 132). As implied in the Delhi Declaration (ILA, 2002, p. 4), intragenerational and intergenerational equity fall under the category of principle, even if French (2005) and Schrijver (2008, pp. 171-207) regard it more as an objective than a principle. Regardless of its status, this principle is set to be a crucial objective or a guiding tool for states in their strive for sustainable development.

5.3.2.3 The Principle of Common but Differentiated Responsibilities

With its origin being grounded in the common heritage of humankind and the principle of equity, common but differentiated responsibilities refer to the different contributions of developed and developing states towards worldwide environmental problems (French, 2005). This principle also recognises the respective economic and technical capacity of various states to rectify these problems (Segger, Khalfan, Gehring & Toering, 2003, p. 56). The first part of this definition refers to the common responsibility of states to protect the environment as a whole (or parts thereof), whether at the national, regional or global level. This common responsibility to protect arises when a resource is not under the exclusive jurisdiction of states nor can it be considered their property as it is of common concern, e.g. outer space and the seabed come under this categorisation. The preamble to the CBD (1992), for instance, reiterates the fact that "biological diversity is a common concern of humankind." Similarly, the UNFCCC (1992), in its preamble, recalls that "change in the Earth's climate and its adverse effects are a common concern of humankind."

As regards the second part of the principle, this directs each state to take up the responsibility of preventing harm. However, such responsibility may differ among states depending on their capacity to make a difference in terms of adopting environmental standards and obligations. This is aptly expressed in Principle 23 of the Stockholm Declaration regarding "the applicability of states which are valid for the most advanced states but which may be inappropriate and/or unwarranted social cost for the developing states" (UNCHE, 1972, p. 5). The same goes for the Rio Declaration, particularly in terms of differentiating the responsibility of developed states in rectifying the problems of the environment ("Report of the United Nations", 1992).[10]

[10] Refer to Principle 7 of the Rio Declaration, which states:

Even the WSSD Plan of Implementation (2002), which refers to Agenda 21 and the Millennium Declaration, similarly referred to the principle as a reminder especially for developed states to fulfil their promise of financial aid, transfer of technology, and trade opportunities accorded to developing states (CSD, 2002, p. 42; United Nations (UN), 2000). In its outcome document, the Future (in paragraph 15) (2012, p. 3), the Rio+20 conference again reaffirmed all states' commitment towards common but differentiated responsibilities even though this was a contentious issue that garnered developed states' objections against developing states' push for the principle's inclusion.

Among international treaties, common but differentiated responsibilities in terms of distinguishing responsibilities between developed and developing states are reflected in the relevant provisions. Differentiated responsibilities mean different legal obligations being spread over a period of time. This allows developing states, for instance, grace periods or delay in implementations, less stringent commitments, and being provided with international assistance such as financial aid and technology transfer. Under Articles 4.1 and 4.2 of the UNFCCC (1992) and the Kyoto Protocol to the United Nations Framework Convention on Climate Change (1997) (hereinafter Kyoto Protocol), there are specific requirements for developed states but there is also differentiation in the reported requirements between developed and developing states. The UNFCCC (1992), Article 3, also provides a leeway for developing states as there is a need to recognise the "special needs and special circumstances of developing country parties, especially those that are particularly vulnerable to adverse effects of climate change." Likewise, Article 7 of the United Nations Convention to Combat Desertification (1994) (hereinafter UNCCD) which requires that "Parties […] give priority to affected African country parties, in the

In view of the different contributions to global environmental degradation, States have common but differentiated responsibilities. The developed states acknowledge the responsibility that they bear in the pursuit of sustainable development in view of the pressures their societies place on the global environment and of the technologies and financial resources they command.

light of the particular situation prevailing in that region, while not neglecting affected developing country parties in other regions."

As far as international case laws are concerned, the said principle has similarly been reflected in reported judgements. In the *Seabed Mining Opinion* (2011, p. 39), it was determined "that the precautionary approach shall be applied by States 'according to their capabilities'", in view of Principle 15 of the Rio Declaration which introduces "differences in application of the precautionary approach in light of the different capabilities of each State" ("Report of the United Nations", 1992).

The same goes for the case of the *Unites States' Import Prohibition of Certain Shrimp and Shrimp Products* (Appellate Body Report, 1998, pp. 65-70) (hereinafter *Shrimp Turtle*) at the World Trade Organisation (WTO), whereby the US was advised to transfer the technology of Turtle Excluder Devices (TED) to Southeast Asian states and India which do not yet possess such capacity, thereby ensuring the safe catch of shrimps while excluding turtles from being caught. In this case, the Appellate Body of the WTO stressed the different capabilities possessed by these Southeast Asian states and India which the US must consider and thus not be too stringent in its imposition of applying the exact technology and capability that the US alone possesses (*Shrimp Turtle*, 1998, p. 71-72). This is in view of the limited financial capability, technology and know-how that these developing states possess (*Shrimp Turtle*, 1998, pp. 71-72). Moreover, the Appellate Body also considered Principle 7 of the Rio Declaration, and urged Malaysia and the US to "co-operate fully in order to conclude as soon as possible an agreement which will permit the protection and conservation of sea turtles to the satisfaction of all interests involved and taking into account the principle that States have common but differentiated responsibilities to conserve and protect the environment" (*Shrimp Turtle*, 1998, p. 102).

As to their legal status, common but differentiated responsibilities are far from being customary international law. This is explained by a lack of clarity concerning the means with which states should cooperate, as this principle is ambiguous and implemented on a case-by-case basis depending on the context and requirement of the treaty in question. Despite not being customary international law just yet, this principle can still provide an objective or framework for cooperation among states towards achieving sustainable development.

5.3.2.4 The Principle of the Precautionary Approach to Human Health, Natural Resources and Ecosystems

The history of the precautionary approach can be traced back to the German version of the principle known as *Vorsorgungsprinzip*, which literally means "showing prior care or worry" as seen in a 1988 review of a German air pollution law (Löfstedt, B. Fischhoff & Fischhoff, 2002, p. 382). Principle 15 of the Rio Declaration refers to the precautionary approach ("Report of the United Nations", 1992).[11] The precautionary approach attempts to prevent damage before it is too late, even if there is a lack of scientific certainty; this is considered preferable to dealing with damage already caused on account of an environmental activity.

The Delhi Declaration prescribes actions to implement the precautionary approach and lays out the consequences of failing to abide by the principle such as accountability for the harm caused that triggers states' responsibility, and requirement for planning based on certain criteria and well-defined goals (ILA, 2002, p. 5). Secondly, the Delhi Declaration links the precautionary approach with the need for an Environmental Impact Assessment (EIA) to evaluate whether an environmental activity entails any risks, and not to proceed if the activity is found too risky (ILA, 2002, p. 5). In the case of the *Johor*

[11] The precautionary approach, referred to in the Rio Declaration, states the following:
In order to protect the environment, the precautionary approach shall be widely applied by states according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

Straits (2002, pp. 17-20), Malaysia's defence team not only referred to Principle 15 of the Rio Declaration but stated that "[a]n independent (EIA) is a central tool of international law of the precautionary principle." In the case of *Pulp Mills* (2010, p. 83), the ICJ affirmed that the requirement for an EIA "has gained so much acceptance among States that it may now be considered a requirement under general international law to undertake an [EIA] where there is a risk that the proposed industrial activity may have a significant adverse impact in a transboundary context, in particular, on a shared resource."

Apart from the Rio Declaration, treaties have also referred to the precautionary approach in their provisions. In its preamble, the CPB (2000) affirms the precautionary approach (from Principle 15 of the Rio Declaration), specifically in Article 10(6) regarding decision-making procedure for genetically modified organisms (GMOs) to be released into the environment and Article 11(8) for the procedure concerning GMOs for food, feed, and processing. In its preamble, even the CBD (1992) or more specifically Article 14 on minimising the adverse impact on biological diversity and Article 8(g) concerning risks of GMOs to the environment all invoked the precautionary approach. In the preamble to the Montreal Protocol on Substances that Deplete the Ozone Layer (1987) (hereinafter Montreal Protocol), it also mentions that member states are "determined to protect the ozone layer by taking precautionary measures to control equitably total global emissions of substances that deplete it, with the ultimate objective of their elimination on the basis of developments in scientific knowledge, taking into account technical and economic considerations."

Likewise, there are soft law documents that have also incorporated the precautionary approach. In the Plan of Implementation of the WSSD (CSD, 2002, p. 13), the precautionary approach is quite visible in paragraph 23 which reminds states to consider Principle 15 from the Rio Declaration in the context of chemicals used and produced that would lead to adverse effects on human health and the environment. Once again, the

precautionary approach appears in paragraph 109(f) of the said Plan of Implementation of the WSSD as one of the means of implementation, recommending states to improve science-based decision making and reiterating Principle 15 of the Rio Declaration (CSD, 2002, p. 50). Ironically though, the outcome document, the Future (2012, p. 3), does not refer directly to the precautionary approach but can indirectly be implied from paragraph 15 which requests that all parties reaffirm all the principles of the Rio Declaration including Principle 15.

As far as the legal status of the precautionary approach is concerned, the following international case laws seem not to point to any evolvement as customary international law. Notably, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products* (Panel Report, 2006, p. 336) (hereinafter *EC-Biotechnology*) saw the European Union (EU) referring to the precautionary approach as a general principle of law under the view that Principle 15 of the Rio Declaration, the CBD, and CPB have all (as binding instruments) referred to the precautionary approach albeit slowly at first to be widely acceptable among states. Despite the EU's assertion, the Panel refused to determine whether the precautionary approach had crystallised as a principle of general or customary international law, consistent with the Appellate Body's decision in 1998 concerning *EC-Hormones* (*EC-Biotechnology,* 2006, pp. 339-340). The Panel justified its position by citing that there has been no authoritative decision by any international court or tribunal that regarded the precautionary approach as a principle of general or customary international law (*EC-Biotechnology,* 2006, p. 339). This has been particularly true in the case of the ICJ which failed to pronounce on the status of the precautionary approach as a general principle of law or customary international law. In *Nuclear Tests* (1992), the dissenting opinion from Judge Weeramantry considered the precautionary approach to be relevant to the said case even though regretfully the ICJ did not avail itself of the opportunity to consider it.

Likewise, the case of *Pulp Mills* (2010) was decided by the ICJ whereby Argentina alleged that Uruguay had to prove that the pulp mills it was building would not harm the marine environment in the Uruguay River. The precautionary approach contained in the 1975 Statute of the Uruguay River, and signed by both parties, shifted the burden of proof to Uruguay (Payne, 2010, p. 5). While the ICJ disagreed with Argentina and still indicated that Argentina had to substantiate its claims since the invocation of the precautionary approach does not shift the burden of proof, a separate opinion by Judge Cancado Trindade asserted that the precautionary approach emanates from the "universal juridical conscience" which is the "ultimate material 'source' of all Law" and the "new *jus gentium* of our time" despite not being reflective of the ICJ's opinion as a whole (*Pulp Mills*, 2010, pp. 52-68).

In the *Seabed Mining Opinion* (2011, pp. 39-41), not only did ITLOS assert that the precautionary approach was one of the obligations of due diligence for states to implement according to their capabilities, but that the same precautionary approach was also setting a trend towards customary international law. Noteworthy, the EU also has its own jurisprudence on the precautionary approach although this has so far been limitedly applied to the European region (Stokes, 2003).

There are national case laws that have also indicated the precautionary approach as customary international law. In Ireland's request for provisional measures in the *Dispute Concerning the Mox Plant, International Movements of Radioactive Materials, and the Protection of the Marine Environment of the Irish Sea* (ITLOS, 2005, p. 48) (hereinafter *Mox Plant*), Ireland submitted "that the precautionary principle is now recognised as a rule of customary international law", while ITLOS itself did not elaborate on the status of precautionary approach. As this amounts to a precarious position for the precautionary approach with differing opinions over its legal status, it cannot as yet be assumed as a

general principle of law or customary international law for that matter, as to date no international court or tribunal has made such a proclamation.

Additionally, the Panel in *EC-Biotechnology* (2006, p. 340) pointed to the difficulty of determining whether the precautionary approach can either be part of the general principle of law or customary international law as it lacks a "precise definition and content". This is because the US itself has been a persistent objector and does not recognise the precautionary approach as a "principle" of international law on grounds that it cannot be considered a "'rule' because it has no clear content and therefore cannot be said to provide any authoritative guide for a state's conduct" (*EC-Biotechnology*, 2006, p. 337). Moreover, the US pointed out that the precautionary approach cannot be uniformly defined by those espousing it which in turn cannot reflect states' practice (*EC-Biotechnology*, 2006, p. 337). Despite the US misgivings about the precautionary approach, the Panel in *EC-Biotechnology* (2006, p. 340) did acknowledge that there were some legal scholars who regard the precautionary approach as a general principle of law or evolving towards becoming customary international law, without overlooking those who have expressed scepticism (Cameron & Abouchar, 1996, pp. 36-37; Deloso, 2011, pp. 31-41; Freestone, 2011, p. 137; McIntyre & Mosedale, 1997, p. 221; Sands, 1995, p. 213; Schrijver, 2008, p. 194; Segger & Khalfan, 2004a, p. 155; Trouborst, 2007, p. 185).

While the precautionary approach has yet to evolve into the status of customary international law, it nonetheless can play a supportive role in realising the objective of sustainable development. In *Vellore Citizens Welfare Forum v. Union of India & Ors* (1996) (hereinafter *Vellore Citizens*), the judges indicated that "['t]he Precautionary Principle' [is an] essential feature […] of 'Sustainable Development' ". This implies that the precautionary approach is subsumed within sustainable development, as the fulfilment of this principle hastens realising the objective of sustainable development.

5.3.2.5 The Principle of Public Participation and Access to Information and Justice

Among the earliest international binding instruments to incorporate public participation is the International Covenant on Civil and Political Rights (ICCPR, 1966), especially Article 21. Public participation became a central objective for equitable socio-economic development as laid out in the preamble of the United Nations General Assembly Declaration on the Right to Development (1986). As for the Delhi Declaration, public participation is considered crucial for the attainment of sustainable development and good governance in promoting a responsive, transparent and accountable government that truly engages civil society organisations while incorporating industrial concerns and trade unions (ILA, 2002, p. 5).

An examination of the WCED Report (1987, p. 107) highlights the need for public participation because the local community must have "an effective say over the use of resources." For instance, the WCED Report does prescribe when public participation should be sought, as in the case of large-scale projects whereby "[p]ublic inquiries and hearings" become relevant if not necessary (WCED, 1987, p. 107).

Effective public participation essentially depends on the mode of participation being sought. Various modes of public participation exist such as public hearings, consensus conference, regulatory negotiations (reg-neg), advisory committees, public notices, and internet consultations. Depending on the mode of participation, this may result in a compromise-opinion among the various parties which, to a varying extent, can be dominated by an interest group knowledgeable about such a technical or technological issue. Alternatively, public participation could merely function as a formality whereby the sponsoring agency only listens to participants without really fully intending to consider their views, and thus merely "rubber stamping its initial position" (Marchant & Askland, 2003, p. 117). Essentially, it is vital that the participating public be equipped

with the necessary knowledge and have access to the relevant information, especially on a scientific matter like genetic engineering. This will enable them not only to participate but also make an informed decision. This means that public participation does not come automatically, as the marginalised must be equipped with technical knowledge about the issues before such participation can be meaningful.

Nelkin (1984, p. 34) also stresses that the public "must have access to experts who can help analyse the material and maintain control of the information and grasp of the policy choices" especially in decisions involving science. As the marginalised community is likely made up of lay people who may end up having to debate with scientists, the former will have to learn quickly and understand the technical jargon involved. This conforms with the Delhi Declaration's recommendation for the public to be accorded "a right of access to appropriate, comprehensive and timely information held by governments and industrial concerns on economic and social policies regarding the sustainable use of natural resources and the protection of the environment" (ILA, 2002, p. 5).

One comprehensive binding agreement calling for public access to information and participation has been Article 1 of the Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters (1998) (hereinafter Aarhus Convention), whereby each signatory to this Convention "shall guarantee the rights of access to information, public participation in decision making, and access to justice in environmental matters." Moreover, the Aarhus Convention (1998) also recommends a public hearing as reflected under Article 6(2) (d) (iii). Reflecting the different modes of public participation, Article 6(7) of the Aarhus Convention (1998) allows the "public to submit, in writing or, as appropriate, at a public hearing or inquiry with the applicant, any comments, information, analysis or opinions that it considers relevant to the proposed activity." Article 9 of the Aarhus Convention (1998) requires member states to inform the public promptly of the decision being made according to the

appropriate procedures. In addition, Article 1 of the Aarhus Convention (1998) stresses that access to justice is in line with the Delhi Declaration's stipulation requiring "access to effective judicial or administrative procedures in the state where the measure has been taken to challenge such measure and to claim compensation."

Other soft law documents have also sought to incorporate public participation and access to information. Principle 10 of the Rio Declaration stresses each citizen's right to have access to information on hazardous materials and activities within their communities which in turn leads to an informed citizenry capable of public participation as well as judicial and administrative proceedings ("Report of the United Nations", 1992). The Plan of Implementation of the WSSD (2002) also incorporates public participation and access to information especially among women in the context of water resource management and project implementation, see especially paragraph 25(b) (CSD, 2002, p. 14). The participation of indigenous people and local communities in decision and policy making concerning their traditional knowledge and lands is also stressed in paragraph 44(l) of the said Plan of Implementation (CSD, 2002, p. 27). Other instances whereby public participation, access to information and judicial review are reflected in the aforementioned Plan of Implementation include paragraph 128 which reaffirms Principle 10 of the Rio Declaration, as mentioned earlier (CSD, 2002, p. 53).

At the Rio+20 conference, paragraph 13 and paragraph 43 of the outcome document, the Future (2012, pp. 2-7), reiterate the opportunity for people to take charge of their lives through public participation via access to information as well as the ability to seek judicial and administrative proceedings – all of which form the crux of sustainable development at the international, regional, national, and local levels involving women, youth, indigenous people, and a wide array of other actors.

Apart from soft law documents, public participation and access to information have similarly been reflected in international agreements. Article 13 of the CBD (1992) stresses public education and awareness, while Article 14.1(a) links public participation to the context of impact assessment. As for the CPB (2000), Article 23(a) also promotes public awareness, education and participation concerning the safe transfer, handling and use of GMOs, while Article 23(2) asserts the public's right to know the results of any decision concerning GMOs. In the same vein, Article 9.2(c) of the International Treaty on Plant Genetic Resources of Food in Agriculture (ITPGRFA, 2001) guarantees farmers' rights to participate.

As to its legal status, it can be said that access to information, public participation and the ability to seek judicial review and proceedings do indeed constitute an emerging norm (Bruch & Filbey, 2002, pp. 9-10; Segger & Khalfan, 2004a, p. 156; United Nations Environment Programme [UNEP], 2009, p. 42). In the case of *Pulp Mills* (2010, p. 87), the ICJ took the view "that no legal obligation to consult the affected population arises" at least in the case of an impact assessment, implying that public participation has no legal force at present. Still, access to information, public participation and the right to seek a judicial review already form an integral part of sustainable development.

5.3.2.6 The Principle of Good Governance

The term "good governance" was first coined by the World Bank in its publication *Sub-Saharan Africa: From Crisis to Sustainable Growth* (World Bank, 1989). Good governance has been understood as a normative principle of administrative law, making it an obligation for states to promote values such as efficiency, non-corruptibility and being responsive to civil society (Rosenau, 1997). In essence, there is no agreed definition of good governance, as various international organisations tend to have their own definition depending on the context in which the term is used. The Office of the United Nations High Commissioner for Human Rights (OHCHR), in its publication on good

governance as it relates to human rights, refers to the said term as "the exercise of authority through political and institutional processes that are transparent and accountable, and encourage public participation" (OHCHR, 2007, p. 2). In this same publication, the OHCHR stresses that good governance embodies four areas, namely: democratic institutions, the delivery of state services, the rule of law, and anti-corruption measures.

Likewise, the United Nations Development Programme (UNDP) (1998, pp. 4-5), in its elaboration on good governance, characterised this term as containing elements of participation, the rule of law, transparency, responsiveness, consensus orientation, equity, effectiveness and efficiency, accountability, and having a strategic vision.

For its part, the Delhi Declaration has similarly listed almost the same characteristics pertaining to good governance. This includes democratic and transparent decision-making procedures, combating official or other forms of corruption, respecting the principle of due process, observing the rule of law and human rights, and implementing a public procurement approach in keeping with the WTO Code on Public Procurement (ILA, 2002, p. 6). Additionally, the Delhi Declaration asserts that good governance should encompass all sectors of society, not only the government machinery but those of non-state actors as well (ILA, 2002, p. 6). Good governance should also cover Corporate Social Responsibility (CSR) and socially responsible investments, as stated in the Delhi Declaration (ILA, 2002, p. 6). Most importantly, the Delhi Declaration asserts that good governance ought to incorporate the principles of the Rio Declaration (ILA, 2002, p. 6).

Good governance has also been reflected among soft law documents. The Plan of Implementation of the WSSD (2002), in paragraph 4 and paragraph 138, reiterates that good governance within each country and at the international level is essential for sustainable development (CSD, 2002, p. 2). Interestingly, the elements that constitute

good governance in this Plan of Implementation include democratic institutions, the rule of law, anti-corruption measures, gender equality, promoting an environment for investment, as well as sound environmental, social and economic policies (CSD, 2002, p. 2). Furthermore, good governance is expanded in this Plan of Implementation to cover freedom, peace and security, domestic stability, respect for human rights including the right to development, and embracing market-oriented policies (CSD, 2002, p. 55). When compared to the Plan of Implementation of the WSSD (2002), good governance, which also features in the Future of Rio+20, covers fewer elements such as democracy, the rule of law, as well as the promotion of transparency and accountability (the Future, 2012, p. 2).

As for binding international agreements covering good governance and its elements, such agreements are few and far between. The UN Convention against Corruption (UNCAC, 2003), for instance, underlines in its preamble that corruption is a threat to society, as it undermines institutions and values of democracy, ethical values and justice, as well as hampering sustainable development and the rule of law. Crucial to the process of good governance is the promotion of transparency among international environmental agreements, especially in ensuring that member states comply with the provisions of these agreements through adherence to procedures and mechanisms. Article 34 of the CPB (2000) reflects a compliance mechanism that was set up to oversee cases of non-compliance and to bring member states towards compliance. Similarly, Article 8 of the Montreal Protocol (1987) requires member states to consider and approve procedures and institutional mechanisms for determining non-compliance.

Good governance has also been similarly promoted in the private sector. The Organisation of Economic Cooperation and Development (OECD) Guidelines for Multinational Enterprises (OECD, 2008, pp. 40-54) and the UN Global Compact (U.N. Global Compact Office, 2011, 2013) both contain recommendations for the private sector

on how to practise good governance. Nevertheless, by virtue of being guidelines that are non-binding, much depend on the goodwill of the private sector to implement good governance, thereby rendering it contingent upon the sector's ethics and discretion.

In the case of international case law, good governance is very seldom interpreted by judges. In the *Seabed Mining Opinion* (2011, p. 15), good governance was interpreted by the Chamber of ITLOS as a duty to ensure compliance with Part XI of the UN Convention of the Law of the Sea and to implement the 1994 Agreement properly, while the regime for deep seabed mining as a whole ought to be properly interpreted and applied.

As to the legal status of good governance, it has yet to crystallise itself into customary international law, even though it would seem to be an emerging legal principle in that soft law documents, some international agreements, and limited case laws have slowly incorporated and given meaning to the concept (Bolewski, 2007, p. 47). As there is no agreed meaning of good governance while its nature and scope of obligation and application are equally unclear, states may find it impossible to implement such an ambiguous concept (Chowdhury & Skarstedt, 2005, p. 20). This in itself is an impediment to good governance, especially if it is to evolve into a principle of international law. Yet, one scholar has argued that good governance does exist in the legal literature (Alfredsson, 2002). Still, Chowdhury and Skarstedt (2005, p. 21) are of the opinion that good governance cannot be constructed in legal terms because of the ambiguity related to its meaning. At best, good governance can be perceived "as a policy or an action-guiding tool that is applied generally at the nation state level" (Chowdhury & Skarstedt, 2005, p. 21).

Although there is scepticism about the legal status of good governance, evidence of it being incorporated into certain soft law documents and international agreements, as discussed, is already an indicator that the international community is willing to embrace

this concept, thereby recognising that some form of effective governance is needed for the attainment of sustainable development. However, embracing this concept alone is insufficient as it needs to be followed by sustained application among states and the international community, which although elusive for now may still change in time to allow for its transformation into a principle of international sustainable development law.

5.3.2.7 The Principle of Integration in Relation to the Social, Economic and Environmental Objectives of Sustainable Development

Answering the call to reconcile environmental and developmental considerations for the attainment of sustainable development is the key notion behind the principle of integration in the Delhi Declaration, which seeks to merge the three separate areas of environmental protection, economic development, and social development in line with the definition of ISDL. According to Jodoin (2005, p. 3), the principle of integration is "the most essential of all seven principles of sustainable development as identified by the [ILA]." This is because the principle of integration functions as "a conceptual framework for 'integrated thinking' in international law relating to sustainable development, which can guide consideration of other principles", making it the most fundamental principle of the Delhi Declaration (Jodoin, 2005, p. 4). Additionally, the principle of integration "influences and informs the elaboration, interpretation and application of other principles of sustainable development law" (Jodoin, 2005, p. 4). As the term itself implies, using "integration" in terms of the three separate components of sustainable development seeks already to reconcile them with one another rather than letting them function disparately.

The idea of integrating separate areas of a particular discipline has its own history. Article 1 of the Charter of the United Nations (1945) (hereinafter UN Charter), which lays out the function of the UN, has the following objective: "[t]o achieve international c[oo]peration in solving international problems of an economic, social, cultural, or humanitarian character". At the same time, it envisages the UN as "a centre for

harmoni[s]ing the actions of nations in the attainment of these common ends." Apart from the UN Charter, Article 31(3) (c) of the Vienna Convention on the Law of Treaties (VCLT, 1969) reiterates the need for a treaty to be interpreted in light "of any relevant rules of international law applicable between the [P]arties." This would mean that different branches of international law, be they international environmental law, international trade law or international social law, should not function disparately on their own but should reinforce one another instead of being "self-contained islands of international law, de-linked from other branches of international law" (Pauwelyn, 2004, pp. 903-927). It is on this basis that the principle of integration is proposed so as to allow the different components of sustainable development to merge with the different branches of international law, thus ensuring they will not be highly fragmented as isolated islands without any reference to one another.

Each branch of international law within the ambit of ISDL would cover its own category of issues. In the area of international economic law, some of the subjects covered include trade in goods and services, financial law, economic integration, international investment law, development law, business regulation, and intellectual property (Segger & Khalfan, 2004b, pp. 53-54). Related international organisations within the scope of international economic law include the WTO, OECD, International Monetary Fund (IMF), UNCTAD, and the World Bank (Segger & Khalfan, 2004b, pp. 53-54).

Apart from international economic law, international social law is another branch of law that contributes towards ISDL. Issues under international social law include international human rights law, international humanitarian law, law of armed conflict, international labour law, gender, population, food security, and social development (Segger & Khalfan, 2004b, p. 23). The last component of ISDL is of course international environmental law which covers various issues ranging from biodiversity, hazardous

waste and the ozone layer to wildlife, fisheries, oil pollution, biosafety, climate change and other related matters.

Although the definition of ISDL asserts itself to be a form of intersection between international economic law, international social law and international environmental law, this study does take issue with and is critical of the fact that ISDL should be made exclusive to these branches of law. For it cannot be said that these three branches of law constitute the only ones subscribing to sustainable development.

Moreover, there is an emerging area of international environmental crime, explained by Hayman and Brack (2002, p. 5) as "[w]here there is movement of goods across boundaries (i.e. smuggling, etc.) or a transboundary impact of offences, so it is possible to speak of 'international' or 'transboundary' environmental crime". International environmental crime would include the transport of controlled biological or genetically modified material as a possible offence under the CPB (Hayman & Brack, 2002, p. 5). It is worthwhile noting that Article 25 of the CPB (2000), which deals with illegal transboundary movement of GMOs, does require states to criminalise such an act, urging that parties "adopt appropriate domestic measures […and thereby] penalising transboundary movement of living modified organisms." This means that in a country's laws pertaining to GMOs, there will have to be provisions punishing the illegal movement of GMOs that includes criminal elements against environmental law.

It would seem that international criminal law, in seeking to address international environmental crime, would support the environmental protection of sustainable development. Nevertheless, as highlighted earlier, the existing ISDL merely covers international environmental law, international social law, and international economic law, thereby leaving no room for international criminal law to address international environmental crime. Therefore, it would seem advisable to do away with these three

categories of international law in favour of one that is open to all branches of international law that support sustainable development.

International agreements also reflect ISDL's principle of integration. Segger and Khalfan (2004a, pp. 108-109) provide four categories of integration among international agreements, from those that are totally fragmented (known as "separate spheres") to those regarded as "highly integrated new regimes", with the latter addressing all economic, social and environmental concerns through relevant provisions identified within them. Segger and Khalfan (2004a, pp. 108-109) view the CPB as highly integrative. In discussing the principle of integration, chapter 6 will later examine whether the CPB is highly integrative as claimed.

(a) ***Integration in International Environmental Law***

There are also other examples of international environmental agreements being highly integrative. Article 4(1) (f) of the UNFCCC (1992) seeks to "[t]ake climate change considerations into account, to the extent feasible, in their relevant social, economic and environmental policies", with equal regard for the three components of sustainable development. In urging to "[i]ntegrate as far as possible and as appropriate the conservation and sustainable use of biological diversity", Article 6(b) of the CBD (1992) intends the preservation of biodiversity to be incorporated into cross-sectoral plans, programmes and policies that are again not limited to the environmental sphere but encompass social and environmental considerations. In its recommendation to reduce hazardous and other wastes, the Basel Convention (1989), in Article 4(2) (a), stresses that social, technological and economic impacts must be considered as well. Besides these international agreements, there are other numerous international environmental agreements that address all three components of sustainable development, as illustrated

in the comprehensive analysis by Jodoin (2005) regarding the application of the principle of integration in the area of international environmental law.

Soft law instruments in international environmental law have also seen the incorporation of the principle of integration. One of the earliest calls for integration has been Principle 13 of the Stockholm Declaration (UNCHE, 1972), which recommends that "[s]tates should adopt an integrated and coordinated approach to their development planning so as to ensure that development is compatible with the need to protect and improve the environment for the benefit of the population". Likewise, Principle 4 of the Rio Declaration ("Report of the United Nations", 1992) which states that "[i]n order to achieve sustainable development, environmental protection shall constitute an integral part of the development process and cannot be considered in isolation from it". Similarly, Article 39.1 (a) of Agenda 21, in furtherance of the international law on sustainable development, emphasises the delicate balance between environmental and developmental concerns (DSD, 1992b, p. 1). The WSSD (2002), through the Johannesburg Declaration, further reinforced the principle of integration, reminding that states have "a collective responsibility to advance and strengthen the interdependent and mutually reinforcing pillars of sustainable development – economic development, social development and environmental protection – at the local, national, regional and global levels" (WSSD, 2002a). Likewise, the Johannesburg Plan of Implementation also promotes integrating the three components of sustainable development (WSSD, 2002a).

(b) ***Integration in International Trade Law***

Also in the area of international trade law, the principle of integration has been considered in some soft law documents. The Doha Declaration, for instance, is not only

concerned with trade but also takes into consideration environmental protection and sustainable development (WTO, 2001).[12]

The following excerpt from the Malmö Declaration also promotes the principle of integration:

> *[A] balanced and integrated approach to trade and environment policies [should be encouraged] in pursuit of sustainable development, in accordance with the decision of the Commission on Sustainable Development at its eighth session* (UNEP, 2000).

(c) ***Case Laws and the Principle of Integration***

Other than soft laws, even some relevant international case laws have made reference to sustainable development and the principle of integration. Referring back to the *Gabčíkovo-Nagymaros* (1997, p. 88) case, the ICJ in its majority opinion states that the "need to reconcile economic development with protection of the environment is aptly expressed in the concept of sustainable development."[13]

In this case, the ICJ wanted both Hungary and Slovakia to negotiate amicably towards a solution whereby Hungary's concerns regarding the environmental impact of building a dam on the Danube River could be reconciled with Slovakia's development needs of electricity generation, flood control, and improved navigation from such a dam (Jodoin,

[12] The Doha Declaration of the World Trade Organisation (WTO) WT/MIN/(01)/DEC/1 mentions the following:

[…]We are convinced that the aims of upholding and safeguarding an open and non-discriminatory multilateral trading system, and acting for the protection of the environment and the promotion of sustainable development can and must be mutually supportive […] We recognise that under WTO rules no country should be prevented from taking measures for the protection of human, animal or plant life or health, or of the environment at the levels it considers appropriate, subject to the requirement that they are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between states […].

[13] In the Gabčíkovo-Nagymaros Project (1997), page 88, the ICJ in its majority opinion stated:
Throughout the ages, mankind has, for economic and other reasons, constantly interfered with nature. In the past, this was often done without consideration of the effects upon the environment. Owing to new scientific insights and to a growing awareness of the risks for mankind - for present and future generations - of pursuit of such interventions at an unconsidered and unabated pace, new norms and standards have been developed, set forth in a great number of instruments during the last two decades. Such new norms have to be taken into consideration, and such new standards given proper weight, not only when States contemplate new activities but also when continuing with activities begun in the past. This need to reconcile economic development with protection of the environment is aptly expressed in the concept of sustainable development. For the purpose of the present case, this means that Parties together should look afresh at the effects on the environment of the operation of the Gabčíkovo power plant […].

2005, pp. 22-23). To achieve this aim, the ICJ referred both Parties to the concept of sustainable development in seeking to reconcile their differences.

Sustainable development once again gained prominence in another international dispute involving the Permanent Court of Arbitration in the *Memorial of the Kingdom of Belgium, Iron Rhine (Belg. v. Neth.)* (hereinafter *Iron Rhine*). In this case, the Permanent Court of Arbitration emphasised that the activation of the Iron Rhine was beneficial not only to Belgium's economic interest but also that of sustainable development policy in the environmental and social fields (*Iron Rhine*, 2003, p. 24). The interplay within the principle of integration was aptly expressed by the Permanent Court of Arbitration in referring to environmental protection when it emphasised the need to invigorate the Iron Rhine railway as an environmentally safe mode of transportation compared to road or air so as to reduce green gas emissions in line with EU members' commitment to the UNFCCC and Kyoto Protocol (*Iron Rhine*, 2003, p. 24). As for the contribution towards economic and social development, the revival of the Iron Rhine railway would not only provide employment opportunities to the Port of Antwerp, the Netherlands, and Germany but will also benefit passenger transportation (*Iron Rhine*, 2003, pp. 30-31). It was concluded thus that the "Iron Rhine is of major international interest, in that it will contribute to sustainable development in each of its ecological, economic and social pillars" (*Iron Rhine*, 2003, pp. 30-31).

A reference to sustainable development was also made in the *Pulp Mills* (2010). The ICJ referred to sustainable development while assessing the relationship between procedural and substantive obligations. It was apparent from the *Pulp Mills* case that Uruguay had failed to comply with its procedural obligations of notifying the Administrative Commission of the River Uruguay (CARU), formed to coordinate the activities of the Uruguay River between Argentina and Uruguay. Instead, Uruguay forged ahead with the development of two pulp mills without informing or coordinating with

Argentina (Tladi, 2007, p. 5). The ICJ then referred to the *Gabčíkovo-Nagymaros* case which called for parties to a dispute to cooperate and find an amicable solution in light of the agreement they had signed up to (*Pulp Mills*, 2010, pp. 38-39).

In the case of Uruguay and Argentina, it was the 1975 Statute of the River Uruguay, in particular Article 7 and Article 11, which was violated. It required Uruguay to notify Argentina and CARU about the two pulp mills and be open to make changes to the project should Argentina have any reasonable objections (*Pulp Mills*, 2010, p. 37). In this regard, "[the] Court observe that it is by co-operating that the States concerned can jointly manage the risks of damage to the environment that might be created by the plans initiated by one or other of them, so as to prevent the damage in question" (*Pulp Mills*, 2010, p. 49). In this scenario, it would seem that sustainable development is associated with the fulfilment of substantive obligations, namely, the cooperation among parties as a preventive measure – as elaborated by the ICJ.

Sustainable development is further mentioned by the ICJ regarding *Pulp Mills* in the context of rational usage of the Uruguay River for economic development while ensuring environmental protection in light of Article 27 of the 1975 Statute of the River Uruguay (*Pulp Mills*, 2010, p. 64). The ICJ stressed "the need to reconcile the varied interests of riparian States in a transboundary context and in particular in the use of shared natural resource, but also the need to strike a balance between the use of waters and the protection of the river consistent with the objective of sustainable development" (*Pulp Mills*, 2010, p. 64). It was emphasised that both Uruguay and Argentina had to consider each other's concern, i.e. Uruguay's economic development in terms of the pulp mills' flourishing and Argentina's concern for environmental protection of the Uruguay River (*Pulp Mills*, 2010, p. 65). Therefore, the ICJ opined "that Article 27 [of the 1975 Statute of the River Uruguay] embodies this interconnectedness between equitable and reasonable utilisation

of a shared resource and the balance between economic development and environmental protection that is the essence of sustainable development" (*Pulp Mills*, 2010, p. 65).

As in the case of *Shrimp-Turtle* (1998), the WTO also refers to the principle of integration with sustainable development. The Appellate Body certainly did not view international trade law as being totally isolated from international environmental law, as each had to take the other into consideration, as described below. In justifying the US concern for protecting turtles from being caught without the usage of TED during shrimp harvesting among a group of Southern and Southeast Asian states, the Appellate Body referred to the preamble of the WTO Agreement and stated "that this language demonstrates a recognition by WTO negotiators that optimal use of the world's resources should be made in accordance with the objective of sustainable development" (*Shrimp-Turtle*, 1998, p. 58). Furthermore, the Appellate Body also referred to the Decision on Trade and Environment by the ministerial meeting at Marrakesh where trade and environmental protection were considered integral to one another (WTO, 1994).[14]

In the *Shrimp Turtle* (1998, p. 75) case, the Appellate Body basically allowed the US to protect turtles from extinction: "[w]e have not decided that the sovereign nations that are Members of the WTO cannot adopt effective measures to protect endangered species, such as sea turtles. Clearly, they can and should." The Appellate Body merely took issue with the way in which the US conducted itself in the latter's desire to take turtle conservation into account. That is, the US took unilateral measures to immediately bar shrimp imports from India and other Southeast Asian states. There was no engagement in a multilateral discussion towards a bilateral or multilateral agreement that will guarantee the protection and conservation of turtles between the US, India, Malaysia, and Thailand

[14] Refer to *Relevant WTO Provisions: Text of 1994 Decision* of 14 April 1994 of the World Trade Organisation (WTO), Geneva. The preamble of the Decision on Trade and the Environment by the ministerial meeting at Marrakesh states the following:

Considering that there should not be, nor need be, any policy contradiction between upholding and safeguarding an open, non-discriminatory and equitable multilateral trading system on the one hand, and acting for the protection of the environment, and the promotion of sustainable development on the other, […].

even though a regional agreement was concluded through the Inter-American Convention (*Shrimp-Turtle*, 1998, pp. 65-70). This was considered discriminatory and unjustifiable by the Appellate Body because the US failed to negotiate with regions such as Southeast Asia (*Shrimp-Turtle*, 1998, p. 70).

Moreover, the Appellate Body pointed to a lack of fairness on the part of the US in trying to impose on India and Southeast Asian states "the same comprehensive regulatory program, to achieve a certain policy goal, […] without taking into consideration different conditions which may occur in the territories of those other Members" (*Shrimp-Turtle*, 1998, p. 65). It is apparent that the Appellate Body was quite sympathetic towards the case of India and Southeast Asian states that do not have the same technology and regulatory programme as the US. It differentiated the technological capability of the US as a developed state against India and Southeast Asian states as developing nations. As a remedy and in order to meet the US goal of conserving turtles, the Appellate Body hinted that the US should transfer the TED technology to the complainant states, just as it had done for the Caribbean/ Western Atlantic states (*Shrimp-Turtle*, 1998, p. 72).

As for the legal status of the principle of integration, the principle cannot constitute customary international law, at least not yet. Jodoin (2005, p. 13) gives one reason for this, namely, the principle of integration has repeatedly been expressed as non-binding instruments and as inspirational terms. Secondly, it is hard to foresee how the principle of integration can be binding customary international law as there is little consensus on how to proceed with such an integration process, as shown in the cases of *Pulp Mills* and *Gabčíkovo-Nagymaros* where the presiding judges themselves were reluctant to pronounce on how the integration process should be achieved. Since the integration process cannot be streamlined and can only be dealt with on a case-by-case basis without any consistency in how the principle of integration for sustainable development can be achieved, it will not fulfil the criterion towards achieving customary international law.

5.4 Measures for Implementing International Sustainable Development Law (ISDL)

While the ILA made its mark by contributing to the drafting of ISDL principles in the form of the Delhi Declaration, the Declaration itself only received international recognition after having been published in a UN document under the heading of "Environment and Sustainable Development" at the 2002 57th General Assembly ("Report of the Second Committee", 2002). Moreover, these principles of ISDL from the Delhi Declaration had been distributed as a UN document by Bangladesh and the Netherlands at the 2002 WSSD in Johannesburg, South Africa ("World Summit on Sustainable Development", 2002b). The distribution of the Delhi Declaration through the UN was intended for states to use the document as a point of reference when implementing the principles of sustainable development.

As for practical steps in the implementation of these ISDL principles, the World Future Council (WFC), a Non-Governmental Organisation (NGO), drafted in 2008 the Future Justice Best Laws / Policies Standards which consists of a series of questions meant to guide researchers in evaluating whether all existing or new treaties, national laws and policies fulfil the seven principles of ISDL in the Delhi Declaration with a view to achieving the objective of sustainable development (Segger et al., 2008, p. 4).

Starting in 2009, the WFC has worked together with UN agencies and other international organisations to hold a competition for the best Future Policy Award (International Parliamentary Union [IPU], 2013). States and regional organisations submit relevant treaties, laws and policies for evaluation by judges familiar with the ISDL principles of the Delhi Declaration, as well as the accompanying guiding questions from the Future Just Best Laws / Policies Standards conducted through questionnaires and interviews (Segger et al., 2008, p. 4). Based on the theme of disarmament, in 2013 the WFC, together with the United Nations Office for Disarmament Affairs (UNODA) and

the IPU, chose the 1967 Treaty for the Prohibition of Nuclear Weapons in Latin America and the Caribbean as a winner, with the second runner up being Argentina's 2006 National Programme for the Voluntary Surrender of Firearms (Riet & Bywaters, 2013, p. 4).

This competition highlighted the ISDL principles in practice as a benchmarking tool beyond the guidance of paper for gauging whether treaties, laws and policies of states (that are to be or already implemented) fulfil sustainable development. While the Biological Weapons Convention (BWC) was not nominated for the WFC's competition, this study continues the unfinished task of evaluating not only the BWC but also the CPB and International Health Regulations 2005 (IHR 2005) against the ISDL principles in light of the WFC's example. This annual competition shows that organisations have further taken specific measures in operationalising those principles beyond mere rhetoric. The WFC's initiative has served to highlight role-model laws and policies that abide by ISDL principles as an inspiration for others to follow suit but also as a means of creating awareness of these principles especially among those totally unaware of their existence, thereby galvanising them into further action.

5.5 Status of Sustainable Development in International Law

This section will consider the legal status of sustainable development in international law after having previously and extensively elaborated on each of the principles of the Delhi Declaration. Debates surrounding the legal status of sustainable development range extensively from it being a concept (Ellis, 2008, pp. 648-649; *Gabčíkovo-Nagymaros*, 1997, p. 51), an objective (French, 2005, p. 36), a principle of international law (*Gabčíkovo-Nagymaros*, 1997, pp. 89-90; Tladi, 2007, p. 103) to the elevated status of customary international law (Barral, 2012, p. 385; Lowe, 1999, p. 19), which remains highly debatable with it being an interstitial norm (Lowe, 1999, p. 31). On the other hand,

sustainable development may very well incorporate each of the above combinations as suggested by Sands (1996, p. 497): "[i]t is a legal term which refers to processes, principles and objectives, as well as to a large body of international agreements on environment, economics and civil and political rights." Briefly, this section will discern each of the different perspectives on sustainable development as put forth by scholars before evaluating them in light of the Delhi Declaration and whether it could be a combination of the above perspectives.

It was the judgement of the ICJ in the *Gabčíkovo-Nagymaros* (1997, p. 78) that aptly referred to sustainable development as a concept.[15] Notably, the majority of judges in the above case evaded the dilemma of determining the legal status of sustainable development by simply referring to it as a concept. Tladi (2007, p. 96) looks at the implication arising from this case, and states that "at best, the court is non-committal on the legal significance of sustainable development; at worst the court does not believe that sustainable development has any legal status at all." Nor is it clear whether sustainable development could be the implied new norm, as the term is mentioned following references to new norms and standards. The above judgment did not go so far as to pronounce whether sustainable development had acquired the status of customary international law. In contrast, the separate opinion of Justice Weeramantry gives more credence to sustainable development that is more than a mere concept. Sustainable development, in his opinion, had crystallised into a principle of international law (*Gabčíkovo-Nagymaros*, 1997, p. 90).[16]

[15] In *Gabčíkovo-Nagymaros* (1997, page 78), sustainable development is referred to as follows:
Such new norms have to be taken into consideration, and such new standards given proper weight, not only when states contemplate new activities but also when continuing with activities begun in the past. This need to reconcile economic development with protection of the environment is aptly expressed in the concept of sustainable development.

[16] In *Gabčíkovo-Nagymaros,* (1997) on page 90, Justice Weeramantry opines:

Both these vital [law of development and the law of environment] and developing areas of law require, and indeed assume, the existence of a principle which harmonises both needs.
To hold that no such principle exists in law is to hold that current law recognises the juxtaposition of two principles which could operate in collision with each other, without providing the necessary basis of principle for their reconciliation.

Apparently, Justice Weeramantry assumes that sustainable development has graduated from a mere concept into a principle in international law. This implies that sustainable development has been lifted up to the status of customary international law (French, 2005, p. 49). Justice Weeramantry also provides the justification for his reasoning in citing its "general acceptance by the global community" having "been expressly incorporated into a number of binding and far-reaching international agreements, thus giving it binding force in the context of these agreements" (*Gabčíkovo-Nagymaros*, 1997, p. 95). Moreover, Justice Weeramantry argues that "[e]vidence appearing in international instruments and State practice (as in development assistance and the practice of international financial institutions) likewise amply supports a contemporary general acceptance of the concept" (*Gabčíkovo-Nagymaros*, 1997, p. 95). Other evidence cited by Justice Weeramantry to reinforce his view of the elevated status of sustainable development as a principle of law concern "the field of multilateral treaties, international declarations; the foundation documents of international organisations; the practices of international financial institutions; regional declarations and planning documents; or State practice, there is a wide and general recognition of the concept" (*Gabčíkovo-Nagymaros*, 1997, p. 93).

In contrast, Lowe (1999, p. 24) strongly criticises Justice Weeramantry's position on grounds of a lack of *opinio juris* but also because even if the term sustainable development is being cited among numerous international agreements and soft law documents, this by no means suggests the evidence of state practice. While Lowe opposes the view that sustainable development has been or is being upgraded to a principle of international law or that of customary international law, other scholars like Tladi (2007, p. 103) and Barral (2012, p. 388) support the view of Justice Weeramantry in terms of sustainable development already being a principle of law and customary international law. Tladi

(2007, p. 104) provides the same reasoning as Justice Weeramantry for sustainable development attaining the status of a principle of law, for he refers to it being cited in among a plethora of national and international instruments and those giving effect to this concept.

Barral (2012, p. 388) gives a slightly different view in justifying his position, for he not only thinks that sustainable development as an objective already constitutes a principle of customary international law but cites the lack of uniformity in state practice when applying sustainable development as what impedes it from achieving its elevated status. In viewing sustainable development as a principle, Barral (2012, pp. 388-391) essentially thinks of it as an obligation to strive for, and states trying their best to achieve it resemble a due diligence obligation or an obligation of means rather than attaining a definite end result. Since sustainable development is an obligation of means, Barral (2012, p. 388) argues that this requires "various types of conduct to be adopted," because it is merely an objective to strive for.

While Tladi, Barral and Justice Weeramantry, as discussed above, agreed that sustainable development has achieved the status of a principle of customary international law, this study begs to differ. As there are different state practices in applying the means towards achieving sustainable development and since there remains an ambiguity in understanding the concept itself and its operationalisation, it is here contended that uniformity (being one of the requirements for customary international law) remains unfulfilled, such that the concept cannot (yet) accede to the status of customary international law. Indeed, French (2005, p. 51) shares a similar view: "it must be conceded that at present sustainable development is not - and is unlikely to become at any point soon - in and of itself a binding principle of international law."

If sustainable development is neither a principle nor elevated to the status of customary international law, it could at least be considered an interstitial norm (Lowe, 1999, p. 31). By this, Lowe refers to sustainable development as "a meta-principle, acting upon other legal rules and principles - a legal concept exercising a kind of interstitial normativity, pushing and pulling the boundaries of true primary norms when they threaten to overlap and conflict with each other" (Lowe, 1999, p. 86). Lowe's opinion of sustainable development (being an interstitial norm) is shared by Justice Weeramantry in his separate opinion in the *Gabčíkovo-Nagymaros* (1997, p. 31) case where he asserts that "there is always the need to weigh considerations of development against environmental considerations, as their underlying juristic bases - the right to development and the right to environmental protection - are important principles of current international law." In this regard, Justice Weeramantry has highlighted that both the right to development and the right to environmental protection would seem to be in a collision course with each other. It then follows that Justice Weeramantry is looking for a principle of reconciliation between these two rights about which he mentions the following: "[i]t is clear that a principle must be followed which pays due regard to both considerations" (*Gabčíkovo-Nagymaros,* 1997, p. 86). He then refers to the principle reconciling both these opposing rights as "[t]he principle of sustainable development and, in my view, it is an integral part of modern international law" – what Lowe regards as only a meta-principle (*Gabčíkovo-Nagymaros,* 1997, p. 86). Thus, while developmental agenda must consider environmental concerns, environmental protection can ill-afford to ignore developmental priorities as they must be equally balanced against each other. Upon evaluation of the Delhi Declaration's principles, it has become quite apparent that the principle of integration which merges both developmental and environmental concerns is none other than Lowe's interstitial norm and meta-principle. This, though, only applies to the principle of integration but it raises a salient question regarding the status of the other

principles of the Delhi Declaration within the ambit of sustainable development. This would require another view – to be elaborated here below.

In trying to situate the position of the other principles of the Delhi Declaration within the realm of sustainable development, it is worth considering the view of Sands (1994, pp. 336-347) who stresses that international laws in the field of sustainable development "point to a body of principles and rules drawn from traditional approaches, evolutionary rather than revolutionary, contributing incrementally to the law and legal process." In this context, French (2005, p. 52) points to the Rio Declaration's stress upon various principles for the attainment of sustainable development as an objective. This view is likewise highlighted by Ellis (2008, p. 643) who regards sustainable development "as an umbrella concept gathering together a range of existing or evolving international legal and political principles." This is also the view to which this study subscribes, for the Delhi Declaration's principles would not simply be referred to unless this study itself views sustainable development as a meta-concept with various principles under its ambit, all striving towards the achievement of sustainable development as an objective.

Apart from the above mentioned view, a final perspective is to view sustainable development as its own specialised body of law (Ellis, 2008, p. 650). This is in line with Principle 27 of the Rio Declaration which promotes the further development of international law in the field of sustainable development ("Report of the United Nations ", 1992). It then raises the question whether there is really a specialised body of law on sustainable development or whether it is composed of subfields of international law such as international economic law, international humanitarian law, international criminal law, international environmental law, international security law, laws of war, international health law, and other areas. At least as far as Justice Weeramantry is concerned, he does not think that there is a specialised body of law on sustainable development, for he mentions that the components of principles constituting sustainable development law

"come from well-established areas of international law - human rights, state responsibility, environmental law, economic and industrial law, equity, territorial sovereignty, abuse of rights, good neighbourliness - to mention a few" (*Gabčíkovo-Nagymaros*, 1997, p. 92).

The same goes for Taldi (2007, p. 106) who extends broad support for the Delhi Declaration as it seeks to combine the three branches of law, i.e. international human rights law, international economic law, and international environmental law, so as not to be bound by any distinct branch or branches of law. Yet, Tladi (2007, p. 107) is still critical of the Delhi Declaration in having confined international sustainable development law merely to these three areas of international economic law, international environmental law, and international social law. For instance, Tladi (2007, p. 107) suggested that sustainable development has been reflected in the areas of water law, treaty law, and the law relating to arms control and trade law. The position in this study fully supports Tladi and is equally critical, for the very thing that the Delhi Declaration seeks not to do (in confining sustainable development law to particular branches of law) is the very thing that it has ended up doing. While it is true that international social law would cover international health law, international humanitarian law and international development law, there are still branches of international law being excluded from these three categories of law such as the arms control law.

Thus, this study supports the notion that sustainable development should be viewed as an umbrella concept with various principles under its ambit. It also advocates for it to be viewed as an interstitial norm. However, this study does take exception to the ISDL definition proposed within the Delhi Declaration which merely confined it to three specialised branches of international law, mainly because this is not broad enough to incorporate the other branches of international law that can equally subscribe to the three components of sustainable development.

5.6 Conclusion

This chapter highlighted the need to identify the principles of international law in the Delhi Declaration of ISDL as an objective. A brief history introducing sustainable development led this study to the ISDL principles. While ISDL principles have begun to be applied through the WFC's initiative, sustainable development has yet to become a legally binding norm or principle within international law. Nevertheless, this chapter has also suggested that sustainable development can be an objective, with claim to principles of international law under its ambit.

Thus, it is envisioned that the principles of ISDL in the Delhi Declaration can be applied to the relevant provisions of international agreements. And as such, in subsequent chapters, the principles of the Delhi Declaration will be applied to biosecurity international agreements and relevant documents such as the CPB, BWC, IHR 2005, and WHO's laboratory biosecurity and biopharming initiatives – in short, wherever applicable.

CHAPTER 6: THE CARTAGENA PROTOCOL ON BIOSAFETY AND INTERNATIONAL SUSTAINABLE DEVELOPMENT LAW

6.1 Introduction

Previously in Chapter 4, it was emphasised that a holistic approach to biosecurity is needed. It was also highlighted earlier in Chapter 1 that International Sustainable Development Law (ISDL), which is based on the New Delhi Declaration of Principles of International Law Relating to Sustainable Development (hereinafter Delhi Declaration; International Law Association [ILA], 2002), can be the means by which the different sectors involved in biosecurity and associated international agreements and initiatives are brought together. In this chapter, the analysis will focus on how the seven principles of the Delhi Declaration are reflected in the provisions of the Cartagena Protocol on Biosafety (CPB) in terms of uniting disparate biosecurity areas and sectors as a means of fulfilling the third objective of this study. The third objective of this study seeks to analyse relevant provisions from selected biosecurity international agreements and initiatives, which reflect principles of international law in the Delhi Declaration.

As such, this chapter will examine the context in which each of the Delhi Declaration's ISDL principles is entrenched among CPB provisions. Whenever applicable, the elaboration of these ISDL principles will also be related to the context of biological warfare and bioterrorism in the CPB. This is because the CPB is the primary international agreement that monitors genetically modified organisms (GMOs), which are released into the environment to affect biological diversity, and is thus relevant to cases of biological

warfare[1] and bioterrorism[2] affecting the environment. This enables the CPB to be viewed in a different light, quite apart from its relevance to GMOs in agriculture.

This chapter begins by providing a brief overview of the CPB. This will be followed by an analysis of the Delhi Declaration regarding principles of ISDL within the CPB, arranged according to the sequel of principles: namely, the principle concerning the duty of states to ensure sustainable use of natural resources, the principle of equity and the eradication of poverty, the principle of common but differentiated responsibilities, the principle of the precautionary approach to human health, natural resources and ecosystems, the principle of public participation and access to information and justice, the principle of good governance, and the principle of integration.

6.2 Introducing the Cartagena Protocol on Biosafety

This section begins by briefly introducing the CPB. Introduced in Article 19(3) of the Convention on Biological Diversity (CBD, 1992), the CPB would set out the appropriate procedures, especially in relation to the Advanced Informed Agreement (AIA) for the safe transfer, handling and usage of GMOs, which may have adverse effects on the conservation and sustainable use of biological diversity. The CPB (2000) was finalised in January 2000 in Montreal, Canada, and came into force on 11 September 2003.

The CPB itself specifically addresses genetic engineering. This has been reflected in Article 3(i), which describes modern biotechnology that refers to this technology as the

[1] See Christensen (2002), particularly pages 51-78. Biological warfare is the deliberate release of viruses, bacteria or other germs (agents) to cause illness or death among humans, plants and animals. In this regard, biological warfare has the goal of incapacitating or eliminating the enemy. Biological warfare uses weapons of mass destruction (WMDs) or small-scale weapons targeted at a nation's armed forces, civilians or the national economy. Small-scale weapons are used against an individual, a unit or facility. The difference between biological warfare and bioterrorism lies in their goals. For biological warfare, the goal is to eliminate or incapacitate the enemy. As for bioterrorism, an attack on a smaller scale without using WMDs is more for the sake of instilling fear in the enemy, so as to achieve a political goal or promote an ideology. For biological warfare, it is most likely that a state with large amounts of funding can finance the creation of biological weapons as WMDs on a large scale. With regard to bioterrorism, funding may be limited, such that the acquisition of pathogens is most likely acquired through illegitimate means, such as stealing from a laboratory, modified from nature, through a culture collection, through illegal transboundary movement across borders or from a state previously involved in biological warfare.

[2] See *Bioterrorism Overview* published by the Centres for Disease Control and Prevention (CDC), US. The CDC defines bioterrorism as "the deliberate release of viruses, bacteria or other germs (agents) used to cause illness or death in people, animals, or plants". The CDC further elaborates that these agents can be found in nature, but could be changed through human intervention, such as using genetic engineering to increase their ability to cause diseases, making them resistant to medicine or increasing their potential to be spread into the environment.

"[i]n vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or [f]usion of cells beyond the taxonomic family [to] overcome natural physiological reproductive or recombinant barriers […] that are not techniques used in traditional breeding and selection" (CPB, 2000). A further indicator showing that the CPB covers genetic engineering is reflected in the definition of living modified organisms (LMOs) in Article 3(g), which refers to "any living organism that possesses a novel combination of genetic material obtained through the use of modern technology" (CPB, 2000). Although the term LMOs in the CPB is restrictive, as it was meant only to cover living organisms "capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids", as in Article 3(h) (CPB, 2000), this study uses the term GMOs because the CPB also covers products thereof or commodities, such as processed food (vegetable oil and soy sauce) containing degraded DNA, which are no longer living and unable to replicate genetic information, and thus more appropriately known as GMOs (Buechele, 2001-2002, pp. 283-324). While the CPB specifically monitors genetic engineering, its objective and scope must be examined. Article 1 explains its objective as "an adequate level of protection in […] the safe transfer, handling and use of living modified organisms […] that may have adverse effects on the conservation and sustainable use of biological diversity taking also into account the risks to human health" (CPB, 2000). Similarly, Article 4 of the CPB (2000), in addressing its scope, reiterates its objective as quoted above. Biological diversity, while not defined in the CPB, is referred to in its parent agreement, the CBD (1992).[3] It can thus be deduced from this definition of biological diversity that living organisms from all sources refer to different forms of plants, animals and other microorganisms, whether living on land, in the sea or in rivers.

[3] Biological diversity in Article 2 of the CBD (1992) is referred to as follows: "[T]he variability among living organisms from all sources, including, inter alia, terrestrial, marine and other aquatic ecosystems and ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems."

6.3 The Duty of States to Ensure Sustainable Use of Natural Resources among Provisions of the Cartagena Protocol on Biosafety

This section begins by noting that the principle of the duty of states to ensure sustainable use of their natural resources will here be used in the context whereby a state is required to inform other states of a contamination incident within its jurisdiction, which is causing significant harm to the environment of other states. This will enable further action to be taken to mitigate that harm. In *Legality of the Threat or Use of Nuclear Weapons* (1996) (hereinafter *Nuclear Weapons*),[4] the International Court of Justice (ICJ) indicated that this principle is already customary international law.

The AIA mechanism in the CPB, which requires a member state to inform the state importing GMOs to be released into the environment in the latter's territory, is part of Prior Informed Consent (PIC) procedure (CPB, art. 7(1), 2000). This places the responsibility on the exporting state that it has a duty to ensure that activities originating from its territory or under its control do not cause genetic contamination to other states, which could impair the territorial integrity of the importing state (CPB, art. 7(1), 2000). In *Consultative Opinion on Liability of Public and Private Actors for Genetic Contamination of Non-GM Crops* (Mestre, 2005, pp. 253-272), it was asserted by the Chamber of Consults that "an obligation to inform or warn may be coined as preventive in nature" as it intends to prevent harm to the environment before a real catastrophic accident actually damages the environment of the importing member state. The Chamber of Consults also emphasised that there has been a practice internationally "to assume that such preventive information or warning obligation exists" by citing the Corfu Channel case (Mestre, 2005, p. 268). Despite this assertion by the Chamber of Consults, it is further doubted whether exporting member states do have an obligation to inform, as it may not

[4] In *Legality of the Threat or Use of Nuclear Weapons (Advisory Opinion)* (1996) ICJ Rep 226, the following is mentioned: "The existence of the general obligation of States to ensure that activities within their jurisdiction and control respect the environment of other states and of areas beyond national control is now part of the corpus of international law relating to the environment."

be a wider state practice, casting doubts that it is an expression of existing public international law (Mestre, 2005, p. 269).

Although the exporting state itself may not directly export the GMOs, its biotechnology companies within its borders are the ones responsible for the exports. Therefore, the exporting state will have to ensure that its biotechnology companies comply with the AIA of the CPB and conduct a risk assessment to be subsequently evaluated by the importing member state. This is because there is unpredictability regarding how these GMOs might react in the environment of the importing state. The criteria to determine the harm caused will need to fulfil a certain threshold to trigger state responsibility, with the harm being either "significant", "appreciable", "substantial" or "serious" to require a state to inform (Mestre, 2005, p. 268). In this case, the Chamber of Consults made a reference to Article 11 of the CPB (2000), but doubted that the failure to inform an importing member state about the properties of GMOs would entail state responsibility, especially if the threshold for damage is not surpassed (Mestre, 2005, p. 272). The Chamber of Consults did indicate that the receiver of the GMOs in the importing state may be liable for any damages caused by the contamination of GMOs released into the environment under tort law (Mestre, 2005, p. 272).

For its part, the importing state, once satisfied that the GMOs to be imported may or may not cause harm to its environment, can give its consent and suggest risk management measures to be complied with by these biotechnology companies (CPB, art. 16, 2000). Unfortunately, this process of the AIA merely applies to GMOs that are released into the environment of the importing state and does not apply to GMOs intended for pharmaceuticals meant for humans, food, feed and processing, in transit and contained used as stipulated in Article 5, Article 7(2), Article 6(1) and Article 6(2) of the CPB (2000), respectively. Indeed, provisions that are being omitted from the AIA procedure are the ones most likely to have biosecurity implications, as will be discussed below.

6.3.1 Pharmaceuticals for Humans in the Cartagena Protocol on Biosafety

It was highlighted earlier that Article 5 of the CPB (2000) "shall not apply to the transboundary movement of living modified organisms which are pharmaceuticals for humans that are addressed by other relevant international agreements or organisations".

There is a possibility that terrorists can create an upfront legitimate company for pharmaceuticals in order to import GMOs under the pretext of pharmaceutical needs. Terrorists may obtain genetically modified biological agents from their counterparts abroad for pharmaceutical purposes, but can later channel them into bioterrorism. By not subjecting GMOs imported for pharmaceuticals to the AIA within the CPB, terrorists can exploit this weakness. Without being subjected to the AIA, there is no documentation about the characteristics of the GMO or the details of the sender. Without the necessary documentation, this can make it complicated for the importing state to trace the sender, who could also be a terrorist accomplice.

In the event of an environmental catastrophe wrought by bioterrorism, the relevant documentation containing information about the characteristics of the biological agent will help medical authorities diagnose the form of ailment and medical treatment in times of emergency. The missing documentation of the sender and receiver without the AIA procedure will also make it more complicated for the police and intelligence services to locate these terrorists and take any necessary enforcement action fastidiously. This is not to mention that environmental contamination can occur as a result of biological agents being released into the open environment by terrorists in the importing state.

The duty of states to ensure sustainable use of its natural resources and not to pollute the environment of other states is relevant to this case. Indeed, states that fail to prevent terrorists from exporting genetically modified biological agents to their counterparts in the importing state through relevant laws of terrorism and enforcement measure may

incur state responsibility. This is compounded when the GMOs released cause further environmental contamination through the release of biological agents in the importing state, due to the exporting state failing to control the actions of terrorists within its jurisdiction.

6.3.2 The Case of Biopharming

Although GMOs as pharmaceuticals for humans have not been subjected to the AIA, it is asserted in this study that Article 5 of the CPB (2000) would cover genetically modified plants and animals used to produce pharmaceutical substances known as biopharming. This is because Article 5 of the CPB explicitly mentions that "it shall not apply to the transboundary movement of living modified organisms which are pharmaceuticals for humans", though not in the case of animals or plants (CPB, 2000).

Indeed, the Report of the Canada-Norway Expert Workshop on Risk Assessment for Emerging Applications of Living Modified Organisms, published in June 2007 in Montreal, Canada, had covered the risk assessment and risk management procedures for evaluating pharma plants used as a biofactory to produce therapeutics, diagnostics and for vaccination purposes (Convention on Biological Diversity Secretariat [CBD Secretariat], 2008, p. 10). The plants producing substances for the above purposes will have to be evaluated through a risk assessment process because these pharma plants can cause harm to biological diversity, such as the impact on non-target organisms or becoming weeds when they accidentally grow in unwanted places as invasive alien species (CBD Secretariat, 2008, p. 9). This will no doubt cover agricultural biosecurity addressed by the Food and Agricultural Organisation of the United Nations (FAO), covering GMO plants and invasive alien species, as mentioned in Chapter 4. Additionally, when pharma plants become weeds or invasive alien species, they will cause genetic contamination to other plants of the same species. The relevance of the duty of states to

ensure sustainable use of their natural resources, while not polluting the environment of another state, requires them to ensure that the exporting biotechnology firm does not cause genetic contamination to the environment of the importing state.

Therefore, segregation and the type of plants chosen for biopharming must be examined to prevent contamination occurring between natural plants for human consumption and those producing substances for therapeutics, diagnostics and vaccinations. Articles 7 and 8 concerning the notification and application of the AIA procedure in the CPB (2000) require the exporting biotechnology company to provide the necessary documentation and risk assessment to be evaluated by the importing state before biopharming plants can be released into the environment.

The concern over biopharming and pharma plants was further discussed at the Fifth Meeting of the Conference of Parties to the Convention on Biological Diversity Serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety (henceforth COP-MOP 5) (CBD Secretariat, 2010a, p. 9). Participants at COP-MOP 5 highlighted that "pharmaceutical proteins in plants in the environment would introduce novel risks as compared to other [GMOs requiring] scientific considerations in the framework of risk assessment" (CBD Secretariat, 2010a, p. 9). These participants called for pharma plants to be handled with "high levels of containment and special handling [to] eliminate any significant hazard to biological diversity" (CBD Secretariat, 2010a, p. 9). Thus, the debate concerning how pharma plants in the biopharming process should be treated in the risk assessment process will continue into the foreseeable future until member states to the CPB reach a consensus on the matter.

There is also the likelihood that compounds derived from pharma plants could be exported for further processing in order to be reproduced as pure drugs. Meyer (2000, pp. 2-7) stressed that pharma plants "exhibit substantial variability in vaccine or drug

concentration due to variations between each organism, climate, soil, etc." Therefore, the raw compound from pharma plants may be exported as drugs for humans in order to undergo purification in the importing state. In this context, nowhere within the CPB, especially under Article 3 (CPB, 2000), is the meaning defined with regard to processing that is relevant to substances produced by pharma plants.

In the past though, the Fifth Open-ended Ad Hoc Working Group on Biosafety, held in August 1998, indicated that biopharming had fallen under the concern of products thereof (CBD Secretariat, 1998, p. 5). References to biopharming at the time were concerned with "[t]ransgenic microorganisms, animals and plant [that] have been developed [for] general important commercial products either as the whole dead organism, components to be harvested and purified from the organism, or as a byproduct of metabolism" (CBD Secretariat, 1998, p. 5). The emphasis on "components to be harvested or purified" (CBD Secretariat, 1998, p. 5) underlines the relation to biopharming, as it intends to extract the substance from pharma plants. This reference to biopharming, or products thereof, also falls within the ambit of commodities. Subsequently, the concern for commodities during the negotiations of the CPB led to Article 11, which concerns the procedure for GMOs intended for direct use as food or feed or for processing (CPB, 2000). If this is correct, it can be ascertained that, rather than the AIA, the substance from pharma plants will only be subjected to a more simplified procedure, which merely requires the importing member state to display its decision regarding the importation of GMOs for processing through the Biosafety Clearing House (BCH) mechanism, along with the necessary documentation to support its decision (CPB, art. 11(1), 2000). This is in view of the fact that Article 7(2) of the CPB (2000) has made it explicit that GMOs for processing are exempted from the AIA.

6.3.3 Transit for Pharmaceuticals

The relevance of Article 6 covering GMOs in transit and contained use (CPB, 2000) also applies to pharmaceuticals being processed. According to Kellman (2002b, p. 32), "[i]t is during transfer that pathogens are most vulnerable to wrongful diversion", while it is emphasised that "[p]athogens could be stolen from a facility during transit". Indeed, the substance derived from pharma plants, which is further destined to be processed for pharmaceuticals, runs the risk of being stolen by a terrorist who knows that the GMO-derived substance (pharma plants containing therapeutic properties) may be useful as an ingredient in creating a biological weapon. Tucker (2011, para. 4), for instance, is of the view that biopharming has its dark side "because it might be used to mass-produce toxic proteins for hostile purposes". Moreover, there is nothing stopping a terrorist from paying and collaborating with an insider within a port facility or a storage area within an airport to obtain the said substance and divert it towards impermissible uses. It is for this reason that Kellman (2002b, p. 32) has stressed that "measures should be implemented to require that specialised transit capabilities, staffed by transit professionals, are available when designated pathogens are to be moved", as trained personnel will be able to detect any tampering with the containers storing those substances. Kellman (2002b, p. 32) also stressed that transfers "should be preceded by notification to relevant government officials, and successful arrival of those transfers should also be noticed".

While the substance in transit may not be subjected to the AIA, Article 6(1) of the CPB (2000) does not obliterate the right of member states to the CPB to regulate GMOs in transit. This is because the wording of Article 6(1) of the CPB (2000) reads: "without prejudice to any right of a member state of transit to regulate the transport of [GMOs] through its territory". The wording of this provision has been interpreted to permit a member state to "regulate the transport and handling of [GMOs] while it is on its territory [such as imposing] handling and other transport and safety health precautions and

regulating measures on transiting [GMOs]" (MacKenzie et al., 2003, p. 59). McKenzie et al. (2003, pp. 59-60) have interpreted Article 6(1) of the CPB's coverage to permit a member state to require "prior notification of transit through national law" and to impose "regulatory and safety rules as they deem necessary including requiring [a] risk assessment, and positive consent by state authorities before transit is permitted". This understands that, under general international law, every state has an inherent right over its territorial sovereignty and to impose its regulations, especially in the case of the transhipment and transit of goods by aircraft, as per the general provision of Article 2(3) of the CPB (2000).

Indeed, notifying member states to the CPB concerning GMOs in transit will enable them to make immediate emergency response measures in dealing with GMOs that are deliberately exposed to the environment in cases whereby terrorists, their accomplices or insiders steal them for their own malevolent intentions. Failure to notify the authorities of the importing state regarding GMOs in transit and providing documentation of their characteristics will only delay identifying organisms and taking appropriate measures by local authorities in an emergency. This delay can cause further contamination, harming public health and leading to fatality. Upon a member state making a decision about GMOs in transit, there is also a requirement to notify the BCH of its decision, as per Article 20 of the CPB (2000). Unfortunately, Article 6(1) of the CPB (2000), which addresses GMOs in transit, has its own loophole, which may invite terrorists to abuse this provision because there is no effective monitoring procedure similar to the AIA. This may be attributed to the failure to recognise the possible misuse of genetic engineering for bioterrorism within the CPB's context.

Related to the substance from pharma plants being in transit, the safe handling, transport and packaging while transporting the substance need to be emphasised. As the substance from pharma plants will undergo further processing, Article 18(2) (a) of the

CPB (2000) requires the substance to be labelled as "may contain" GMOs and is not intended to be introduced into the environment. This provision will alert a state of the presence of GMOs in transit as the necessary documentation will have to be provided, together with the contact details of individuals and institutions responsible for the movement of GMOs from one destination to another. Article 18(1) of the CPB (2000) envisages that a member state must consider the relevant international rules and standards currently available, e.g., the UN Recommendations on the Transport of Dangerous Goods, when categorising GMOs according to the types of risk they pose.

Hence, the duty of states to ensure sustainable use of their natural resources, while not polluting the environment of another state, also applies to the case of GMOs in transit involving pharmaceuticals. When a state of origin fails to detect a plan among terrorists within its jurisdiction and liaise with its counterparts overseas, to where the GMOs for pharmaceuticals will be transited and from where they will subsequently be stolen, it may incur state responsibility. This occurs when the state of origin does not use all the means at its disposal to prevent terrorists within its territory or strictly enforce its laws in order to foil plans to steal pharmaceutical substances, which could be channelled into bioterrorism. The situation is made worse if the GMOs as pharmaceuticals are then released into the environment in the state of transit by terrorists, having carried out their plan of misdeeds with their counterparts in the state of origin.

6.3.4 Excluding Contained Use from the Advanced Informed Agreement

Using the example of processing the pharma plant substance, it is acknowledged that processing will take place in a contained facility. Meyer (2000, pp. 2-7) has mentioned that the further processing of the pharma plant substance can also invoke Article 6(2) of the CPB (2000), which addresses contained use. The import of biological agents to be genetically modified, or those that are already modified for research purposes, in a

contained facility would fall under Article 6(2) of the CPB (2000). Article 3 of the CPB (2000) defines contained use as "any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment". This definition implies the need for any laboratory and industrial facility with the necessary biosafety level to contain the GMOs, so as to prevent them from escaping into the environment. However, there is no definition in the CPB itself that pertains to biosafety, especially considering that the title of the protocol itself refers to biosafety. Using the World Health Organisation's (WHO's) definition of biosafety, this term "describes the containment principles, technologies and practices that are implemented to prevent the unintentional exposure to pathogens and toxins, or their accidental release" (WHO, 2006, p. 7). Notably, the CPB does not subject GMOs for contained use to the AIA, as implied by Article 4(2) of the CPB (2000).[5] At the same time, Article 6(2) of the CPB (2000) does not totally bar a member state from wanting to regulate GMOs for contained use, as it stresses the "right of a member state to subject all living modified organisms to a risk assessment prior to decisions on import and to set standards for contained use within its jurisdiction". In this regard, the CPB leaves it to the discretion of member states to decide the form of regulation to be imposed on GMOs in contained use without detailing any best practices in terms of preventing these GMOs from escaping, being stolen and subsequently being misused for bioterrorism purposes.

In view of the fact that the CPB has failed to prescribe any suggestions to member states concerning how contained use within a facility through best practices can be accomplished, the WHO guidelines on laboratory biosecurity will have to be consulted (WHO, 2006). While biosafety is meant to minimise the unintentional contact of GMOs with the environment, laboratory biosecurity provides the means for preventing GMOs

[5] Article 4(2) of the CPB states that "the advance informed agreement procedure shall not apply to the transboundary movement of living modified organisms destined for contained use".

from intentionally being released into the environment by foiling theft, as well as preventing loss or diversion of these GMOs by terrorists for their malevolent intentions (WHO, 2006). Therefore, biosafety and laboratory biosecurity are integral to each another. The WHO's guideline on good practices for laboratory biosecurity will be discussed in Chapter 8. Meanwhile, Article 2(5) of the CPB (2000), which seeks "available expertise, instruments and work undertaken in international forums with competence in the area of risks to human health", can be a facilitator for the CPB to form links with the WHO, so that member states can learn more about laboratory biosecurity.

Failure to address the importance of laboratory biosecurity towards preventing the deliberate release of GMOs will open up an avenue for terrorists to utilise the vulnerability of Article 6(2), addressing containment, in the CPB (2000). Seicho Endo, a member of the Aum Shinrikyo group of terrorists in Tokyo, once tried to steal seed stock from a laboratory in a quest towards developing a biological weapon (Danzig et al., 2011, p. 21). Aum Shrinrikyo also used one of its members to pose as a student studying at a Japanese university to illegally retrieve a vaccine strain of anthrax in order to create a biological weapon in a laboratory (Danzig et al., 2011, p. 23). Indeed, Aum Shinrikyo had the intention of utilising genetic engineering to accomplish their aim of developing a biological weapon (Danzig et al., 2000, p. 23). If the above real-life example from a terrorist group is not enough proof that such organisations could breach laboratory biosecurity for their malicious intentions, it is timely for member states to the CPB to incorporate laboratory biosecurity, especially steps in preventing theft and misuse.

Another inherent weakness of Article 6(2) in the CPB (2000) is that the exporter has no obligation to ensure that the GMOs, which are intended for usage in a contained facility, will merely be used for that purpose by the importer. For instance, in 1986, the University of Baghdad (Iraq) once ordered germs causing gas gangrene and the West Nile virus from the American Type Culture Collection (ATCC) in Virginia for its biological

warfare programme, claiming that it was for legitimate medical research (Kelley, 2002b, p. 1). It later surfaced that Iraq had used all of the three samples to create biological weapons, which it admitted to UN inspectors after the 1991 Gulf War (Kelley, 2002b, p. 1). Moreover, the Centres for Disease Control (CDC) in Atlanta, US, had also shipped several shipments of *Escherichia coli (E. coli)*, genetic materials, and human and bacterial DNA to Iraq's Atomic Energy Commission, all for legitimate research and medical purposes, or so it was claimed (McAlvaney, 1996, p. 5). Other Iraqi agencies were listed as having received biological samples from their American counterparts including the Ministry of Higher Education, the State Company for Drug Industries, and the Ministry of Trade (McAlvaney, 1996, p. 4). The CDC even sent samples of botulinum toxin and botulinum toxoid directly to Iraq's chemical and biological weapons complex, Al-Muthanna (Kelley, 2002b, p. 1). When the ATCC was asked about its actions in supplying Iraq with the necessary seed stock, its Vice President for Human Resource and Public Relations mentioned that the US Department of Commerce had given its approval for the shipment on the basis that it was for a legitimate research programme (Shennon, 2003, p. 1).

Since then, the US has set far more stringent rules in monitoring requests by states for seed stocks from agencies within its borders, as they have to verify the purpose of the request (Shennon, 2003, p. 1). It must also be noted that Iraq was one of the states wanting to utilise the genetic engineering technique in order to modify the vaccine strain of anthrax during the 1991 Gulf War, but this came to a halt when US forces invaded Iraq (Koblentz, 2009, p. 20).

The implication regarding Article 6(2) of the CPB (2000) in terms of the Iraqi example above, is that it cannot be taken for granted that, when an importer requests biological samples for legitimate research, they will be utilised only for that purpose. There may be a cover-up, given that, once the biological samples are obtained, they may be used for

malicious intentions, such as developing biological weapons for biological warfare as was the case in Iraq. Therefore, there is need to consider an inspection team from abroad and national Institutional Biosafety Committees (IBCs), which consist of experts who are capable of detecting any development of a biological weapon in laboratories or other contained facilities with their trained eye. This is to ensure that any GMOs imported purportedly for scientific research are genuinely used for that noble intention and not something sinister. An exporting member state to the CPB should monitor and keep documentation on its biotechnology companies, especially when they export GMOs intended for contained use. This is to ensure that, if the importing state finds that the GMOs are being used for other purposes apart from contained use, there is a reference that will enable the exporter to be tracked down concerning any false declaration and dealt with accordingly by the laws of the importing state. As a consequence of the exporting state monitoring and keeping the necessary documentation, it is fulfilling its state responsibility to act as well as its duty to ensure a sustainable use of its natural resources or those under its control, so as not to cause environmental contamination and damage in the jurisdiction of the importing member state.

It is worth examining how terrorists can acquire biological samples for terrorism. The Rajneeshpuram cult, which poisoned salad bars in restaurants in Oregon, US, back in 1984 by using *Salmonella typhimurium*, had acquired the seed stock through its front company, the Rajneeshee Medical Corporation (RMC), which had a legitimate licence to obtain the necessary stock from VMR Scientific, a medical supply company in Washington DC (Carus, 2001, p. 55). Once the *S. typhimurium* was acquired, a cult member cultivated the seed stock in a laboratory to create a biological weapon (Carus, 2001, p. 55). In another case, Al-Qaeda was reputed to have given the Philippines' Moro Front £2,500 to purchase anthrax spores from a culture collection company in South East Asia and cover extra shipping costs without the supplier checking the suspicious

background of the requester (Rock, 2001, p. 1). It can be observed from the above cases that there is a trend among terrorist groups to obtain biological agents through culture collections and subsequently to cultivate them in laboratories.

Referring back to Article 6(2) of the CPB (2000), it should not be impossible for any terrorist groups to either request or obtain a biological agent or seed stock from the various sources already mentioned under the pretext that it will be used for legitimate scientific or medical research. However, in reality, these biological agents or seed stocks could then be used for bioterrorism purposes in a laboratory somewhere. Already, Article 6(2) of the CPB (2000) is exempted from the AIA, making it a weak provision that only permits a member state to require a risk assessment in accordance with its domestic law, or to set an appropriate standard for contained use. In line with Article 6(2) of the CPB (2000), addressing contained use, the formation of a code of conduct for scientists and companies, which supply seed stock or biological agents, is needed as a guide to member states to be more alert and properly scrutinise from whom and where a request comes. This will allow for an informed decision to be made in terms of rejecting a biological agent request, should it come from a rogue state reputed to be developing biological weapons or suspected terrorist groups and their affiliates.

Thus, with the CPB forum keeping issues pertaining to biological warfare and bioterrorism out of the discussion, there is no chance to truly scrutinise the said issues mentioned among its relevant provisions, as in the case of contained use.

6.3.5 Illegal Transboundary Movement and Implications for Biosecurity

Another most likely provision to be considered in the CPB, especially regarding acts of bioterrorism, involves Articles 25(1) and 25(2), covering the illegal transboundary movement of GMOs (CPB, 2000). During the negotiations of the CPB, member states referred to this provision as illegal traffic and was initially defined under Article 3

concerning use of the terms (CBD Secretariat, 1997, p. 38). A definition of illegal traffic was agreed at the Third Open-ended Ad Hoc Working Group on Biosafety Meeting in 1997 (CBD Secretariat, 1997, p. 38).[6]

While the above definition does provide a clue concerning the meaning of illegal transboundary movement of GMOs, the reason for omitting this definition in Article 3 of the final Protocol (CPB, 2000) is not known. Based on the definition of illegal traffic, it is sufficient to know that any exporter making a false declaration about an intended use of GMOs, which would subsequently lead to illegal usage, will be in contravention of Article 25 of the CPB (2000). This also applies to the earlier discussion above, when a terrorist group, such as Rajneeshpuram, may use a legal front company to import a biological agent or seed stock for scientific or medical research in a contained facility, even though, in actuality, it is using it to develop a biological weapon illegally. If caught by the authorities for utilising the biological agent for nefarious intent, this will involve an illegal transboundary movement, especially if it involves importation from overseas. Furthermore, if the importation of the biological agent was intended to be used in a contained facility, but the perpetrator subsequently decided to deliberately release it into the environment, this would also fall under Article 25 of the CPB (2000) because its intended use has been malevolent from the start.

Since the final form of the CPB omitted any definition of illegal transboundary movement, it has been left to member states to decide upon which actions fall under the classification of illegal transboundary movement by means of its "domestic measures at preventing and, if appropriate, penalising transboundary movement of [GMOs] carried

[6] See *Report of the Third Meeting of the Open-ended Ad Hoc Working Group on Biosafety*, issued following the third meeting of the Open-ended Ad Hoc Working Group on Biosafety, UNEP/CBD/BSWG/3/6 (1997), in which, on page 38, illegal traffic is referred to thus: "Illegal traffic means any transboundary movement or transfer without notification to, or advance informed agreement of, all Parties concerned; pursuant to the provisions of this protocol; or with advance informed agreement obtained from Parties concerned through falsification, misrepresentation or fraud; or with advance informed agreement which does not conform in a material way with the documents submitted or which results in the deliberate release of living modified organisms in contravention of this protocol and of general principles of international law [and of general principles of international law]."

out in contravention of its domestic measures" (CPB, art. 25(1), 2000). Domestic measures in Article 25(1) of the CPB (2000) are understood to refer to the legal and institutional framework that a member state is bound to apply to prevent an illegal transboundary movement. The strong wording of "shall adopt" in Article 25(1) of the CPB (2000) also makes it a mandatory state responsibility, through any means, to prevent and penalise the illegal transboundary movement of biological agents, which could lead to the making of biological weapons through the respective state's criminal and penal code legislation prescribing the necessary punishment.[7] As it stands, Article 25(1) of the CPB applies to all forms of GMOs covering those released into the environment by applying the AIA procedure, and those destined for contained use, in transit, as well as for food, feed and processing. While Article 25(1) of the CPB (2000) does not set a universal standard concerning crimes classified as illegal transboundary movement, the higher the threshold set by a member state in addressing crimes under its domestic legislation, the more stringent and committed it is to curb this menace.

Recent reports by member states to the CPB indicate the forms of crime that are categorised as illegal transboundary movements. In 2005, Japan indicated that genetically engineered corn (B+10), which was inadvertently cultivated by a non-party to the CPB, had been exported to Japan, with measures subsequently taken to prevent its distribution in the country (CBD Secretariat, 2012a, p. 2). Likewise, New Zealand and the Netherlands both encountered the illegal importation of GloFish (*Danio rerio*) for the pet trade, only to destroy them for fear of contaminating the environment (CBD Secretariat, 2012a, p. 2; CBD Secretariat, 2007, p. 14). In this regard, the CPB is more inclined to acknowledge the agricultural biosecurity proposed by the FAO, namely, that GMOs could

[7] Article 25(1) of the Cartagena Protocol on Biosafety (CPB) reads as follows: "Each member state shall adopt appropriate measures aimed at preventing and, if appropriate, penalising transboundary movements of living modified organisms carried out in contravention of its domestic measures to implement this Protocol. Such movements shall be deemed illegal transboundary movements."

become pests or invasive alien species when they are released into any environment where they are not wanted, as in the case of the GloFish mentioned previously. In another case in Asia, a member state to the CPB reported three forms of illegal transboundary movement of GMOs involving killifish, GloFish and corn, all because the importer did not recognise them as genetically modified (CBD Secretariat, 2012a, p. 2). This same member state was also investigating the illegal import of papaya and pharmaceuticals for human consumption within its territory (CBD Secretariat, 2012a, p. 2). An observation regarding the above cases suggests that these forms of illegal transboundary movement of GMOs would definitely harm biological diversity, even though they involve more mundane forms of the crime.

The relevance of Article 25 of the CPB (2000) should also be interpreted in light of the illegal importation of GMOs intended for bioterrorism. A meeting for capacity building within the CPB, however, has highlighted the need to identify factors contributing to the illegal transboundary movement of GMOs, such as the transportation of illegal shipments and informal transboundary patterns, which are the most likely means of illegally smuggling biological agents (CBD Secretariat, 2012c, p. 5). Examples of the illegal transboundary movement of a biological agent include Al-Qaeda, under the former leadership of Osama bin Laden, who purchased anthrax and plague viruses from arms dealers in Kazakhstan (Daley, 2000). It must be noted that a terrorist group is most likely to obtain biological agents through illegal means, so as not to arouse suspicion in the authorities. In another case, it was reported that Al-Qaeda even tried to smuggle a biological weapon into the US through tunnels under the Mexican border (Universal Detection Technology [UDT], 2009, p. 1). Al-Qaeda reputedly purchased *E. coli* and *Salmonella* from producers in the Czech Republic and elsewhere in Eastern Europe for USD$5,000 (Rock, 2001, p. 1).

It has become apparent that Al-Qaeda has been trying to produce biological weapons; otherwise, this terrorist group would not have been purchasing biological agents illegally. In 2009, Al-Qaeda members had to abandon their cave hideout in the Tizi Ouzu Province (150 kilometres east of Algiers) when their experimentation with the plague went wrong and ended up killing 40 of its members ("40 Al-Qaeda", 2009, p. 1; "Al-Qaeda", 2009, p. 1). Daan Goosen, who was charged with the responsibility of creating biological weapons to destroy the African community in South Africa under the apartheid government, together with his fellow scientists, had also been approached by private individuals and foreign member states whose identities remained undisclosed (Warrick & Mintz, 2003). They were willing to pay a hefty sum to acquire the various genetically modified microbes under Project Coast, signalling the possibility of a black-market transaction (Warrick & Mintz, 2003).

In all of the above examples, the likelihood of terrorist groups using a legitimate channel to "legally" acquire biological agents is disputable and likely to trigger Article 25 of the CPB (2000), should it involve the genetic modification of biological agents. As Kellman (2002a, p. 736) has pointed out, "while it is hypothetically true that a weapons producer could voluntarily enrol in an oversight system and, at least superficially, meet its criteria, the likelihood of this happening is less than the likelihood of a weapons producer trying to stay outside the system altogether". Based on the evidence of Al-Qaeda, Aum Shinrikyo and the South African case cited above, there is merit in Kellman's statement that terrorist groups will illicitly acquire biological agents, rather than use a legitimate channel. This is to avoid the monitoring of any governmental overseeing system, which could detect their illegal activities. This implies that it is highly unlikely for terrorist groups to seek permission to export biological agents to their counterparts in another state, under the pretext that they are meant for legitimate medical research in a contained facility, or to invoke Article 6(2) or Article 11 of the CPB (2000) addressing

GMOs for food, feed and processing. These terrorist groups may use front companies receiving these imports to disguise their sinister intentions to create biological weapons.

Having shown that the illegal transboundary movement of GMOs has its dark side, in that it can lead to the creation of biological weapons, awareness among member states to the CPB of this malice, along with capacity-building initiatives to deal with this scourge, must be initiated and promoted. One of the measures recommended to member states to the CPB, as a way of detecting the illegal transboundary movement of GMOs, is to conduct overt and covert inspections, along with "monitoring activities to know how and why breaches occur" (CBD Secretariat, 2012a, p. 6). This is very relevant in cases where the smuggling of biological agents by terrorists requires authorities to observe illegal and remote routes of transport, which are normally hard to detect, especially by land and sea, due to having to spy over a long period of time and establishing a pattern of these terrorists' mode of operation.

As part of capacity building, member states to the CPB must also compile data on "the legal and illegal transboundary movement of [GMOs] into and outside their respective countries" (CBD Secretariat, 2012a, p. 6). While the idea of compiling data over time regarding the illegal transboundary movement of GMOs sounds novel, this will be a difficult task to accomplish. This is because it will not be easy to single out the smuggling of biological agents, since they are entrenched within other smuggling activities. Kellman (2002a, p. 737) highlights that "terrorists will increasingly make use of smuggling networks that are currently used for drugs, guns, or other contraband". Compounding the difficulty in detecting these smuggled biological agents is that the "seed culture of dried anthrax spores could be carried in a sealed plastic vial the size of a thumbnail", making the detection of such contraband at a country's borders impossible (Tucker, 1999, p. 5). Furthermore, this seed culture is not easily detected by radiation or X-rays (Tucker, 1999, p. 5). If the smuggling of seed stock involves military strains, it will likely be smuggled

within a simple plastic cigarette package (Tucker, 1999, p. 5). Therefore, there is a need to adopt a biological detection system using a bacterial spore detector, which is capable of identifying such biohazardous substances. This form of technology is currently available for customs and other officials at a national border control, but they should be trained to use such a detection system in order to detect a biohazard before it is deliberately or even accidentally released into the environment, causing contamination and endangering public health.

With regard to the need to compile data about the illegal transboundary movement of GMOs inside and outside a member state's borders, this will be a tremendous challenge. By way of illustration, Russia faces difficulty in detecting whether its disease agents, including those that are genetically modified, and fragments of genetic material have been smuggled out of its borders (Gormley, 2007, p. 5). This is because it is not easy to track elusive smugglers, while custom officers may not have received the necessary training and specialised detection equipment (Gormley, 2007, p. 5). This has resulted in relatively sparse data concerning smuggled biological agents, which by no means signify the complete absence of any smuggling of biological agents. This may well indicate the difficulty in detecting the diversion and smuggling of such biological agents. Therefore, it is anticipated that member states to the CPB will face an uphill task in gathering data on illegally smuggled biological materials, given the Russian precedent.

Indeed, it would be useful, even necessary, for the CBD Secretariat managing the CPB to work closely with Interpol and the UN Office on Drug Cooperation (UNODC), which also deals with transnational organised crime matters. This is because covert activities to detect culprits involved in the illegal movement of biological agents and the gathering of data on their activities are best handled by organisations dealing with transnational organised crime. In facilitating mutual cooperation between the CPB and other bodies of the UN and relevant international organisations, Article 29(8) of the CPB (2000),

covering work with other international organisations, encourages such forms of cooperation.

Article 25(2) of the CPB (2000) involves the provision whereby a state of origin, from where the GMO originated, is required to dispose of it at its own expense through repatriation or destruction in the event that the illegal transboundary movement of the said GMO causes damage to the affected member state. Hence, Article 25(2) of the CPB (2000) relates to the duty of states to ensure a sustainable use of their natural resources or those under their control, so as not to cause contamination in other states. Exporting and importing states to the CPB will have to take all necessary measures to detect the illegal smuggling routes of GMOs, at every legal and illegal entry point at their borders, as part of their responsibility to be seen as taking appropriate action. Otherwise, both the exporting and importing states could be held liable for not having the appropriate laws and enforcement in place, thus failing in their state responsibility to prevent the illegal transboundary movement of GMOs into another state's jurisdiction causing environmental harm.

While it is true that a state cannot be held accountable for acts of terrorism beyond its control, it must nonetheless be seen as having taken all necessary measures to prevent bioterrorism from occurring. Domestic legislation can also prescribe that a person or entity be held responsible for the illegal transboundary movement of GMOs. Alternatively, that person or entity may be asked to bear the costs of measures to either dispose or destroy GMOs that damage biological diversity. This aforementioned provision is also related to Article 27 of the CPB (2000), covering liability and redress. When a state to the CPB makes a decision about the illegal transboundary movement of GMOs, such a decision will have to be made available to the BCH, in accordance with Article 25(3), as a means of sharing experiences among member states on how to deal with the said issue (CPB, 2000).

6.3.6 Unintentional Transboundary Movement of Genetically Modified Organisms

In the event that an illegal transboundary movement of GMOs, destined to be used as a biological weapon, trespasses the territory of a member state to the CPB and, by chance, is known to the authorities, it is possible to categorise such forms of GMO as involving unintentional transboundary movement under Article 17 (CPB, 2000). McKenzie et al. (2003, p. 118) interpret unintentional transboundary movement as the accidental release of GMOs from a contained facility giving rise to unintentional movement. In this case, McKenzie et al. highlight the importance of laboratory biosecurity in preventing the theft of biological agents from a laboratory or other contained facilities. The Alma-Ata Institute in Kazakhstan holds genetically modified biological agents, such as anthrax, tularaemia and plague, but has lax security, prompting the likelihood of these biological agents being stolen from a contained facility and subsequently released into the environment (Guterl & Connant, 2002). Guterl and Connant (2002) reported that at the Alma-Ata Institute, it would be easy to smuggle these biological agents for the purposes of selling on the black market because there are very few security guards, low fences and no heavy metal doors to secure access to their laboratories. Furthermore, refrigerators storing these biological agents are secured with a simple padlock (Guterl & Connant, 2002). This is worrisome because terrorists can get hold of these biological agents easily. As discussed previously, Al-Qaeda procured seed stocks of anthrax and plague from arms dealers in Kazakhstan on a black market trading in stolen biological agents (Daley, 2000, p. 1).

Since other research institutes in Kazakhstan are in a more vulnerable position, there is the danger that terrorists could secure the required biological agents easily for creating biological weapons. In Georgia, it was reported that mustard gas was accidentally discovered by its customs agents in an unrelated roadside check in 2003, and similarly with regard to a customs shipment inspection in Ukraine (Gormley, 2007, p. 3). The aforementioned cases underline the need to consider the dark side of biology in terms of

unintentional transboundary movement, whereby biological agents can turn up illegally and unannounced in a state's territory. Once accidentally discovered and released into the environment, these biological agents, which have undergone genetic modification in order to make them more potent, can endanger human health, especially those who come into initial contact with them, such as custom officials, the police and military personnel manning border controls and patrols. Illegal smugglers can easily fool custom officials, the police or military personnel into believing that the biological agents in their possession are meant for legitimate purposes, such as pharmaceutical or industrial purposes. This is how the dual-use dilemma applies, whereby biological agents can be used for either deviant or legitimate purposes. Unless these officials have been expertly trained to be able to technically verify the claims of these smugglers, there is always the alarming possibility that the latter could avoid detection, especially when officials do not have the required technical know-how.

At the Sixth COP-MOP of the CPB, it was emphasised that member states should build capacities under Article 22 "in the use and development of easy to use, rapid, reliable and cost-effective sampling and detection techniques for [GMOs]" (CBD Secretariat, 2012e, p. 4). Therefore, officials controlling borders among member states to the CPB must familiarise themselves with bacterial spore detectors, handheld assays for detecting bioterrorism agents, radiation detection systems and antimicrobial products. To date, the Sixth COP-MOP of the CPB has not emphasised the need for officials guarding a state's territorial borders to have the necessary knowledge about these biological weapons detection systems. Thus, training must be conducted into how to prevent these biological agents from being used for bioterrorism. Since the Sixth COP-MOP to the CPB indicated the need to share methods of detection and identification of GMOs, and to make them available to the BCH, the more affluent states at the forefront of the development of

biological weapons detection systems ought to share this information with other members of the CPB (CBD Secretariat, 2012e, p. 4).

Additionally, Articles 17(1) and 17(4) of the CPB (2000), addressing the unintentional transboundary movement of GMOs, require states affected by the transboundary movement to be notified as a practice of customary international law, enabling the affected member states to take prompt action. This conforms to the duty of states to ensure sustainable use of their natural resources, while not polluting the environment of other states. By informing the affected state, this will enable it to take emergency response measures to deal with the environmental harm caused by the unexpected release of any biological agents within its territory. Not only must the affected state be informed, but this information should also be channelled to the BCH and relevant international organisations in line with Article 17(1) of the CPB (2000).

The WHO is also one of the organisations to be informed if the unexpected release of a biological agent causes disease. This takes into account that the International Health Regulations 2005 (IHR 2005) also deal with emergency response measures (IHR 2005, art. 43, 2005). The IHR 2005 also covers public health events involving the intentional use of biological agents (Fidler, 2005, p. 354). Article 6 of the IHR 2005 (2005) requires WHO members to inform one another of any disease occurrence constituting a Public Health Emergency of International Concern (PHEIC). In this regard, it seems apparent that the IHR 2005 is complimentary to Article 17 and Article 2(5) of the CPB (2000), encouraging both the WHO and the CBD Secretariat overseeing the CPB to cooperate in times of emergencies on account of naturally occurring or man-made diseases.

In the event of an unintentional transboundary movement, Article 17(2) of the CPB (2000) requires member states to designate the necessary contact points, normally the relevant government agencies competent to deal with the said issue. The notification

process must be accompanied by documentation indicating the estimated quantities and relevant characteristics or traits of the GMOs in accordance with Article 17(3) (a) (CPB, 2000). This same provision also requires documentation with regard to the possible adverse effects on the conservation and sustainable use of biological diversity, as well as risks to human health (CPB, art. 17(3) (a), 2000).

In the case of bioterrorism, it is also doubtful that customs officers, and marine, police and military personnel will obtain such documentation. This is because smugglers prefer their smuggling activities to remain undetected and would never go through a legal channel that requires official documentation. Otherwise, there is a risk of being tracked down and being caught. Without any documentation detailing the characteristics of a biological agent, this will be an encumbrance to disease diagnosis and treatment. In such an event, however, terrorists would succeed in their aim to cause panic and kill as many victims as possible.

With regard to Article 17(4) of the CPB (2000), consultation is required among affected states due to any unintentional transboundary movement of GMOs. Upon notification, consultation among affected states must take place in a group if it involves more than one state. The consultation process will have to be continuous throughout the whole emergency crisis until the problem at hand is resolved. The consultation process must also determine the appropriate measures to be taken by the affected states, the nature and magnitude of these actions, and the form of emergency measures required. Article 17(4) of the CPB (2000) does not specify the form of emergency measures to be taken; presumably this is left to the discretion of affected states to decide on their own the kind of emergency measures that must be taken.

At the Sixth COP-MOP of the CPB, the Republic of Korea and Japan proposed the setting up of guidelines regarding how to operationalise emergency measures (Lim &

Stabinsky, 2012, p. 5). At this same meeting, other countries, such as Malaysia, Jordan, Uganda and Tunisia, proposed capacity-building initiatives to enlighten member states with the meaning and scope of unintentional transboundary movement and the form of emergency measures needed (Lim & Stabinsky, 2012, p. 5). Therefore, there is a need to further delve into the illegal transboundary movement of GMOs destined for bioterrorism (as it may be an unintentional movement that is not expected to occur within a state's borders), the steps to mitigate this problem, and emergency measures to deal with this menace. This takes into account the fact that these biological agents are more contagious, requiring not only a spontaneous reaction, but also handlers of these agents to fully consider their own security and that of the public, given that diseases may spread fastidiously, wreaking havoc among the general population.

6.4 The Principle of Equity and the Eradication of Poverty within the Cartagena Protocol on Biosafety

The testing or deliberate release of biological agents in biological warfare can also affect the environment and biological diversity, ultimately affecting local communities. This can also be applied in light of Article 26 of the CPB (2000), addressing the socio-economic considerations of GMOs and their impact on the conservation and sustainable use of biological diversity pertaining to indigenous and local communities.

The case involving the testing of genetically modified anthrax for biological warfare on Vozrozhdeniye Island in the former Soviet Union is relevant here (Tucker & Zilinskas, 2002b, p. 1). Economic activities cannot anymore be conducted on this island for fear that the anthrax spores would affect animals and humans (Kozlova, 2007, p. 2). It is apparent that the FAO's form of agricultural biosecurity is of relevance in this context, as the issue at hand concerns the spread of disease to humans and animals caused by anthrax. The communities surrounding Vozrozhdeniye Island, which once used to rely on fishing for their livelihood, can no longer fish as a result of the shrinking of the Aral Sea from a

disastrous irrigation project run by the former Soviet Union (Miller, 1999b). Oil-drilling activities, which could have brought an income to Uzbekistan and Kazakhstan and stirred the economy of local communities within the vicinity of this island, have also been shelved (Miller, 1999b). This is in view of the danger posed to oil drillers as they could be affected by anthrax spores and other biological agents that the former Soviet Union once tested on this island (Miller, 1999b). Since fishing, animal grazing and oil exploration can no longer be conducted on this island, local communities are deprived of an income, thereby affecting their livelihood and further exacerbating their level of poverty. In this regard, the local communities on this island comprise socially disadvantaged groups suffering from the Soviet Union's disastrous legacy of biological weapons testing.

In the above case, intergenerational equity will apply because past generations from the Soviet Union era should not have tested biological agents on this island, which has caused environmental damage for generations to come. The present generation on this island can hardly conduct any economic activities as a result of biological weapons testing during the Soviet era. In the past, the Soviet Union could have utilised genetic engineering on agriculture to better the livelihood of the people on Vozrozhdeniye Island but failed to do so. If the former Soviet Union had disarmed itself much sooner, it would have released its budget allocation, initially channelled for the development of biological weapons, towards the betterment of its people. This would be in line with the Resolution on Relationship between Disarmament and Development that "underlines the importance of reallocating valuable resources released as a result of disarmament for development purposes" ("Thematic", 2001, p. 2). Based on the analysis of the Vozrozhdeniye Island case, it has become apparent that Article 26 of the CPB (2000), covering socio-economic considerations regarding GMOs, can also be applied at present to any similar incident of biological weapons testing gone wrong, partly because the CPB is already in place.

6.5 The Principle of Common but Differentiated Responsibilities in the Cartagena Protocol on Biosafety

The initial negotiations for the compliance mechanism saw developing states wanting to include the principle of common, albeit differentiated, responsibilities under Article 34 of the CPB (2000), which is also entrenched in the Delhi Declaration (ILA, 2002). This was subsequently rejected by developed states (CBD Secretariat, 2002a, p. 2). Common, but differentiated, responsibilities would have made a distinction between the different contributions of developed and developing states concerning the negative repercussions of GMOs. It would also have differentiated these states' capacities to abide by the provisions of the CPB in the area of biosafety. Instead, a compromise language was adopted in Article 34 of the CPB, which paid particular attention to the special needs of developing states and states with their economy in transition, as well as considered the difficulties faced by them in implementing the CPB (Koester, 2009, p. 294). It was noted that the compliance mechanism "should apply and be available in equal measures to all member states" (CBD Secretariat, 2002a, p. 2). Furthermore, developing states would have to be assisted in implementing provisions of the CPB through capacity building and information exchange, as reflected in Article 22 of the CPB (CBD Secretariat, 2002a, p. 2).

This study considers common, but differentiated, responsibilities as relevant in a context where the more affluent states with the technical expertise and technology to detect biological agents for bioterrorism and biological warfare that are party to the CPB should share their knowledge and technological know-how with developing states. For instance, the knowledge and technology needed to detect biological agents intended for bioterrorism, through the use of biosensors, may now be shared with developing member states to the CPB. Developed states can then train developing states' law enforcement officials on how this technology can be effectively used to detect illegal transboundary movement of GMOs destined for bioterrorism. In this way, all member states to the CPB

share a common goal of preventing bioterrorism, which could ultimately lead to environmental contamination, even while remaining differentiated by their capabilities in terms of technical expertise and know-how.

Moreover, developed states possessing knowledge in the use and misuse of genetic engineering can also impart this knowledge to developing states that are less aware on this issue, allowing them to take the appropriate action. This was evident in Minehata's (2010, p. 19) survey, where most states in the Asia-Pacific region seem to have paid scant attention to the issues of arms control and biological weapons, as well as the dual-use dilemma, as evidenced by the university courses being offered. In another 2006 survey conducted in Asia by the Sandia National Laboratories from the US (U.S. Sandia National Laboratories, 2006), it was similarly found that awareness levels and perceived threats among scientists about bioterrorism have been very low, thereby underscoring the level of vulnerability of laboratories and their safeguards. This being the case, the more affluent member states to the CPB, which are knowledgeable about the dangers of genetic engineering being misused, should raise awareness levels and share their knowledge with developing states.

Therefore, common, but differentiated, responsibilities apply, as developed states to the CPB can share their knowledge with developing states as a way to educate and share technical expertise and technology, all in the hope of mutually combating bioterrorism.

6.6 The Principle of the Precautionary Approach to Human Health, Natural Resources and Ecosystems in the Cartagena Protocol on Biosafety

The relevance of the precautionary approach to achieving biosecurity within the CPB is embedded within its preamble, as well as in Article 10(6) and Article 11(8) of this Protocol (CPB, 2000). The precautionary approach found in the preamble of the CPB adopts the wording of Principle 15 of the Rio Declaration on Environment and Development, which asserts that "where there are threats of serious or irreversible

damage, lack of scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environment degradation" (Sirinskiene, 2009, p. 351). In Article 10(6) and Article 11(8) of the CPB (2000), the precautionary approach is reflected in the context of GMOs being released into the environment and those intended for food, feed and processing.[8]

It is asserted that the invocation of the precautionary approach in the CPB should also be interpreted within the context of biological warfare. This is because the danger posed to human health and biological diversity can be more severe in view of the fact that genetically modified biological agents for biological warfare can cause much more harm to the environment. The former Soviet Union should have undertaken a scientific risk assessment as a precautionary approach in order to gauge the impact of genetically modified anthrax on the biological diversity of Vozrozhdeniye Island before testing it. This would have been necessary in order to ensure that, in the long term, the island would have been habitable for future generations, while the soil remained fertile and suitable for the grazing of animals. Hence, as long as research institutions and universities, whether for civilian or military purposes, conduct any genetic modification activity, a risk assessment must be made mandatory to avoid the dismal situation of Vozrozhdeniye Island, not to mention that, as the CPB is already in force, compliance from among signatory member states is required.

Likewise, a precautionary approach is also relevant in terms of making an assessment of the likelihood that bioterrorism could occur; hence, a risk assessment would be required. Zilinskas, Hope and North (2004, p. 903) have highlighted the difficulty of conducting a risk assessment for bioterrorism because it is hard to gauge a terrorist

[8] Article 11(8) of the CPB mentions: "[A] lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the member state of import, taking also into account risks to human health, shall not prevent that member state from taking a decision."

group's technical capability in terms of acquiring and deploying a biological weapon, as well as the target population or facility to be attacked. It is equally tough to assess the quantity of biological agents and toxins used, not to mention the form of deployment, whether aerosolised, foodborne or through water contamination. Therefore, there is reliance on espionage to obtain reliable information that will enable an analyst to identify the hazard, estimate exposure and calculate the dose response for antibiotics or vaccine needed in preparation for a bioterrorist attack. Information gathered will also enable the analyst to calculate the likely number of casualties within a target population. Hence, there is a need for governmental authorities in charge of GMOs in any state to work together with the police and espionage teams to obtain as much reliable information as possible, which would allow for conducting a risk assessment about the probability of a bioterrorist attack.

As a point of illustration, the US Court of Appeals for the Ninth Circuit in *Tri-Valley Cares v. United States Department of Energy (DOE)* (2012, p. 20) (hereinafter *Tri-Valley Cares*) asserted that it was not necessary for the DOE to consider every likely form of a terrorist attack on a Biosafety Level-3 (BSL-3) laboratory to be built by the Lawrence Livermore National Laboratory in California, US. In this case, the DOE was requested by the US Court of Appeals for the Ninth Circuit to consider the impact of a terrorist attack on the BSL-3 laboratory to be built because its submitted environmental assessment (EA) lacked such an assessment (*Tri-Valley Cares*, 2012, p. 19). The DOE resorted to using a simulation hypothetical model regarding the terrorist attack on the BSL-3 laboratory, as it reasoned that any terrorist attack, either by an airplane crash or by suicide bombing, would be the equivalent of a catastrophic event, such as an earthquake, affecting the laboratory (*Tri-Valley Cares*, 2012, pp. 22-23). Tri-Valley Cares disagreed with the DOE's simulation of a terrorist attack, which relied upon the US Army's centrifuge model to measure the environmental impact of a terrorist attack, and then referred to the National

Research Council (NRC) of the National Academy of Sciences report, which alleged the incapability and inadequacy of the centrifuge model as a way to discredit the DOE (*Tri-Valley Cares*, 2012, p. 37).

Based on the elaboration made above, it is not so straightforward to conduct an accurate risk assessment to project the environmental consequences of a terrorist attack, as there are many scenarios of terrorist attack. Therefore, while the precautionary approach may be relevant as a preventive measure to prevent bioterrorism by conducting a risk assessment, in reality this is tough for the reasons already discussed.

6.7 The Principle of Public Participation and Access to Information and Justice in the Cartagena Protocol on Biosafety

This section will investigate and analyse Article 23 of the CPB (2000), which addresses public awareness and participation, and whether they can be utilised to create an awareness about the misuse of genetic engineering for biological warfare and bioterrorism. Rhodes (2004, p. 3) has aptly pointed out that awareness concerning the impact of applying modern biotechnology is high, but only skewed towards the effects that arise from the genetic modification of crops, food and those involving human genetics. This implies that public awareness regarding the misuse of genetic engineering has been given a low priority as compared to the use of this technology for agriculture and human genetics in medicine. At the Meeting of Experts for the Biological Weapons Convention (BWC) in August 2008, Pearson (2009, p. 4), a biological weapons expert, highlighted that the BWC, the WHO's biosafety and biosecurity programme, and the CPB are all working towards a similar goal of creating public awareness on their own turf of work. Therefore, Pearson (2009, p. 4) calls for collaboration among the three international instruments, as he foresees "significant benefits in all three activities working together on awareness raising and education".

As it stands, public awareness and participation initiatives under the National Biosafety Framework (NBF), funded by the UN Environment Programme's (UNEP) Global Environmental Facility (GEF) project, have been biased towards emphasising the importance of food safety, labelling and the impact of GMOs on the environment (UNEP, 2005, p. 48). Regrettably, the focus has not been on the misuse of genetic engineering for malicious intent, which can similarly cause harm to the environment (UNEP, 2005, p. 48). By creating awareness about bioterrorism among the public, they will be able to notify the relevant authorities of any suspicious conduct among individuals acquiring biological agents for the said purpose, before it leads to the destruction of the environment and harm to human health. Therefore, there are benefits in educating the public about the dark side of genetic engineering.

Indeed, the European Union (EU), in one of its documents entitled *Inventory of EU Instruments Relevant for Addressing Chemical, Biological, Radiological and Nuclear Risks* (henceforth *CBRN Inventory*) (Council of the European Union (COE), 2008, pp. 53-58), highlighted the importance of the Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters (hereinafter Aarhus Convention) in enabling the public to have access to information held by public authorities, thereby allowing them to take the necessary emergency actions in terms of an attack using biological weapons. A subsequent document issued by the EU, known as Strengthening Chemical, Biological, Radiological and Nuclear Security in the European Union - An EU CBRN Action Plan (European Parliament, 2012, p. 15), has explained the reason for the EU's emphasis on public awareness and participation as per the Aarhus Convention in the context of fighting terrorism. The above document "[e]mphasises that the fight against terrorism must be conducted with full respect for […] the principles of the Aarhus Convention on public access to information, participation

and judicial review in matters relating to the environment" (European Parliament, 2012, p. 15).

Taking its cue from the EU's example, Article 23 of the CPB (2000) on public participation and access to information also advocates a similar strategy in the context of bioterrorism. By linking Article 23 of the CPB (2000) on public participation and access to information on bioterrorism, this also conforms to the principle of good governance as defined in the Delhi Declaration (ILA, 2002). This is because public participation permits people at large to voice their views, thereby promoting transparency and accountability as the norm in democratic institutions (ILA, 2002). In one of its documents, the Office of the UN High Commissioner for Human Rights (OHCHR) confirmed that the promotion of good governance is "the exercise of authority through political and institutional processes that are transparent and accountable, and encourage public participation" (OHCHR, 2007, p. 2). Similarly, the UN Development Programme (UNDP), in its elaboration on good governance, has mentioned that "among other things, [good governance is] participatory, transparent and accountable" (OHCHR, 2007, p. 3). In the fight against terrorism, the 2003 Ulaanbaatar Declaration on Democracy, Good Governance and Civil Society ("Support", 2003, p. 5) emphasised the need for the masses to be heard, as it is imperative that "[a] democratic society is an inclusive and participatory society". Therefore, public participation and awareness should not only be confined to the positive contribution of genetic engineering for agriculture, industrial uses and medicine, but must also be extended to the area of bioterrorism, as discussed earlier.

6.8 The Principle of Good Governance in the Cartagena Protocol on Biosafety

6.8.1 Compliance of Biosafety Laws

One of the indicators showing that the CPB complies with good governance is Article 34 regarding its compliance mechanism (CPB, 2000). As elaborated by Chowdhury and

Skarstedt (2005, p. 15), "compliance procedures and mechanisms within the Multilateral Environmental Accords […] represent crucial mechanisms for which transparency is ensured in fulfilment of the obligations of member states". The Second Intergovernmental Committee for the CPB also underlined that the compliance mechanism of the CPB should be based on the principles of expeditiousness, fairness, transparency, predictability and due process, all of which are elements of good governance (CBD Secretariat, 2001a, p. 7). Moreover, Decision BS-1/7 indicated that the compliance mechanism must be simple, facilitative, non-adversarial and cooperative in nature (Ragni, 2009, p. 105).

The Compliance Committee can receive complaints by any member state to the CPB, but not Non-Governmental Organisations (NGOs) (CBD Secretariat, 2004b, p. 3; Ragni, 2009, p. 110). The Compliance Committee can also decide whether a member state to the CPB has complied with its obligations by accessing the BCH, as provided by Article 20, in terms of the laws, regulations and other administrative actions listed by a member state, which will also provide clues as to whether it has fulfilled its obligations (CPB, 2000).

6.8.2 Compliance as Verification Measures in Contained Facilities

While the CPB has a compliance mechanism, this does not include a verification procedure requiring on-site visits by experts to verify whether an intended use of GMOs for release into the environment for purposes of agriculture or contained use is indeed being used for such an intention. It is crucial to have a physical verification procedure to ensure that biological agents imported and used within a contained facility are not channelled towards bioterrorism or biological warfare. Lacking any verification mechanism, this will make it easy for terrorists and rogue states, whose intent is to create biological weapons, to exploit such a loophole within the CPB.

Article 6(2), covering contained use and which permits member states to set standards for contained use within their jurisdiction, can provide the option of incorporating a

physical verification mechanism (CPB, 2000). Since most states are members to the CPB and could thus form IBCs at the national level among research institutions and universities, experts on biological weapons may be incorporated as part of the IBCs. The involvement of biological weapons experts relates to the fact that they have a trained eye to verify whether self-styled innocent research on GMOs is as intended or could lead to the development of a biological weapon.

For this reason, there is a need for the CPB to work closely with the WHO in order to utilise the latter's expertise and knowledge on laboratory biosecurity, which can help enlighten member states regarding security measures to prevent GMOs in contained facilities from being lost, stolen or misused for bioterrorism or biological warfare purposes. This is because the CPB itself is inadequate in terms of its capacity to address laboratory biosecurity among contained facilities, often leaving the matter to domestic measures undertaken by member states when it comes to the precise action to be taken. This will also fulfil the principle of integration in the Delhi Declaration (ILA, 2002), which brings together the CPB and the WHO in the areas of the environment and health.

6.8.3 A Liability and Redress System Meets Good Governance

The liability and redress system under Article 27 of the CPB (2000) promotes accountability in order to ensure that states and private actors, be they Multinational Corporations (MNCs) or NGOs, are accountable for any decisions and actions they take pertaining to GMOs. Moreover, Article 27 of the CPB has now been elaborated as the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety (hereinafter Nagoya-Kuala Lumpur Supplementary Protocol), adopted in October 2010 (CBD Secretariat, 2010b). Briefly, this Nagoya-Kuala Lumpur Supplementary Protocol provides for the operator or the relevant public authority among member states to the CPB to take the necessary measures to prevent further

damage to biological diversity and human health (CBD Secretariat, 2010b). This Protocol also states that the operator responsible for the transboundary movement of GMOs will also be held responsible for any compensation in the event of GMOs causing harm to biological diversity (Nagoya-Kuala Lumpur Supplementary Protocol, art. 5(5), 2010). If the operator is unable to fully honour the compensation, then the member state of origin wherefrom the GMO originates will have to supplement the payment of compensation.

Notably, there are exemptions from compensation in the case of *force majeure,* that is, circumstances or events beyond the control of a member state to the CPB that cause damage to the environment and biological diversity, as addressed in Article 6 of the Nagoya-Kuala Lumpur Supplementary Protocol (2010). Article 6(2) of this Protocol (2010) permits a member state to provide, within its domestic law, any other exemptions deemed necessary, apart from acts of god, *force majeure* or civil unrest as already mentioned in Article 6(1). During the negotiations of the Nagoya-Kuala Lumpur Supplementary Protocol, member states to the CPB, such as the Republic of Palau and Romania, expressed concern that terrorist attacks were beyond the control of the operator or a member state to the CPB, and should thus be exempted from reparation or payment of compensation (CBD Secretariat, 2004a, pp. 44-49). Therefore, in the case of a terrorist attack, a member state to the CPB can apply an exemption in its relevant environmental domestic law in line with the present Article 6(2) of the Nagoya-Kuala Lumpur Supplementary Protocol (2010) (CBD Secretariat, 2004a, pp. 44-49). This is consistent with the general rules of customary international law concerning states' responsibility, whereby a state will not be accountable for the wrongdoings of its private actors including terrorists (CBD Secretariat, 2012b, p. 3; "Responsibility of States for Internationally Wrongful Acts", 2002).

Nevertheless, a member state to the CPB is not totally exonerated from its responsibility to ensure that it provides the necessary laws and administrative actions to

prevent, deal with and punish terrorists. Failure to do so implies that a member state to the CPB can "be in breach of an obligation if it fails to take the necessary measures to prevent the effects of private actors [i.e., terrorists]" (CBD Secretariat, 2012b, p. 3).

Using state responsibility as a guidance, the question may be raised as to whether a member state to the CPB should be held responsible for preventing terrorists from acquiring any biological agents illegally through a black market that trespasses its territory. In *Military and Paramilitary Activities in and against Nicaragua (Nicara. v. U. S.)* (1986, p. 69) (hereinafter *Military and Paramilitary Activities*), the ICJ considered the fact that President Ortega (Nicaragua's president at the time) had offered to stop the illegal flow of arms from rebels within its territory to El Salvador in a meeting on 12 August 1981. It was provided that the US would supply covert information on the rebels, which the US had declined following its accusation that Nicaragua supported and supplied arms to its rebels to bring down the El Salvadorian government (*Military and Paramilitary Activities*, 1986, p. 69). The ICJ recognised Nicaragua's goodwill in its overture to stem the flow of illegal arms from its rebels into El Salvador, stating that: "evidence has been provided, in the report of the meeting on 12 August 1981 […] of a degree of cooperation between the [US] and Nicaragua for the purpose of putting a stop to these arm deliveries" (*Military and Paramilitary Activities*, 1986, p. 74). The ICJ went further in asserting that Nicaragua was not at fault in trying to prevent the illegal flow of arms from its rebels, while the US was uncooperative in providing the necessary information (*Military and Paramilitary Activities*, 1986, p. 74). The ICJ also considered "the four draft treaties submitted by Nicaragua within the Contodora process in 1983" as part of the effort to stop the illegal flow of arms in the future among countries involved within the inter-American regional system (*Military and Paramilitary Activities*, 1986, p. 76). This shows the emphasis placed by the ICJ upon a state's responsibility to make constructive efforts

to stop the activities of rebels (also regarded as terrorists by some) in illegally supplying arms to their counterparts in another state, in this case, El Salvador.

By the same token, if a member state to the CPB fails to prevent its territory from being used as a black market and trespassed by terrorists to acquire biological agents, it can be held responsible for its failure to have taken the necessary steps to prevent these illegal activities in terms of putting the necessary laws into place or taking administrative actions. The International Law Commission (ILC) once asserted that "a state may be responsible for the effects of the conduct of private member states, if it failed to take necessary measures to prevent those effects" (United Nations General Assembly [UNGA], 2001a, p. 39). From the precedent case of Nicaragua discussed above, a member state to the CPB is not precluded from enacting the relevant laws and taking the necessary administrative actions as part of state responsibility to stop its territory from being used as a base for terrorists, who would illegally procure biological agents for bioterrorism. Although the Nagoya-Kuala Lumpur Supplementary Protocol has been designed to largely hold the operator causing damage responsible, including in terms of paying compensation, should a member state not accept such responsibility, it will be held responsible for any internationally wrongful acts under Article 11 of this Protocol (Nagoya-Kuala Lumpur Supplementary Protocol, 2010).

6.9 The Principle of Integration within the Cartagena Protocol on Biosafety

This section will analyse how the principle of integration in the Delhi Declaration of ISDL (ILA, 2002) within the CPB can be utilised to link with the BWC and the WHO's IHR 2005, laboratory biosecurity and biopharming initiatives. While it is construed that the CPB itself mainly refers to genetic engineering for peaceful purposes, it does not explicitly mention the exclusion of this technology in biological warfare or bioterrorism per se as long as its impact affects biological diversity and human health. Notably, at the Fifth Meeting of the Intergovernmental Committee for the CPB (CBD Secretariat,

2001b), one delegation expressed its concern that biological warfare went beyond the realm of the CPB because it was only Ethiopia and Ecuador that were bringing this issue within the CPB's ambit.

This study contends that the CPB should be applied to both biological warfare and bioterrorism. The ICJ, in its advisory opinion in *Nuclear Weapons* (1996, p. 226), determined that cited environmental instruments, such as the Convention on the Prohibition of Military or Any Other Hostile Use of Environmental Modification (hereinafter ENMOD Convention), Principle 21 of the Stockholm Declaration and Principle 2 of the Rio Declaration, would "apply at all times, in war as well as in peace". This was despite the fact that other states challenged these environmental instruments' applicability in times of peace (*Nuclear Weapons*, 1996, p. 226). The ICJ further asserted that "[s]tates must take environmental considerations into account when assessing what is necessary and proportionate in the pursuit of legitimate military objectives", so as not to destroy the environment randomly during war (*Nuclear Weapons*, 1996, p. 226). Subsequently, the ICJ referred to Principle 24 of the Rio Declaration, which states that warfare is destructive to sustainable development, while all states must respect international law and provide protection for the environment (*Nuclear Weapons*, 1996, p. 226). It cannot be made plainer in the ICJ's verdict that environmental law instruments would apply at all times, which likewise applies to the CPB in terms of biological warfare and bioterrorism.

The idea of viewing the CPB as an instrument capable of addressing the impact of biological warfare and bioterrorism, along with averting the hostile use of genetic engineering, given its connection to the BWC, was raised by one NGO, namely, the Sunshine Project, at the Third Intergovernmental Committee for the CPB (ICCPB) in April 2002 (CBD Secretariat, 2002b, p. 28). At the First Meeting of the ICCPB in December 2000, Ecuador (backed by Ethiopia) raised its concern about the use of

genetically modified illicit crops for biological warfare in countries growing such crops, thereby requiring the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) of the CBD to address the said matter (CBD Secretariat, 2001, p. 16). While this proposal essentially wanted to highlight the misuse of GMOs as illicit crops for biological warfare, another delegation rebutted it for the reason that the BWC was the best instrument to address the said issue and not the CPB (CBD Secretariat, 2001, p. 16).

Apart from the above, scholars such as Anuradha (1999, pp. 125-134), Mauro (2000, pp. 119-122), and Parker and Pate (2005, pp. 166-173) have, in passing, all called for an examination of the synergistic relationship between the CPB and BWC, as well as highlighted some virtues and lessons from the CPB, which could act as a point of reference for the BWC. While the CPB merely addresses GMOs in how they affect the environment and biological diversity, this agreement has the capacity to acknowledge biological warfare, provided there is mutual cooperation between international organisations or agencies of the UN, which address the said matter.

Indeed, the principle of integration in the Delhi Declaration of ISDL (ILA, 2002) provides the means for the CPB to consider other areas beyond its scope, instead of being purely an international environmental law agreement. Jodoin (2005, p. 29), for instance, viewed the CPB as being an integrative international environmental agreement when examining Article 26 of the CPB (2000), which addresses the socio-economic considerations of GMOs, as well as found that it also covers social and economic matters affecting indigenous and local communities as a result of introducing GMOs in agriculture. An examination of the CPB's preamble indicates that it is highly integrative with the international trade regime because of "[r]ecognising that trade and environment agreements should be mutually supportive with the view to achieving sustainable development" (CPB, 2000). Article 2(4) of the CPB (2000) reaffirms a member state's right "to take action that is more protective of the conservation and sustainable use of

biological diversity than that called for in this Protocol", provided that it is "in accordance with the member state's other obligations under international law". This provision requires a member state to the CPB to mainly consider its international obligations under the World Trade Organisation (WTO), especially in barring GMOs for agriculture. Regarding Article 2(5) of the CPB (2000), this provision requires a member state to the CPB to consider the "expertise, instruments and work undertaken in international forums with competence in the area of risks to human health". The history of the CPB indicates that the reference to health has become an important issue in terms of the labelling of GMO foods, which refers to the Codex Alimentarius standard under the auspices of the WHO (MacKenzie et al., 2003, p. 22).

In this regard, Article 2(5) of the CPB (2000) is a catalyst for including other WHO initiatives, such as the Biorisk Management: Laboratory Biosecurity Guidance and Responsible Life Sciences Research for Global Health Security (WHO, 2006, 2010), which emphasises the importance of laboratory biosecurity to complement the CPB's contained use provision in Article 6(2). Similarly, Article 2(5) of the CPB (2000), which requires consideration to be given to other international organisations' work, is the impetus for the CPB's consideration of the WHO's IHR 2005 and biopharming guidelines, which assist the CPB in approaching biosecurity in a wholesome manner. Further elaboration on the IHR 2005, as the WHO's laboratory biosecurity and biopharming guidelines, will be made in Chapter 8, as this chapter exclusively focuses on the CPB. Besides, Article 4 of the CPB (2000) also indicates that this Protocol is not exclusively focused on the environment, but includes health aspects as well.

The case of Article 5 in the CPB (2000), covering pharmaceuticals, which emphasises that pharmaceuticals for humans are not covered under the CPB, is a similar matter. Pharmaceuticals are not subjected to the AIA in Article 7 of the CPB (2000), which merely applies to GMOs that are released into the environment. Article 5 of the CPB

(2000) implies that pharmaceuticals for humans will be addressed by other relevant international agreements or organisations that refer to the WHO's monitoring of pharmaceuticals. Despite this constraint in Article 5 of the CPB (2000), this does not totally preclude a member state from subjecting it to a risk assessment process because of the following wording in the provision: "without prejudice to any right of a member state to subject all living modified organisms to risk assessment prior to the making of decisions of import". If a member state subjects pharmaceuticals to a risk assessment, Annex III of the CPB will become relevant, as it is intended to "evaluate the potential adverse effects of living modified organisms on the conservation and sustainable use of biological diversity in the likely […] receiving environment, taking […] into account risks to human health" (CPB annex III, 2000). The importing member state under paragraph 8(f) of Annex III in the CPB may also request additional information if it is uncertain about the level of risk involved, as well as possibly subject it to a stringent risk management process or monitor the GMOs that are released into the environment (CPB annex III, 2000). Thus, to address the pharmaceuticals for humans, the CPB needs to refer to the relevant WHO initiatives. Therefore, the principle of integration would certainly be relevant to Article 5 of the CPB in enabling this Protocol to work closely with the WHO.

It can also be assumed that Article 29(8) of the CPB (2000), which will enable the CPB to form linkages with other international organisations, permits invitees from the UN's specialised agencies and the International Atomic Energy Agency (IAEA). This same provision also allows any agency at the national, international, governmental or non-governmental level, which is qualified in matters related to the CPB, to be represented at the said meeting (CPB, art. 29(8), 2000). This is a catalyst for facilitating mutual cooperation between the CPB and other international organisations that may also share an interest in GMOs within their scope of specialisation, while being equally

interested in the ongoing issues within the CPB. Therefore, it is clear that the CPB can work closely with other international organisations, such as the WHO, the Implementation Support Unit (ISU) of the BWC and other UN agencies dealing with bioterrorism, since Article 29(8) (CPB, 2000) can facilitate the necessary conditions. This leaves one option for the CBD Secretariat (if agreed to by member states to the CPB) to invite these relevant organisations as observers to the CPB's meetings. While being an observer is the first step, member states to the CPB can decide to take it further by forming a closer alliance with these other international organisations and UN agencies that address other forms of biosecurity, thereby complementing the CPB's work.

Likewise, Article 22(1) of the CPB (2000) addresses capacity building to strengthen human resource and institutional capacity in biosafety among member states, which permits cooperation with other global, regional, sub-regional and national organisations in the area of biosecurity. Therefore, it is only a matter of political will as to whether member states to the CPB are willing to utilise this Protocol to build linkages with other international agreements and initiatives on biosecurity, given that its provisions are highly integrative.

Moreover, this study asserts that Resolution 1540 of the UN Security Council (UNSC) (United Nations Office on Drugs and Crime [UNODC], 2009), which covers export controls on the trade of biological agents and equipment from getting into the hands of non-state actors, is also relevant to the CPB. This Resolution (S.C. Res. 1540, 2004), by virtue of its connection to Chapter VII of the UN Charter, is binding upon member states because Article 25 of the UN Charter requires member states to carry out the decisions of the Security Council in its effort to restore international peace and security (UNODC, 2009, p. 14). In line with the view that biological agents being imported under the CPB could be diverted for malevolent intentions, such as bioterrorism, the CPB's preamble, which refers to trade (CPB, 2000), should also refer to Resolution 1540, since the latter

seeks to keep biological agents away from the clutches of terrorists. It must be noted that Resolution 1540 (S.C. Res. 1540, 2004) came into being because the BWC merely addressed biological warfare among states, rather than bioterrorism among non-state actors. As discussed earlier, since Article 29(8) of the CPB (2000) permits an observer to attend the Conference of the Parties' Meeting of the Parties (COP-MOP) to the CPB, it is crucial for the CPB to coordinate its efforts with the Resolution 1540 Committee, given that GMOs can be diverted from its noble intention to a malevolent one. Through mutual understanding with the Resolution 1540 Committee, this will impart the notion among CPB member states that GMOs do have the potential to be misused for bioterrorism.

Based on the analysis of the principle of integration within the CPB, it is quite clear that its provisions are not solely concentrated on the environment, but also acknowledge other areas of trade and health. There are other provisions that permit the CPB to work closely with other international organisations. In this way, the CPB can work closely with the ISU of the BWC and UNSC 1540 Committee if it chooses to. Preventing the CPB from discussing other biosecurity issues, such as biological warfare, is the prerogative of the member states themselves, who may not permit the CPB forum to discuss other matters that lie beyond its scope. This signifies that the sectorial approach is still prevalent within the CPB forum. This can prevent an integrated approach, which envisions biosecurity international agreements, including that of the CPB, to build mutually cooperative relationships with other international organisations that are administrators of other biosecurity international instruments.

In summary, the results of the analysis regarding the reflection of ISDL principles among provisions of the CPB and its accompanying soft law documents are displayed in Table 6.1, based on all of the elaborations made previously in this chapter.

Table 6.1: Reflection of International Sustainable Development Law Principles among the Cartagena Protocol on Biosafety Provisions and Soft Law Documents

2002 New Delhi Declaration	**Relevant CPB provisions/soft law documents to the CPB**
The duty of states to ensure sustainable use of natural resources	• Reflected in Article 25 on the illegal transboundary movement of GMOs, as well as Article 6(1) and Article 6(2) on GMOs in transit and in a contained facility for biopharming, this duty assumes state responsibility when a state fails to take preventive measures, that is, adequate laws and enforcement mechanisms to prevent smuggling of biological agents or conspiracy among terrorists across state borders in the pursuit of access to a biopharming substance for acts of bioterrorism in order to cause environmental contamination.
The principle of equity and the eradication of poverty	• Reflected in Article 26 on the socio-economic considerations of GMOs when indigenous people are deprived of their livelihood (fishing activity) and oil exploration from the effects of testing biological weapons, as in the case of the former Soviet Union (Vozrozhdeniye Island on the Aral Sea).
The principle of common, but differentiated, responsibilities	• Reflected in Article 22 on capacity building, whereby developed states transfer technological knowledge (usage of biosensors), as well as provide education and training, to developing states to prevent bioterrorism, which could cause environmental contamination.
The principle of the precautionary approach to human health, natural resources and ecosystems	• Reflected in the preamble, Article 10(6) and Article 11(8) of the CPB, this principle should also be invoked before prior testing of biological weapons for biowarfare to prevent environmental contamination, along with carrying out a risk assessment to gauge the likelihood of bioterrorism.
The principle of public participation and access to information and justice	• Reflected in Article 23(1) (b), this principle can apply to education and public awareness on the misuse of genetic engineering for bioterrorism, so that the public will be encouraged to alert the authorities of any misuse.
The principle of good governance	• Reflected in Article 27 on liability and redress regarding state responsibility to prevent bioterrorism occurring in another state and Article 34 concerning compliance with the CPB.
The principle of integration	• Reflected in Articles 1 and 4 (human health), Article 2(5) (expertise and instruments of other international forums in the area of human health), Article 5 (pharmaceuticals for humans), Article 22(1) (capacity building), Article 29(4) (services of other international and intergovernmental organisations), and the preamble (covers trade and environment and sustainable development) of the CPB.

6.10 Conclusion

From among the relevant provisions of the CPB, this chapter has analysed a reflection on the seven principles of international law from the Delhi Declaration of ISDL. Since the CPB is primarily an agricultural biosecurity and international environmental agreement covering GMOs, the findings indicate there was nothing unusual about the fact that the CPB would conform to all of the principles of ISDL because ISDL, as indicated in Chapter 5, naturally covers international environmental law. The difference here is that the CPB was analysed within a bioterrorism and biological warfare context in light of the seven principles of ISDL, about which there exists a sparse amount of literature. The implications from the findings of this chapter is that the CPB should not be viewed exclusively as an international environmental law agreement that is merely applicable during peacetime activities involving agriculture, but one that can also be located in the context of bioterrorism and biological warfare, which similarly have environmental repercussions if this involves GMOs. Notably, the CPB is about the only international environmental law agreement to refer to the impacts of GMOs on the environment, on the basis that, to the best of knowledge, there are no other exclusive international instruments or non-binding initiatives that are strictly focused on GMOs, meaning that the CPB must be relied upon in both peacetime and warfare circumstances.

While the CPB has provisions to form mutual cooperation between the ISU of the BWC, the Resolution 1540 Committee and the WHO through the principle of integration, the work of the BWC and WHO will be examined in Chapters 7 and 8, respectively, with a view to determining how they can complement the CPB in addressing the biosecurity of biotechnology, laboratory biosecurity and biopharming in a holistic manner.

CHAPTER 7: THE BIOLOGICAL WEAPONS CONVENTION AND INTERNATIONAL SUSTAINABLE DEVELOPMENT LAW

7.1 Introduction

In this chapter, the task being set forth is to analyse the principles of the New Delhi Declaration of Principles of International Law Relating to Sustainable Development (hereinafter Delhi Declaration; International Law Association [ILA], 2002) in terms of the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction (hereinafter Biological Weapons Convention [BWC], 1972), thus fulfilling the third objective of this study. The analysis of the BWC in this regard is only applicable during peacetime activities, such as testing biological weapons and disarmament, and will not refer to international humanitarian law.

The analysis of the principles from the Delhi Declaration in terms of the BWC provisions (wherever applicable) will be structured as follows. It will begin with the principle of the duty of the states that ensures the sustainable use of natural resources, the principle of equity and the eradication of poverty, and the principle of common but differentiated responsibilities. This continues with the principle of the precautionary approach to human health, natural resources and the ecosystem, the principle of public participation and access to information and justice, the principle of good governance, and finally the principle of integration.

7.2 The Duty of the States to Ensure the Sustainable Use of Natural Resources as It Relates to the Biological Weapons Convention

In this section, the relevance of the above principle in its application within the BWC will be illustrated using a few examples of biological weapons testing and disarmament that have taken place across the states that became victims of biological weapons. It must be noted that the discussion in this section is not meant to cover all known examples of

biological weapons testing. Therefore, the first example chosen will be the Vozrohdeniye Island in the former Soviet Union, followed by China and the Republic of Panama.

7.2.1 The Case of the Vozrozhdeniye Island, former Soviet Union

One of the best known biological weapons test site of the former Soviet Union operated from 1936-1992 on Vozrozhdeniye Island in the western part of the Aral Sea (Atshabar, 2003, p. 79; Tucker & Zilinskas, 2002a, p. 8). In 1954, a large complex facility for testing biological weapons and defensive equipment known as Aralsk-7 was built by the Soviets on this island (Atshabar, 2003, p. 79; Tucker & Zilinskas, 2002a, p. 8). Microbial pathogens that were tested on this island included plague, anthrax, Q-fever, small pox, tularaemia, Venezuelan Equine Encephalitis (VEE), brucellosis, typhus and botulinum toxin (Atshabar, 2003, p. 79; Tucker & Zilinskas, 2002a, p. 8). Some of these biological agents were genetically modified in order to make them more potent and resistant to existing medications, complicating diagnosis and treatment and were tested in aerosolised form (Atshabar, 2003, p. 79; Tucker & Zilinskas, 2002a, p. 9). As the Soviet Union had signed the BWC on 10 April, 1972 and ratified it in 1975, Moscow had an obligation to comply with the provisions of this agreement (Tucker & Zilinskas, 2002a, p. 9). An accidental release of anthrax in 1979 at Sverdlovsk, in the Soviet Union, had triggered the suspicion of Western states that the former was developing and testing biological weapons (Tucker & Zilinskas, 2002a, p. 10).

Facing suspicion that the Soviet Union was indeed developing biological weapons, in 1988 Mikhail Gorbachev issued a directive to transport the hundreds of tons of anthrax bacteria (poured with bleach) to Vozrozhdeniye Island to be buried (Miller, 1999a, p. 1). On 18 January 1992, an edict ("On Urgent Measures for Radically Improving the Living Conditions of Aral Area Residents") was issued by the Supreme Soviet of the newly independent Kazakhstan, requiring all offensive biological weapons programmes to be

closed down (Miller, 1999a, p. 1). Subsequently, the biological weapons testing site located on Vozrozhdeniye Island was shut down and set to become part of Kazakhstan and Uzbekistan's territory.

However, the large quantities of anthrax that were hastily buried on Vozrozhdeniye Island survived the bleach treatment ("Anthrax", 1999, p. 1). These anthrax spores could be grown into a culture in order to form live anthrax bacteria ("Anthrax", 1999, p. 1). Uzbekistan and Kazakhstan, which inherited Vozrozhdeniye Island, then signed an agreement with the United States (US) on 22 October 2001 as part of the Cooperative Threat Reduction (CTR) initiative, with the US pledging US$ 6 million to destroy the remaining anthrax spores and to dismantle the biological weapons laboratory complex (James Martin Centre for Nonproliferation Studies, 2002, p. 1).

Of interest to this study is the relevance of analysing the Vozrozhdeniye Island case in its association with the duty of the states to ensure the sustainable use of natural resources and not to pollute the environment of other states. A lesson can be drawn from the case in *Memorial of the Republic of Nauru, Certain Phosphate Lands in Nauru (Nauru v. Austral.)* (1990, p. 178)[1] (hereinafter *Memorial of the Republic of Nauru*), whereby in its memorial against Australia, Nauru had invoked the principle of permanent sovereignty over natural resources based on the General Assembly Resolution 1803 (XVII) (G.A. Res. 1803, 1962) that contained the said principle. Nauru was once under the then United Nations (UN) Trusteeship Council governance, with Australia, New Zealand and the United Kingdom (UK) acting as overseers of its territory (*Memorial of the Republic of Nauru*, 1990, p. 236). The said principle was invoked because "a major resource [phosphorous] was being depleted on grossly inequitable terms but the extraction of the

[1] Refer to page 155 of the *Memorial of the Republic of Nauru too.*

resource necessarily involved the physical reduction of the homeland" (*Memorial of the Republic of Nauru*, 1990, p. 156).

While this case was filed by Nauru at the International Court of Justice (ICJ) long after its independence in 1968, this state never relinquished its claim against Australia (*Certain Phosphate Lands in Nauru (Preliminary Objections)*, 1992, p. 259). Nauru highlighted the breach of duties of a caretaker state, in this case Australia, and stated that "it is a general principle of international law that a state which is responsible for the administration of territory is under an obligation not to bring about changes in the condition of the territory which will cause irreparable harm to, or substantially prejudice, the existing or contingent legal interest of another state in respect of that territory" (*Memorial of the Republic of Nauru*, 1990, p. 167). Nauru indicated the manner in which a predecessor state would be responsible for its actions, namely, in circumstances when "a state which has agreed to cede territory to another not to derogate from the grant by substantially and materially damaging or injuring the territory in question, and to transfer public property located in or properly attributable to the successor state to it without payment" (*Memorial of the Republic of Nauru*, 1990, p. 168).

Nauru also referred to Article 13 of the Vienna Convention on Succession of States in Respect of State Property, Archives and Debts (VCSPAD, 1983) regarding the responsibility of the predecessor state not to cause undue damage to a territory it controls before the handing over to the successor state (*Memorial of the Republic of Nauru*, 1990, p. 168). While this Vienna Convention is yet to come into force and there are not many parties to it, one guideline issued by the Justitia et Pace Institut de Droit International (2001, p. 6) on State Succession in Matters of Property and Debts in Article 18 regarding the preservation of state property stresses the need to "take all measures necessary to prevent damage to, or the destruction of, property which passes, or may pass to another State". Based on this, Nauru asserted that it had a strong case against Australia because

"of a principle of law which requires a state not to use its own territory in such a way as to cause substantial harm to a successor [highly relevant in the case of Nauru] under the regime of trusteeship" (*Memorial of the Republic of Nauru*, 1990, p. 171). This dispute between Nauru and Australia did not reach the merits case as both parties reached an agreement whereby Australia agreed on an ex gratia payment to Nauru with both contenders agreeing to discontinue proceedings with the ICJ (Institut de Droit International, 2013, pp. 35-36).

On the basis of *Certain Phosphate Lands in Nauru*, Kazakhstan and Uzbekistan do have the option to bring a case against Russia for not fully clearing the contaminated land following the testing of biological weapons that took place on Vozrozhdeniye Island. Although *Certain Phosphate Lands in Nauru* involves a trusteeship council case and is not exactly similar to a case between a predecessor and successor state, there are lessons to be drawn for both Kazakhstan and Uzbekistan. Russia was the predecessor state that reneged on its promise to fully decontaminate Vozrozhdeniye Island prior to passing this island on to Kazakhstan and Uzbekistan. If a predecessor state has to ensure that a territory ceded to successor states is not damaged from environmental contamination, then Russia would definitely not be able to fulfil this requirement. Indeed, the Vozrozhdeniye Island case shows the possibility of invoking the principle of permanent sovereignty over natural resources (just as in the case of Nauru in *Certain Phosphate Lands in Nauru*) by Kazakhstan and Uzbekistan.

Despite the decontamination efforts undertaken by the US on the Vozrozhdeniye Island, the aforementioned island became connected with Uzbekistan's mainland in 2004-2005 through a natural land bridge (Kozlova, 2007, p. 2). Infected animals, such as plague carrying rodents including gerbils and mice, freely roam this island while the fleas from those rodents could serve as potential carriers of the disease thus being capable of infecting humans, particularly if these creatures reach mainland Uzbekistan (Pala, 2003,

p. 2). This is indeed an agricultural biosecurity issue, as highlighted by the Food and Agriculture Organisation of the United Nations (FAO), because it involves zoonoses whereby the rodents infected with the plague (from fleas) can transmit the disease to humans.

Likewise, scavengers that flock to Vozrozhdeniye Island in order to collect the equipment, building materials and scrap metal that the Soviets left behind could also be infected and could pass on the diseases to other humans, causing an epidemic on mainland Kazakhstan and Uzbekistan (Kozlova, 2007, p. 2; Pala, 2003, p. 2). Having elaborated extensively on the case of the Vozrozhdeniye Island, the UN Secretary General's Report is to the point when declaring that "[t]he development, use and destruction of weapons have substantial costs for the environment" as the contamination from the biological agents on Vozrozhdeniye Island "can devastate the environment and pose significant social, financial, logistical and scientific challenges" (United Nations Office of Disarmament Affairs [UNODA], 2004, para. 33). This is evident from the substantial costs that the US spent on decontaminating the island (Nuclear Threat Initiative [NTI], 2011, p. 2). At present, the scientists monitoring this island will face the continuous challenge of ensuring that anthrax and other biological agents will not resurface to pose any health threat to human beings and other animals.

7.2.2 The Case of Zhejiang and Hunan, China

Another similar example of environmental contamination due to biological weapons testing and disarmament is that of Japan in its famous Unit 731 and Unit 1644 from 1940-1942, which sought to spread an epidemic of plague and cholera in the Chinese cities of Quzhou, Ningbo, Changde, Jiangshan, Yiwu, Dongyang and Chongsan Village (or Taxiazhou), as filed by a group of plaintiffs on 30 August, 2002 at the Tokyo District Court (Tokyo District Court, 2002b, p. 2). Unfortunately for the Chinese who filed this

lawsuit, the Tokyo District Court, the Tokyo High Court, and Supreme Court all rejected the claims for compensation ("Japan rejects", 2005, p. 1). It was cited that international law prohibits foreign citizens from seeking compensation directly from the Japanese government ("Japan rejects", 2005, p. 1). Still, the Tokyo District Court admitted that Japan had a role in the atrocities in the Zhejiang and Hunan provinces in China, for it stated: "it is appropriate to conclude that the defendant [Japan] has sovereign responsibility for this case of germ warfare according to international customary law as established in Article 3 of the Hague Convention for War on Land" – but denied compensation to the Chinese (Tokyo District Court, 2002a, p. 5). Another reason for rejecting the Chinese plaintiffs' claim was attributed to a joint communiqué signed between China and Japan on 12 August 1978 (referred to as the China-Japan Treaty of Peace and Friendship) whereupon Japan alleged that China had agreed to waive any claims to war reparations from Japan (Tokyo District Court, 2002a, p. 5).

The Japanese atrocities described above have a bearing on the duty of the states to ensure the sustainable use of natural resources and not to pollute the environment of another state, in this case China. Just like the Vozrozhdeniye Island case, which the Soviet Union handed over to Kazakhstan and Uzbekistan without full decontamination, it may be asserted that Japan should have decontaminated the areas of the Zhejiang and Hunan provinces that were contaminated with plague and cholera. Obviously, Japan did not do so as this was a wartime atrocity purposefully committed. These provinces now bear the brunt of environmental contamination. Qiu Mingxuan, a Chinese epidemiologist from Quzhou in the Zhejiang province, reiterated the need to conduct medical examinations on the rats infected with the plague germs because the test conducted showed that the rats were still carriers of the bubonic plague ("The horrors", 2001, p. 3). Qiu further indicated that the plague legacy left behind by the Japanese could cause another outbreak anytime, while houses, hospitals and other buildings contaminated by these germs had to be

abandoned for decades ("Japan accused", 2001, p. 1). Additionally, Qiu asserted that environmental contamination and the damage to the ecosystem were repercussions of the decades of Japanese wartime atrocities ("Japan accused", 2001, p. 1).

7.2.3 The Case of Fort Sherman, Panama

At Fort Sherman, the United States National Institute of Health's Middle America Research Unit (MARU) experimented with VEE that can decapitate humans without killing them, making it a good candidate for a biological weapon (Choffnes, 2001, p. 6; Poland, 2003, p. 70). Likewise, the Gorgas Memorial Laboratory conducted experiments among humans at Almirante from 1960-1962, at Darien, and in the urban communities of Patoistown and Zegla in 1968 (Poland, 2003, p. 71). In 1981, an outbreak of VEE occurred among the military personnel that underwent training at the Jungle Warfare Training Centre at Fort Sherman, Panama under the suspicion that VEE had lingered from the testing of the 1960s until 1970 (Choffnes, 2001, p. 6; Poland, 2003, p. 71). As a result of the previous VEE experiments at Fort Sherman, VEE still remains an endemic threat in selected areas of Central America (Choffnes, 2001, p. 6).

In addition to VEE, the US also tested another biological agent referred to as the *Bacillus globiggi* bacteria (BG) related to anthrax on the basis of a test called Big Jack, Phase A near the Fort Sherman Military Reservation at the Panama Canal Zone in February-March, 1963 (Kelley, 2002a, p. 1). Although BG was considered to be harmless at the time, it was later determined that it could cause life-threatening infections among people with a weakened immune system (Kelley, 2002a, p. 1).

The legal implications arising from the Fort Sherman case relate to the issue of whether decontamination efforts were in fact conducted before the US ceded this territory back to Panama in 1999 in accordance with the Panama Canal Treaty (1977). Article IV (4) of that Panama Canal Treaty (1977) obliges the US to eliminate any military hazard at the

site.[2] Additionally, Article VI of the same Panama Canal Treaty (1977) also obligates the US to consult and cooperate with Panama in addressing the military activities affecting biological diversity.[3]

To date, information on whether the US did in fact decontaminate the Fort Sherman area before leaving remains scarce. In another development, the US of course had always been reluctant to clean up the chemical weapons residue on the San José Island, prompting Panama to appeal to the Organisation for the Prohibition of Chemical Weapons (OPCW) in order to act against the irresponsible behaviour by the US (Lowe, 2013, p. 2). Likewise, Panama's report regarding the UN Resolution Concerning Observance of Environmental Norms in the Drafting and Implementation of Agreements on Disarmament and Arms Control of 2002 sought to find "a solution to the problem of contamination of some areas that were part of the former United States military bases in the country, and especially the problem of clean-up of the contamination caused by chemical weapons on the island of San José" (The Secretary General, 2002, p. 3).

In November 2013, Panama and the US reached an agreement, with the US military expected to study San José Island and then dispose of the chemical weapons left there prior to 2014 (Oswald, 2013, pp. 1-2). If the US had been reluctant to clear out the chemical weapons on Panama's territory, it can then be expected that the country will act in a similar manner when having to decontaminate the Fort Sherman area where biological weapons were also tested.

[2] Article IV (4) of the Panama Canal Treaty mentions that:
The United States shall be obligated to take all measures to ensure insofar as maybe predictable that every hazard to human life, health and safety is removed from any defense site or a military area of coordination or any portion thereof, on the date the United States Force are no longer authorised to use such site.
[3] Article VI of the Panama Canal Treaty (1977) mentions that:
The United States of America and the Republic of Panama commit themselves to implement this Treaty in a manner consistent with the protection of the natural environment of the Republic of Panama. To this end, they shall consult and cooperate with each other in all appropriate ways to ensure that they shall give due regard to the protection and conservation of the environment.

In terms of the invocation of international law in Panama's case, Wagner and Popovic (1998, p. 440) cited the case of *Trail Smelter,* Principle 21 from the Stockholm Declaration, and Principle 2 of the Rio Declaration regarding customary international law, whereby no state has the right to use or permit the use of its territory in such a manner as to cause injury to the territory of another (Government Printing Office [GPO], 1941; "Report of the United Nations", 1992; United Nations Conference on the Human Environment [UNCHE], 1972). While Wagner and Popovic (1998) merely referred to chemical weapons contamination without emphasising the need for biological weapons decontamination on Panama's territory by the US, their justification for invoking the *Trail Smelter* case shows that Panama can invoke the law of state responsibility, for even the Articles on Prevention of Transboundary Harm from Hazardous Activities (United Nations General Assembly [UNGA], 2001b, p. 43) concur that states must take appropriate measures in order to prevent transboundary harm so as to avoid liability. Obviously, in Panama's case, the issue of transboundary harm arises from the presence of the US in Fort Sherman, Panama, where its testing and disarmament of biological weapons were not accompanied by an effective decontamination process, thus polluting Panama's territory.

The US also has a stronger obligation to clean up any decontamination of biological weapons at Fort Sherman after having signed a bilateral treaty with Panama, making it an obligation on the part of the US, thus being unable to derogate from its commitment. This section has therefore shown that the testing and disarmament of biological weapons involve transboundary harm, and based on the three cases highlighted, the duty of the states to ensure the sustainable use of natural resources and not to pollute another's territory becomes even more relevant.

7.3 The Principle of Equity and Eradication of Poverty in the Biological Weapons Convention

The discussion of the above principle will be divided into two sections. The first section will focus on the development issues championed by developing states as an issue of contention among the present generation covering intragenerational equity within the BWC. The second subsection elaborates on intergenerational equity in the BWC concerning the rights of future generations to be protected from the long-term environmental impacts of biological weapons.

7.3.1 Intragenerational Equity within the Biological Weapons Convention

7.3.1.1 Overriding Development Concerns

Biotechnological development matters have been a contentious issue among the developing states of the BWC. Article X (2) of the BWC (1972) specifically addresses the development aspect asserted by the Non-Aligned Movement (NAM) states. Article X (2) of the BWC (1972) dictates that the "Convention shall be implemented in a manner designed to avoid hampering the economic or technological development of States Parties […] or international cooperation in the field of peaceful bacteriological (biological) activities […]". During the negotiations of the aborted Protocol to the BWC, the NAM states highlighted that "given the importance of biotechnology for economic development, any verification regime of the [BWC] should contain specific provisions to safeguard the security and economic interests of developing countries […]" (NAM), 1997, para. 44).

In particular, the NAM states are keen for developed states to transfer their knowledge and technology towards "building defences against new and emerging diseases and developing national capacity for responding to biological threats through detection, containment and decontamination" (Daryaei, 2013, p. 3). At the BWC Meeting of Experts in 2013, the NAM underlined the urgency of identifying and addressing their needs in

terms of equipment, materials, scientific and technological information (Daryaei, 2013, pp. 3-4). The NAM also highlighted the need to mobilise financial resources and to facilitate the development of human resources in the context of bacteriological and toxin agents for peaceful purposes, particularly in detecting and responding to infectious disease outbreaks whether natural, accidental, or deliberate (Daryaei, 2013, pp. 3-4).

That being said, the outcome documents from the BWC Intersessional Process (ISP) of 2004 and 2010 does not make it mandatory for the developed states to transfer the necessary knowledge, technology and equipment (in the area of combating diseases) to developing states, as these initiatives are non-binding and voluntary (United Nations Office at Geneva [UNOG], 2009, p. 9; UNOG, 2010b, p. 6). Indeed, on particular occasions, a developed state such as Germany for instance "does not interpret the requirements set out in Article X in a narrow sense but understands cooperation and assistance in the wider perspective of Official Development Assistance (ODA), as defined by the Organisation for Economic Co-operation and Development (OECD)" (Nikel, 2011, p. 4). In other words, Germany believes that developed states have already provided enough assistance to their developing counterparts via other channels such as the ODA under the tutelage of the OECD, and there is thus no need to ask for further assistance as mandated by the BWC. Other states, such as Russia, would want the discussion of health and diseases within the BWC to be avoided in case there are requests for technology and knowledge transfers, as reflected in its statement to the Seventh Review Conference of the Biological Weapons Convention (Gatilov, 2011, pp. 3-4).[4]

Despite this, the NAM states have continuously asserted their need for technology and knowledge transfers in order to combat infectious diseases and foster capacity building

[4] Excerpt from the *Statement by H.E. Mr. Gennady Gatilov, Deputy Minister of Foreign Affairs of the Russian Federation at the Seventh Review Conference of the Biological Weapons Convention* stating: "*We do not question the importance of countering infectious diseases or bioterrorism. However, it is not a topic of consideration within the BTWC. These issues are actively dealt with by other specialised international organisations and forums."*

and human resource training. Failure on behalf of the developed states to transfer knowledge and technology on grounds of security for fear of misuse of biotechnology is perceived as a trade barrier by the developing states. Scepticism exists about the commitment of developed states to providing assistance in other regimes. As emphasised by Müller et al. (2013, p. 63): "Western reluctance to comply with transfer obligations in other regimes such as the Convention on Biological Diversity and the limits placed on biotechnology transfer by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) provide grounds for developing countries to generally mistrust 'the West'". As assistance from other regimes has not been satisfactory, it is no wonder that developing states have raised the same matter within the BWC forum.

Developing states perceived the imposition of export controls over biological agents, toxins and equipment in line with Article III of the BWC (1972) (barring transfers) as secondary because they have more pressing needs such as addressing matters of poverty, food, medical care, shelter and sustaining fragile environments. Wright (1992, p. 472) reiterates that "[t]he problems of disease and famine in these developing countries are just as devastating as those that might be caused by biological warfare and far more immediate". As a point of illustration, Gould (2009, p. 171) indicated that biosecurity "has very little currency in South Africa", as it is not a term understood to refer to biological warfare, weapons of mass destruction and safety at the policy-making level. Additionally, Gould (2009, p. 171) emphasises that South African scientists and policy makers reject biosecurity as a connotation associated with terrorist acquisition of biological weapons as their country requires more access to food, improved health services, affordable medicine, as well as clean water. For South Africa, diseases deliberately caused by biological warfare and bioterrorism are not uppermost, but rather communicable diseases associated with poverty and underdevelopment such as the acute human immunodeficiency syndrome (AIDS), tuberculosis (TB) and malaria constitute

their main priorities (Gould, 2009, p. 175). Wright (1992, p. 472) has also asserted that for developing states "[e]xpanding resources on arms control and disarmament is seen as a luxury of the rich". Furthermore, given the speculative nature of biological warfare and bioterrorism, developing states are not convinced about allocating a large budget and devoting extensive policy-making resources to this menace. Indeed, Singer and Daar (2009, p. 23) have cautioned that "the world must not let legitimate concerns about biosecurity undermine the promotion and use of biotechnologies for human development", particularly as "[i]nternational laws and rules that inhibit investment and growth in these technologies because of security concerns therefore could jeopardise these future benefits". The message conveyed by Singer and Daar is that too much emphasis on biosecurity and the misuse of biotechnology can downplay the need to address biotechnology for development purposes and thus ensure the continuous economic growth of the developing states.

Singer and Daar's concern about an overemphasis on biosecurity does have some legitimacy. Enemark (2000, p. 29) has warned that the imposition of export controls exerts an impact on the humanitarian concerns about health, as evidenced by the United Nations Special Commission (UNSCOM) in Iraq, which imposed biotechnology restrictions nationwide. A World Health Organisation (WHO) report from 1996 reportedly demonstrated that health conditions deteriorated at an alarming rate because of such restrictions (Enemark, 2000, p. 29). While there were legitimate concerns over Iraq's development of biological weapons for biological warfare, this deprived the Iraqi people of adequate medical care equipment, vaccines and other medical supplies to the point of raising humanitarian concerns. Thus, there is need for moderation in addressing the concerns about biotechnology being misused for biological warfare in order to ensure that the legitimate use of biotechnology for development purposes is not overlooked.

Despite the NAM states continually calling for cooperation and assistance from their developed counterparts in implementing Article X of the BWC (1972), there is still uncertainty on whether developed states are willing to transfer biotechnological knowledge or share their equipment and expertise as mandated by the said provision. At the Meeting of Experts to the BWC between 12 and 16 August, 2013, the NAM underlined the need for education exchange, training and twinning programmes in training human resources in the biological sciences and technology among developing states (Daryaei, 2013, p. 4). On behalf of the NAM, Iran's submission mentioned that developed states should provide full access among students, scientists and other personnel from developing states to universities, advanced laboratories, research institutions and production facilities in developed states without the limitations imposed by restrictive visa regimes (Daryaei, 2013, p. 5).

Indeed, certain developed states have imposed limitations concerning foreign students' access to their universities because of terrorism concerns. In 2008, the UK reported that one hundred potential terrorists posing as postgraduate students had tried to enrol in science courses in order to obtain materials and expertise from the laboratories of the universities and research institutions in their bid to create biological weapons (Towsend, 2008, paras. 1-16). The UK's Foreign Commonwealth Office conducted background checks based on the information from its intelligence unit using a new vetting scheme which led to the rejection of foreign students wanting to take science courses with the intention of developing weapons of mass destruction (Towsend, 2008, paras. 1-16). Under its Academic Technology Approval Scheme (ATAS), the UK rejected students from countries of concern such as Iran and Pakistan (Towsend, 2008, paras. 1-16). This initiative was implemented "to stop the spread of knowledge and skills that could be used in the proliferation of weapons of mass destruction and their means of delivery" (Towsend, 2008, paras. 1-16). Infiltration into the UK laboratories located in hospitals,

universities and private firms holding select agents such as Ebola, polio and avian flu would certainly constitute an outlet for foreign students with the intent of not only gaining knowledge about creating a biological weapon but possibly about smuggling out valuable biological agents.

While there may be a genuine reason to bar developing states if it is indeed proven that they truly are sending their human resources to acquire knowledge from developed states in order to build biological weapons, there should also be an exemption. Developed states should not bar all NAM states from sending students to their higher education institutions as this could signify reluctance on their part to transfer biotechnological knowledge.

Additionally, developed states can benefit from sharing their biotechnological knowledge, such as detecting and diagnosing infectious diseases, as well as training the human resources from developing states in using biosensors in order to detect biological agents at their borders. Containing the spread of biological weapons at the borders is a crucial issue, the failure of which could lead to the spread of a catastrophic pandemic of diseases. In Southeast Asia for instance, Abu Sayyaf, the famous terrorist group, reportedly mixed a range of biological chemicals into Improvised Explosive Devices (IEDs) which wounded ten soldiers in a landmine explosion in 2010 and also used it during an ambush in Sumisip, Basilan, southern Philippines (Dacanay, 2010, p. 1). Moreover, a Jemaah Islamiah (JI) manual was also found in October, 2003 in a hideout in Cotabato (southern Philippines) indicating their intent to develop biological weapons even though no other evidence was found at that point in time (Dragffy & Feakes, 2003, p. 51; Gunaratna, 2004, p. 1). Moreover, the US Country Reports on Terrorism 2012 (U.S. Department of State, 2013, p. 206) reiterate the fact that states with porous borders around the Sulu or Sulawesi Sea such as the Philippines, Malaysia and Indonesia with weak strategic control laws and inadequate maritime law enforcement provide an environment conducive to the proliferation of weapons of mass destruction (WMDs). Indeed, training

the personnel from developing states to be able to utilise biosensors for the detection of biological agents in developed states is in line with Article X of the BWC (1972). A fastidious detection of biological agents will allow law enforcement staff to avoid further harm to their health in the course of duty. Should law enforcement staff succumb to an infection or sickness, the doctors will be able to diagnose the symptoms and prescribe medications because prior knowledge already exists about these biological agents based on the information obtained through biosensors.

Developing states with the necessary human resources who have been trained to detect genetically modified biological agents causing diseases through microbial forensics and biosensors can also facilitate the diagnostic process. Furthermore, there is no longer the need to wait for experts from developed states to arrive. In this way, more lives can be saved, not to mention that it will also ensure the right prescription of medication. The containment of infectious diseases is also crucial, as this can help prevent their spread to other states including developed states. By sharing their expertise and allowing developing states to obtain the necessary equipment for detecting and diagnosing diseases, this can render them more independent, without having to continuously rely on developed states. If Article X of the BWC (1972) promoting cooperation and assistance can help achieve this goal between developed and developing states, this should be pursued by all means as it is for the betterment of all. In any case, the Seventh Review Conference of the Biological Weapons Convention in 2011 consequently agreed that one of the topics for the ISP process from 2013-2016 will concentrate on cooperation and assistance in the context of Article X, showing that the grievances of developing states are starting to be heard (Council for Security Cooperation in the Asia Pacific [CSCAP], 2012, p. 8).

Based on the above discussion, it is quite obvious that the different roles assigned to developed and developing states, i.e. between the giver of knowledge, technology and

equipment and those to receive them, reflect the principle of equity and eradication of poverty as in ISDL. That is why the BWC references a provision in Article X that addresses economic development issues, contrary to the export controls barring the transfer of biological agents, toxins and dual-use biotechnology equipment, as per Article III (BWC, 1972).

7.3.1.2 Ignoring the Biosecurity of Biotechnology is Risky

Although developing states have been right to emphasise that the misuse of biological weapons should not override developmental concerns, developing states can ill afford to ignore the biosecurity of biotechnology for the following reasons. Borrie and Loyle (2005, p. 97) assert that African states need to take steps in preventing the hostile use of biotechnology because they have inadequate public health infrastructure and resources to overcome the infectious diseases targeted by terrorists. A delayed public health response can cause diseases to spread, which can constitute a devastating economic catastrophe to tourism and business travel. Borrie and Loyle (2005, p. 98) have also emphasised that African states with the fewest safeguards are likely to be targeted by terrorists who may want to show that security barriers can be overcome so as to cause widespread pandemonium and mayhem while developed states stand helplessly by. Borrie and Loyle (2005, p. 98) also cite the very lax security measures in many African states, making it easy for terrorists to target them. Borrie and Loyle (2005, p. 99) also argue that African states ought to take action because they may have legally binding obligations as members of the BWC, while all states are obligated to implement Resolution 1540. Borrie and Loyle (2005, pp. 99-100) have also underlined that the measures seeking to prevent the hostile use and spread of deliberate diseases fulfil the obligations of the International Health Regulations 2005 (IHR 2005) of the WHO. The views of Borrie and Loyle are well supported, with the exception that the biosecurity measures to prevent hostile use are applicable to all vulnerable developing states.

7.3.2 Intergenerational Equity within the Biological Weapons Convention

In this discussion over intergenerational equity, there is a need to revert back to the case of the Vozrozhdeniye Island in the former Soviet Union. As the case of the Vozrozhdeniye Island has shown, Uzbekistan and Kazakhstan have had to embark on a continuous monitoring of anthrax on the contaminated ground that once saw the testing of biological weapons by the Soviet Union (Pala, 2003, p. 2). The said island is so contaminated that the oil exploration which could potentially revive the island's economy has had to be executed with caution, as the personnel involved in the oil exploration could be exposed to anthrax (Pala, 2003, p. 2). In turn, being unable to conduct oil exploration has a negative effect on the economic development in these states, depriving their people of prospective jobs that could free them from the shackles of poverty. This demonstrates the legacy left by the former Soviet Union, where the actions of past generations have subsequently affected the future generations of Uzbekistan and Kazakhstan, who are now being deprived of conducting any economic activities on their island. This is a case of sheer negligence, with no consideration whatsoever about the long-term environmental repercussions due to the testing of biological weapons. Moreover, scientists monitoring this island will face the continuous challenge of ensuring that anthrax and other biological agents are contained and do not resurface to pose a threat to the human beings and other animals populating the island (Kozlova, 2007, p. 2). It is envisioned that the process of monitoring biological agents on this island will not conclude with the present generation. Future generations will have to continue the monitoring process given the long lifespan of biological agents, which survive in the ground and continue to contaminate the environment and natural resources.

Similarly, the Zhejiang and Hunan provinces that became testing sites for plague and cholera during World War II under the Japanese have borne the brunt of those tests even across current generations, as plague is still present among rats as previously discussed

("The horrors", 2001, p. 3). During World War II, the Japanese were responsible for spreading the plague to these provinces, which has rendered the Chinese unable to live in the homes, hospitals and other buildings contaminated by the plague ("Japan accused", 2001, p. 1). There is no doubt that the usage of biological weapons has a lasting legacy that cannot be wiped off easily even for generations to come in terms of environmental contamination and endangering human health. This being the case, there is evidence that the usage of biological weapons would have a bearing on future generations in accordance with the intergenerational equity of sustainable development.

7.4 The Principle of Common but Differentiated Responsibilities in the Biological Weapons Convention

In the context of the Delhi Declaration, the principle of common but differentiated responsibilities recognises that developed and developing states have respectively contributed towards environmental degradation, but their level of development will determine the actions they have to take in remedying the environmental contamination (ILA, 2002, p. 4). The said principle also recognises the special requirements of the developing states that are unable to address environmental contamination because they lack the financial means, technical knowledge, equipment and technology, thereby needing the developed states to provide all of these necessities (ILA, 2002, p. 4).

This principle can be applicable to past cases of biological warfare, whereby developed states have caused the environmental contamination of the territories of other states. Those developed states that had caused such contamination thus have an obligation to clean up the residues of the testing and usage of biological weapons. For example, the former Soviet Union, which produced biological weapons on a mass scale, should have assisted Kazakhstan and Uzbekistan in decontaminating Vozrozhdeniye Island but it was the US that shouldered this burden given Russia's dire financial position at the time ("US to destroy", 2001, p 1). In this sense, there is truth to the assertion that the production of

biological weapons is an indulgence of the developed states according to Wright (1992, p. 472) who stated that "[e]xpanding resources on arms control and disarmament is seen as a luxury of the rich". The same applies to Japan that created, experimented and used biological weapons in the Zhejiang and Hunan provinces in China before and during World War II, another rich and affluent state that should rightfully bear the responsibility for the decontamination of the provinces, but failed to carry out its obligation ("The horrors", 2001). As discussed in an earlier section of this chapter, environmental contamination is a direct result of the experimentation with biological weapons by the former Soviet Union and Japan.

Therefore, it is only right for these states to share their knowledge and technology with the developing states because the latter may not have the technological know-how and equipment to decontaminate former biological weapons test sites. Perhaps even more convenient for the developed states would be to transfer the technology, knowledge and equipment so as to enable the developing states to be self-reliant in terms of further decontamination efforts in order to prevent environmental degradation. This is indeed an issue worth pursuing in the context of the BWC, as the states suffering from the contamination of biological weapons should be provided with the necessary assistance.

For this to happen, the Final Declaration from the Seventh Review Conference of the Biological Weapons Convention in 2011 requires that assistance should be rendered to the developing states whenever possible (UNOG, 2011, p. 17),[5] providing a window of opportunity for the latter to seek assistance regarding the decontamination of the biological weapons testing sites.

[5] Refer to the document UNOG (2011) in particular paragraph 56 that states: "*Recognising that all States Parties have a role to play, the Conference [7th Review Conference of the BWC] stresses that those States Parties seeking to build their capacity should identity their specific needs and requirements and seek partnerships with others, and that those States Parties, in a position to do so, should provide assistance and support."*

Nevertheless, the need to provide assistance under Article X of the BWC (1972) has been rendered ineffective through the insertion of a saving clause into the Reports of the Meeting of States Parties to the BWC from 2007-2010 which mentions in the annex that the said provision "was not discussed or agreed upon and consequently has no status" (UNOG, 2008a, p. 6; UNOG, 2008b, p. 8; UNOG, 2009, p. 9; UNOG, 2010b, p. 6). Consequently, there is no obligation on the part of the developed states to render assistance to the developing states to implement Article X of the BWC (1972). Thus, the principle of common but differentiated responsibilities in the context of the BWC is indeed contentious among the developed and developing states due to the aforesaid clause.

7.5 The Principle of the Precautionary Approach to Human Health, Natural Resources and Ecosystems in the Biological Weapons Convention

This section will examine the applicability of the principle of the precautionary approach to human health, natural resources and ecosystems and whether it is reflected either explicitly or implicitly in the BWC. It is to be observed that none of the provisions in the BWC explicitly refers to the precautionary approach, which by no means indicates that the BWC is totally devoid of the precautionary approach, as this study would assert (see below) that the said principle can be implied implicitly in certain situations.

7.5.1 The Precautionary Approach as a Deterrent against Biological Weapons

It is argued that the BWC indirectly applies the precautionary approach in stressing that member states should identify ways and means to enhance national implementation by means of legislation, strengthening institutions, and coordinating law enforcement agencies in order to prevent the creation of biological weapons, as discussed in the ISP of 2007 (UNOG, 2008a, p. 12). Borgers and Sliedregt (2009, p. 187), Goldsmith (2008, pp. 162-163) and Kittelsen (2009, p. 64), all indicated that the precautionary approach is necessary because it can help mitigate a possible future attack using biological weapons

by having criminal laws put in place as a deterrence. These aforementioned scholars are indeed applying the precautionary approach in a different way within the context of urging states to enact criminal laws that would penalise and prevent the activities that breach any of the prohibitions of the BWC, thereby prosecuting the prohibited activities towards creating biological weapons (UNOG, 2008a, p. 5). In applying this principle to the BWC, the ISP of 2007 requires that BWC members enact laws that prohibit assisting, encouraging or inducing others to breach the BWC, as well as drafting export control laws to prevent the transfer of biological agents, toxins and equipment in line with the national measures of Article IV (BWC, 1972; UNOG, 2008a, p. 5). By implementing such measures, the BWC member states are also complying with Article III of the BWC (1972) in preventing the transfer of biological agents, toxins and equipment directly or indirectly to any state, group(s) of states, international organisations or non-state actors. Moreover, in line with the existing export control laws, the BWC member states are to formulate a control list that prohibits the possession of certain biological agents, toxins and equipment, as well as criminalise all prohibited activities mentioned above on the basis of the penal and criminal codes of law of each member state (UNOG, 2008a, p. 8).

7.5.2 The Precautionary Approach for the Dual Use Research of Concern (DURC)

The precautionary approach can also be applied in terms of requiring the BWC member states to ensure oversight, education, raise awareness and have codes of conduct that can guide scientists to avoid or prevent the misuse of knowledge in biosciences and biotechnology research, as indicated in the ISP of 2008 (UNOG, 2008a, p. 1). These said initiatives were meant to create awareness and to educate scientists that the methods, data and results of their research disseminated particularly through publications have the potential of being misused for bioterrorism. Glatter (2013, p. 5), Kuhlau, Hogland, Evers and Eriksson (2009, p. 5) and Resnik (2013, p. 27) have all prescribed the usage of the precautionary approach especially among scientists, scientific committees and publishers

who ought to be aware of the likely misuse of biotechnological knowledge in terms of biological select agents. This is known as Dual Use Research of Concern (DURC), experiments that can make biological agents more virulent, thus evading diagnostics, and rendering antibiotics and vaccines resistant. Since there is a risk that terrorists may potentially misuse the knowledge shared through scientific publications as in the deliberate release of biological select agents in order to damage the environment (Carus, 2001),[6] it only highlights the urgent need for the precautionary approach. Due to the continuous presence of biological agents as in the case of the Vozrozhdeniye Island, the precautionary approach will have to be applied as a deterrent to the scientists wanting to test biological weapons. Alternatively put, "when an activity raises threat of harm to the environment or human health, precautionary measures should be taken even if some cause and effect relationship are not fully established scientifically" (Perdan, 2004, pp. 12-14).

However, the applicability of the precautionary approach is not without its critics, for example both Resnik (2013, p. 27), as well as Kuhlau et al. (2009, p. 6) have argued that its application may stifle scientific development because of an extensive risk-averse approach. Applying the precautionary approach means choosing one over another in weighing up which choice will prevail in the end.

Regardless of the controversy surrounding the application of the precautionary approach, it would seem that the BWC forum has certainly embraced the dual use research in the life sciences. The BWC forum has appealed to scientists and other experts involved in the DURC to think about the moral and ethical implications of their research as a result of misuse and to take preventive steps such as censoring publications and building a culture of responsibility (UNOG, 2008b, p. 7). In line with this, the ISP of 2008 called on all member states to the BWC to formulate codes of conduct covering the ethical and

[6] See Carus (2001) in "Bioterrorism and Biocrimes" in the reference list. For further information on cases of bioterrorism, Carus provides a very useful documentation of such cases that are known worldwide.

moral obligations of scientific research from the proposal and funding stages to the execution and dissemination through publications as a set of guidelines for the scientists conducting the DURC (UNOG, 2008b, p. 16). Indeed, such codes of conduct will complement the oversight of science and fulfil Articles III and IV of the BWC (1972) regarding the national measures taken in order to prevent their transfer to any state(s) and international organisations that may use them to manufacture or acquire any biological agents, toxins, weapons or equipment.

7.5.3 The Precautionary Approach in the Context of Disease Surveillance

A final observation on the applicability of the precautionary approach within the BWC is the need for member states to have a national regulatory framework regarding disease surveillance and the necessary infrastructure network that can monitor diseases in line with the ISP of 2009 (UNOG, 2009, pp. 4-6). The ISP 2009 of the BWC emphasises capacity building in the areas of disease surveillance, detection, diagnosis, and containment of infectious diseases (UNOG, 2009, pp. 4-6). Essentially, having disease surveillance networks and a national regulatory framework is vital in detecting naturally occurring or deliberately released biological agents that cause harm to human health, particularly resulting from an act of bioterrorism. This requires spontaneous action before the spread of the diseases becomes endemic. Thus, implementing a national regulatory framework and a disease surveillance network system may be regarded as preventive actions towards preventing a Global Catastrophic Risk (GCR) from occurring, hence the call by Baum and Wilson (2013, pp. 59-72) for the application of the precautionary approach.

The analysis in this section found that the BWC does not explicitly refer to the precautionary approach. However, this principle has been indirectly applied and can also be applied to a number of scenarios, as already discussed.

7.6 The Principle of Public Participation and Access to Information and Justice in the Biological Weapons Convention

In this section, the focus will be on examining the applicability of the principle of public participation and access to information and justice, as reflected within the BWC. The above principle will be applied in two scenarios, namely in relation to examining public participation and access to information as a functionality of the BWC itself, and secondly, in the BWC's initiative of oversight, education and awareness about the dual-use nature of genetic engineering, as will be discussed below.

7.6.1 Public Participation and Access to Information as a Functionality of the Biological Weapons Convention

Historically, throughout the 1970s, the states were the sole custodians of the BWC, as most decisions were made without much intervention from non-state actors (Zanders, 2011, p. 39). The first ISPs (that started from 2003-2005) slowly began to incorporate non-state actors in the Meeting of the States Parties and Experts that focused on the different themes discussed throughout the aforementioned period (UNOG, 2002, pp. 3-4). The Meeting of Experts to the BWC in 2005, with a focus on the implementation of a national mechanism in order to establish and maintain the security and oversight of pathogenic microorganisms, concentrated on the codes of conduct for scientists to include states, international organisations, Non-Governmental Organisations (NGOs), academics, industries, and scientific professional bodies (Pearson, 2005, p. 12). These were included because they would have been impacted by the code of conduct introduced at the national level (Pearson, 2005, p. 12). Some of the NGOs, universities and research institutes that provided their inputs concerning the proposed codes of conduct at this Meeting of Experts in 2005 include the Landau Network-Centro Volta, the Monterey Institute, the Pax-Christi International, the London School of Economics and Political Science (LSE), and the University of Bradford (Pearson, 2005, p. 14). Likewise, the Meeting of Experts in 2008 for the BWC included experts from the American Biosafety Association, Asia-Pacific

Biosafety Association, European Biosafety Association (EBSA), the International Union of Biochemistry and Molecular Biology (IUBMB), and the International Union of Pure and Applied Chemistry (IUPAC) that provided feedback concerning the ISP 2008 theme on biosafety and biosecurity, the oversight on education, awareness raising and the codes of conduct for the scientists pertaining to the DURC (Pearson, 2009, p. 2). As indicated by Dando (2009, p. 2), the BWC's "annual meetings [the Meeting of States Parties and Experts] have not only involved diplomats but also have been imaginatively expended by successive chairmen to incorporate more of the relevant stakeholders - particularly members of national and international scientific communities".

Although there is no provision within the BWC that explicitly mentions that decision-making should incorporate public participation, it is left to the discretion of the chair of the BWC to decide whether any experts could be invited as guests to the meeting (Ijssel, 2011, p. 14). For example, Ambassador Paul Van Den Ijssel from the Netherlands who was chair of the Seventh Review Conference of the Biological Weapons Convention in 2011 decided to invite many experts with comprehensive knowledge on particular topics relevant to the discussions of the BWC (Ijssel, 2011, p. 14). Likewise, a panel for industry representatives was being formed at the Seventh Review Conference of the Biological Weapons Convention (Ijssel, 2011, p. 4). Yet another way for the non-state actors to be included in the BWC meetings is for them to be part of national delegations even though it is up to the national governments to decide whether they should be included. However, this implies openness and transparency in conformance with the principle of good governance.

Other than the channels already mentioned, the BWC meetings have also permitted the industry and the academia to participate in their own capacity by registering at the BWC review conferences and other BWC meetings (Ijssel, 2011, p. 14). Nevertheless,

there are some limitations to their participation, as they are excluded from certain sensitive discussions and decision-making processes.

Another way for non-state actors to contribute to the BWC review conferences and meetings has been through side events, such as panel discussions with experts from various backgrounds debating themes related to the BWC (Ijssel, 2011, p. 15). At the Seventh Review Conference of the Biological Weapons Convention in 2011, three side events addressed the linkages with the industry, while five addressed the implications of the advances in life sciences and technology (Ijssel, 2011, p. 15).

In addition, there is a website called the "Think Zone" maintained by the ISU that allows any individual to submit papers relevant to an ISP theme of the BWC, whether focusing on biosafety and biosecurity, the codes of conduct for the alleged use of biological weapons, or other topics (Ijssel, 2011, p. 15).

Indeed, the participation of these non-state actors provides the following advantages. Since the industry and the academia form the bigger part of research and development within the BWC's scope, they are able to share their practical experience regarding laws, regulations and policies. Opinions regarding the biotechnology regulation indicate that it can either be too cumbersome to stifle a robust biotechnology industry or too lenient to allow perpetrators with malicious intentions to circumvent these laws and regulations.

Therefore, it can be said that the BWC has been somewhat progressive in allowing the participation of non-state actors and for being as democratic as possible even though there is no provision within the BWC itself to that effect. In this regard, the BWC process itself fulfils the principle of public participation and access to information as it engages relevant civil society organisations in addressing industrial concerns in the spirit of the Delhi Declaration of ISDL (ILA, 2002, p. 5). Therefore, according to the analysis in this

subsection, public participation and access to information as a functionality within the BWC itself are only indirectly implied, as no provision of the BWC reflects this.

7.6.2 Public Participation and Access to Information in the Context of Oversight, Education and Awareness Concerning the Dual Use Nature of Genetic Engineering

Public participation and access to information have also been reflected within the BWC, namely through oversight, education and awareness of the dual use nature of genetic engineering. The need to create awareness about the misuse of biology for malevolent intentions can be traced to the Final Declaration of the BWC from the Second Review Conference in 1986, whereby it stressed the "inclusion in textbooks and in medical, scientific and military educational programmes of information dealing with the prohibition of bacteriological (biological) and toxin weapons" (UNOG, 1986, p. 4). Despite this, in his survey in 2010, Minehata (2010, p. 19) found the Asia-Pacific region to be lacking in this regard because universities within this region paid scant attention towards arms control, biological weapons and the dual use dilemma. In another survey conducted in Asia by the Sandia National Laboratories from the US, it was found that the awareness about the threats perceived from bioterrorism is rather low among scientists, thus raising the vulnerability of laboratories and their safeguards (U.S. Sandia National Laboratories, 2006). There is also a dismal awareness about the misuse of biological weapons in the Asia-Pacific, for as Pearson (2003, p. 9) has pinpointed, "all too often the situation even in developed countries [is] that students in universities are unaware of the BWC and its prohibitions or of national legislation to implement the [BWC]". Pearson (2003, p. 9) further adds, "[t]here is little evidence that medical, scientific or military education programmes even in developed countries include information about the prohibitions and provisions of the [BWC] apart from specialised courses for those interested in international relations, security and arms control".

Further efforts of the BWC to create awareness about the potential misuse of biological agents and toxins as weapons received an additional boost as the ISP of 2008 was specifically tailored towards oversight, education, awareness-raising and adopting codes of conduct with the aim of preventing misuse in relation to the advances in bioscience and biotechnology (UNOG, 2008b, p. 1). The said initiative urged scientists working in the biological sciences to be aware of their obligations in the BWC because this could possibly have social, environmental, health and security repercussions (UNOG, 2008b, pp. 6-7). Furthermore, other professionals working in the biological sciences must be aware of the risks associated with the potential misuse of the biological sciences and biotechnology (UNOG, 2008b, p. 7). The oversight seeking to ensure that the biological sciences and biotechnology are not misused must also cover materials and knowledge both in the public and private sectors.

Pearson (2003, p. 6) divides oversight into two categories, the first being the oversight of the nature and purpose of the proposed work. This first form of oversight requires an overseer to be responsible for the approval of a proposed scientific experiment and to be aware of any prohibitions and regulations (Pearson, 2003, p. 6). Any proposed scientific experiment will have to be evaluated whether it raises any moral, ethical, social, cultural concerns and means to address them prior to being approved. The second type of oversight is the one that monitors the misuse of publicly available information by non-compliant states or subnational groups with vicious intentions (Pearson, 2003, p. 6). This would cover intangible information also available in public domains such as the internet and databases (Pearson, 2003, p. 6). This second form of oversight is the one that concerns the publications of research results, particularly in scientific journals needing censorship. This is because the methods of scientific experiment can be misused for bioterrorism purposes. Glatter (2013, p. 6) though dismisses the simplistic nature of repeating these complex scientific experiments for she argues that tacit knowledge of a practical

experience beyond the textbooks is needed in order to ensure that such experiments are successful. Other scholars like Novossiolova, Minehata and Dando (2012, p. 42) have acknowledged that while modifying biological agents to make them more virulent and resistant to vaccines or antibiotics is not that simple, this is not beyond an individual with basic knowledge of molecular and cell culture techniques. Therefore, there is still a possibility for those having only a basic knowledge of molecular biology and cell culture to repeat such experiments, even more so if they can solicit other experts in this area.

While the BWC forum has proposed the implementation of an oversight mechanism, the ISP of 2008 had stressed the need to involve and obtain inputs from all stakeholders including those from governments, regulatory authorities, funding bodies, academia (administrators and practitioners), industry, publishers and civil society (UNOG, 2008b, p. 14). This can be interpreted to involve a form of public participation from stakeholders in sharing their views based on their respective areas of expertise and competence. This is crucial, as the involvement of scientists in an oversight mechanism involves the tendency to overlook other issues beyond their area of specialisation, and that the decision made to approve an experiment or publication may be biased without the input from other stakeholders. As Kuhlau (2013, p. 59) has stressed, "predetermined notions about risk and benefits or research may change when we interact with other people's perspectives and experiences engaging in deliberative processes may allow scientists [……] to provide more informed, context-sensitive and nuanced messages to the public". By engaging other stakeholders, the decision reached will be based on a consensus that all stakeholders will be responsible for. Moreover, this participatory process should be incorporated in the research proposal stages, findings, execution and dissemination of knowledge through publications, as underlined by the ISP of 2008 (UNOG, 2008b, p. 14). The same ISP also recommended that a scientific advisory panel be formed to oversee the said oversight mechanism (UNOG, 2008b, p. 14).

In creating awareness about the misuse of bioscience and biotechnology, the ISP of 2008 emphasised the need for relevant stakeholders to have access to relevant information such as accessible teaching materials that highlight vital aspects of the BWC (UNOG, 2008b, p. 15). Imparting knowledge about the misuse of bioscience and biotechnology among scientists and other stakeholders will have to be conducted through workshops, seminars, publications, and audio-visual materials (UNOG, 2008b, p. 15). This is indeed a form of public access to information, for before they can participate effectively, there is a need to educate them about the risks associated with the misuse of biotechnology (UNOG, 2008b, p. 15). Most importantly, the ISP of 2008 emphasised the need to coordinate these outreach activities with those of the WHO on biosafety and biosecurity and with the UN Security Council Committee 1540, as these international bodies also have a stake in biosecurity (UNOG, 2008b, p. 15).

A bird flu research that involves the DURC incorporating public participation illustrates such a point. Butler (2012, p. 1) has commented that the WHO meeting that convened in February 2012 in order to discuss the controversial bird flu, i.e. the H5N1 experiment by two researchers from the University of Wisconsin-Madison and Erasmus University, lacked representation from all stakeholders. There were almost no public-health officials of international stature attending or experts in risk assessment, biosafety, and biosecurity (Butler, 2012, p. 1). A pathogen genomics scholar, Paul Keim from the Northern Arizona University in Flagstaff, US, also acting as chair for the National Security Advisory Board for Biosecurity (NSABB) seemed to have been the most obscure individual representing biosecurity at this WHO meeting (Butler, 2012, p. 2). Given the imbalanced participation of stakeholders, having excluded those in bioethics and the social sciences (Butler, 2012, p. 2), it was obvious that the decision of the WHO would be skewed in favour of publishing the controversial bird flu research. Upon review by the NSABB, it was felt that the research on bird flu should only be permitted for publication

after revision to censor certain steps of the experiment and an emphasis on its significance for public health (Greenfieldboyce, 2012).

Thus, the importance of public participation cannot be underestimated as it serves to provide different perspectives from stakeholders in various disciplines. If public participation occurs for the sake of just fulfilling the process without really meaning to seriously consider the views of various stakeholders, this defeats the purpose, particularly if it is clear that the authorities will maintain their views and expect others to endorse those views. In such a case, it would be better to do without public participation at all unless all stakeholders with an open mind are at least willing to consider other views in the decision- making process.

In one US law case, *Klare Allen v. National Institutes of Health* (2013, pp. 14-15) (hereinafter *Klare Allen*), the residents of South End and Roxbury (Boston), who were concerned about the building of the National Emerging Infectious Diseases Laboratories (Biolab) at the Boston University Medical Centre, protested because the Environmental Impact Statement (EIS) prepared by the US National Institute of Health (NIH) had limited inputs from them over their concern for the risk posed by the Biolab. During the drafting of the Final Supplementary Risk Assessment (FSRA), seven meetings were held with the public from 2008-2010 (*Klare Allen*, 2013, p. 68). Among the issues addressed by the public, reference was made to the cost, need and purpose of building the Biolab and the risks of an accidental or deliberate release of select agents, which would disproportionately affect the minority populations in South End and Roxbury (*Klare Allen*, 2013, p. 69). Notably, the public at Roxbury and South End had raised the issue that the FSRA was too technical and they sought to understand it (*Klare Allen*, 2013, p. 70). Subsequently, the NIH prepared an executive summary for the lay audience and a summary of Chapter II of the FSRA that interprets the major findings in plain language for the public to understand (*Klare Allen*, 2013, p. 70). In this context, the NIH has

fulfilled the principle of public participation and access to information by providing the public of Roxbury and South End with the necessary information, thus enabling them to make comments about the Biolab to be built. Indeed, any technical issue, such as biotechnology, as it applies to the Biolab case of Boston University, requires an authority to translate any information disseminated in the simplest of terms in order to enable the public to understand and provide their comments. Regardless of the initiative by the NIH, the plaintiffs from Roxbury and South End were dissatisfied, for they claimed that the NIH developed the FSRA without meaningful public inputs, and so they referred the case to the US District Court of Massachusetts for further review (*Klare Allen*, 2013, p. 66).

The above case also demonstrates the right to seek access to justice, in this case with the District Court of Massachusetts, when the Roxbury and South End residents in Boston felt that their rights were being infringed upon. Indeed, the Biolab in Boston University which would experiment with anthrax, tularaemia, plague and the 1918 H1N1 influenza virus would surely raise ethical and moral concerns needing public opinion on its suitability.

As shown in this section, the principle of public participation and access to information and justice applies to the BWC itself. Secondly, the said principle also applies to the BWC's ISP, with an emphasis on oversight, education, awareness-raising, and the implementation of codes of conduct, as already discussed.

7.7 The Principle of Good Governance in the Biological Weapons Convention

The discussion in this section will analyse the principle of good governance in the context of the BWC. It will be explored whether the BWC has mechanisms that promote mandatory compliance in line with its provisions, since good governance means that member states to the BWC must implement its obligations accordingly as part of their state responsibility. Additionally, merely being compliant with the implementation of the

BWC provisions is not sufficient, as the latter must be conducted in a responsible and transparent manner that promotes accountability. In this context, this section will thus be divided into three sub-sections that elaborate on the mechanisms of the BWC, namely Confidence Building Measures (CBMs), the proposal for a verification Protocol, and the Implementation Support Unit (ISU). It will evaluate whether each of these can potentially contribute towards the principle of good governance which is the crux of the Delhi Declaration.

7.7.1 Confidence Building Measures (CBMs)

CBMs require member states to the BWC to make yearly declarations and provide relevant information concerning their scientific activities, particularly those that can be associated with the development of biological weapons. The Final Declaration of the Second Review Conference to the BWC, held in 1986 in accordance with Article V of the BWC, underlined the importance of member states annually providing information to the United Nations Office for Disarmament Affairs (UNODA) concerning their activities conducted in research centres and laboratories with high levels of containment and involving legitimate biological activities (UNOG, 1986, p. 6). Additionally, member states were to exchange information on the outbreak of infectious diseases and toxins deviating from the normal pattern with regard to the type, development, place and time of occurrence thereof (UNOG, 1986, p. 6). This same Final Declaration also required member states to the BWC to list and encourage the publication of the results from biological research in scientific journals to be shared with the international community in an endeavour to promote transparency (UNOG, 1986, p. 6). The final obligation is to report on any active promotion of contacts between the scientists engaged in biological research, and whether it concerns joint research on a mutually agreed basis (UNOG, 1986, p. 6). It was also agreed at the Second Review Conference of the BWC to determine the modalities for the exchange of information and data among the member states to the BWC

by designing relevant forms that would eventually be filled by the BWC member states (UNOG, 1986, p. 6).

Further requirements to strengthen the CBMs were made at the Third Review Conference of the BWC in 1991 with three additional elements (UNOG, 1991, p. 3). The Final Declaration of the Third Review Conference indicated that the Parties to the BWC would additionally have to declare their relevant legislation, regulations and other measures demonstrating their compliance with the BWC, declaring past activities in offensive or defensive biological research and development programmes, as well as declaring vaccine production facilities, particularly those for human use (UNOG, 1991, pp. 14-15). Thus, all member states to the BWC were to comply with these non-binding CBMs through annual declarations to be provided to the UNODA no later than April 15 of each year (UNOG, 1991, p. 15).

Participation in terms of submitting these declarations in compliance with the CBMs has been far from satisfactory. Dando and Pearson (1997, p. 120) for instance, indicated that seventy member states submitted their CBMs in 1995 and there was an increase to seventy-five submissions in 1996. However, the number of CBM submissions in 2007 had dipped to sixty-one (UNOG, 2008a, p. 7), whereas in 2008 and 2009 it had decreased further despite a slight increase in 2010 (UNOG, 2008b, p. 8; UNOG, 2009, p. 9; UNOG, 2010b, p. 7). As the US has aptly indicated at the Meeting of the States Parties to the BWC in 2013, the average participation rate for CBMs since 1987 (after the Second Review Conference to the BWC was held) merely amounted to 35% (UNOG, 2013c, p. 2). Only in 1991 did participation for CBMs amount to slightly more than 50%, and since the Sixth Review Conference of the BWC in 2006 the CBMs increased to 40% or slightly more (UNOG, 2013c, p. 2). Overall, since 1987 the CBMs hardly exceeded more than 50% (UNOG, 2013c, p. 2). As of 27 November, 2013, merely 34% of the BWC Parties submitted their CBMs, the lowest number since 2005 (UNOG, 2013c, p. 2).

Since there is a dismal participation rate as far as CBMs are concerned, the Seventh Review Conference of the BWC in 2011 agreed that one of the discussion topics that will be revisited for the ISP from 2012-2015 would certainly be CBMs (Kennedy, 2012, p. 1). At the ISP of 2012, the US was certainly supportive of the French, Canadian, UK and Swiss proposal for a peer review and assessment process in reforming the CBMs (Kennedy, 2012, p. 4; "Permanent Mission of the United States", 2012, p. 1). France called for a transparent peer review process whereby each member state will have to submit data (presumably information) with regard to national legislation, regulations and other initiatives obtained through the distribution of questionnaires that will be evaluated by other members through a standardised form (UNOG, 2012a, pp. 2-3). France envisages a peer review mechanism in a modular fashion that enables member states to select particular areas for review, for instance in the area of export controls or biosecurity and biosafety initiatives (UNOG, 2012a, p. 3). A small team of reviewers that are evenly represented geographically will then conduct the review in evaluating whether the key aspects of particular laws are in place (UNOG, 2012a, p. 3). The team of reviewers will critically evaluate a member state's law for deficiencies, recommending changes based on best practices, and the sharing of experiences that will have to be completed within a certain time frame (UNOG, 2012a, pp. 2-4).

While the peer review allows for a consultation and clarification process regarding the implementation of a member state's laws, France (supported by the UK and Australia) proposed on-site mutually agreed visits, in particular to the facilities of the member state being evaluated (UNOG, 2012a, p. 3; UNOG, 2013b, p. 4; UNOG, 2013d, p. 5). This idea of on-site visits for clarification through staff interviews and observation of practices is certainly not new at all as it is similar to the proposal in the aborted verification Protocol that the US vehemently rejected in 2001 (Bailey, 2002, pp. 15-16). The US objected on grounds that such visits are inconclusive in distinguishing whether a member state's

practice is legitimate because of the dual use nature of facilities, equipment and knowledge that can equally apply to both legitimate and illegitimate practices (Bailey, 2002, pp. 15-16). The US cited the case of Iraq in 1991, whereby the UNSCOM inspectors failed to verify whether Iraq was churning biological and toxin weapons, because the equipment and procedures used by the Iraqi facilities resembled civilian use and as a result did not arouse the suspicion of the UNSCOM inspectors (Bailey, 2002, p. 13). In the past, the US also objected to on-site inspections as these would divulge trade and intellectual property secrets concerning how biotechnology companies have maintained their leading edge, fearing that these inspectors could leak valuable information to rival biotechnology firms in other states (Bailey, 2002, pp. 14-15). Therefore, this could be another impediment towards convincing the US to accept on-site inspections.

Indeed, Chevrier (2000, p. 167) had highlighted the merits of on-site inspections in the context of the aborted verification Protocol, stating that "relatively frequent, short-notice, non-challenge visits would increase the probability and risk of detection, thereby increasing deterrence and strengthening grounds for confidence in the [C]onvention [BWC]".

With regard to the peer review mechanism proposed under the ambit of the CBMs, notably these CBMs can now be submitted by any member state through an electronic submission process if they choose to, even though printed forms are still being made available for utilisation (UNOG, 2010a, p. 2). The US, for instance, envisages that such improved electronic reporting will make such information more accessible to other member states for evaluation (UNOG, 2012b, p. 2). This is in line with the Canadian proposal of seeking a clarification procedure to be implemented, whereby other members to the BWC can ask questions and clarifications about another state's CBM submission. This can clarify a state's national laws or regulations in implementing the BWC through the request made to the ISU beyond the existing bilateral channels (UNOG, 2010a, p. 2).

This study suggests that the on-line database maintained by the ISU can be modified to include a section that allows for a question and answer response to any member state's submission of the CBMs, enabling other states to channel queries. The US itself has remarked that the transition towards publicly available CBMs facilitates civil society access, particularly to those in the academia and has enabled them to analyse the CBM data (UNOG, 2012b, p. 2). Whether the peer review mechanism being proposed will receive recognition, this will only be known at the Eighth Review Conference of the BWC in 2016.

7.7.2 The Verification Protocol to the Biological Weapons Convention

The history of the aborted verification Protocol to the BWC began at the Third Review Conference of the BWC in 1991 whereby it was agreed that a group of governmental experts known as VEREX would identify and examine potential verification measures from a scientific and technical standpoint without incorporating any additional measures to the BWC (UNOG, 1991, p. 16). VEREX then considered both off-site and on-site measures and concluded that if these measures were used in combination, it would certainly render the verification procedure more effective (Chevrier, 2000, p. 157).

In September 1994, a special conference to the BWC was convened to consider the findings of VEREX which led to the establishment of a new Ad Hoc Group (AHG) that would draft proposals incorporating some of the VEREX findings into a legally binding instrument strengthening the BWC in the form of a verification Protocol (Chevrier, 2000, p. 157). For the purpose of this study, the focus of the AHG will relate to the measures that promote compliance in accordance with the principle of good governance. Building from the CBMs of the BWC, the proposed verification Protocol would have made it mandatory for all member states to submit their declarations, rather than on a voluntary basis. The verification Protocol included four types of on-site visits. The first type referred

to rather impromptu random visits with very short notice in order to confirm whether the information submitted through the declarations was accurate so as to prevent proliferators from hiding offensive programmes (Chevrier, 2000, p. 159; Keefer, 1999, p. 135). The second type encompassed clarification visits with the intention of clarifying any ambiguities arising from any member state's declarations (Keefer, 1999, p. 135). Requested visits were those that would occur at the request of a BWC member state in order to help them to prepare full and accurate declarations, as well as to enhance the cooperation and assistance among member states in an attempt to resolve any unclear issues related to these declarations (Chevrier, 2000, p. 160). Then, there was the voluntary confidence-building visit whereby a member state submits a list of declared and undeclared facilities to be evaluated by experts nominated by the member state (and not professional staff from the envisioned BWC organisation) so as to increase transparency, communication and regular contact (Chevrier, 2000, p. 160). Under the envisaged international organisation of the BWC, the processing of these declarations will be under the ambit of a Technical Body tasked with conducting the verification and on-site visits as well as analysing data on the disease outbreaks (Keefer, 1999, p. 134). In turn, this Technical Body would be accountable to an Executive Council, another organisation consisting of the member states elected for two-year terms and evenly distributed geographically (Keefer, 1999, p. 133).

The verification Protocol also provided the procedure for lodging a complaint in the alleged non-compliance of any member state in tandem with Article V of the BWC, whereby the complainant must make all attempts to resolve allegations of non-compliance through consultation and cooperation (Keefer, 1999, p. 136). Should this fail, the complainant must then provide all evidence showing that the accused state had indeed violated its obligations under the BWC known as the green light procedure (Chevrier, 2000, p. 162). The green light procedure implicates exposing the complainant, as it has

to reveal any espionage secrets that allowed it to obtain information about non-compliance by the accused state. If the Director General of the Technical Body was satisfied that there was a good cause for further investigations, the matter will be brought to the Executive Council to vote whether a field investigation ought to be initiated (Keefer, 1999, p. 136). The accused state would have to cooperate and provide access to the investigators subjected to its constitutional limitations, proprietary rights and the right to limit access to certain areas unrelated to the investigation (Keefer, 1999, p. 136). At the end of the investigation, a Final Report is issued and should the Executive Council determine that non-compliance occurred, the accused state's rights under the Protocol could be suspended, and collective measures by other member states could be implemented or the matter could be brought before the UN General Assembly (UNGA) or the Security Council (Keefer, 1999, p. 137). Indeed, Russia was quite unhappy with the prospect of the BWC organisation having investigative powers and asserted that the Security Council should solely be vested with investigative powers of the alleged usage of biological weapons (Chevrier, 2000, p. 162). The rationality for Russia's position is understandable since it could use its veto power within the Security Council against any decision taken against it.

Unfortunately, the proposal for on-site visits and in particular random visits became a major stumbling block in accepting the verification Protocol. As already discussed in the sub-section on the CBMs, the US stance has indicated that the Protocol was unverifiable because of the dual use nature of biological agents, toxins and equipment that can concurrently be used for benevolent and malevolent intentions, making it difficult to distinguish apart from the real intention that differs (Bailey, 2002, p. 9). This culminated with the US making a statement at the Fifth Review Conference of the BWC that the "United States will simply not enter into agreements that allow rogue states or others to develop biological weapons. We will continue to reject flawed texts like the BWC draft

Protocol […]" (Bolton, 2001, p. 1). Without the US support and participation particularly in endorsing the Protocol, the negotiations for a verification Protocol broke down completely. It was unfortunate that the negotiations for the verification Protocol broke down simply because it would have created a specific international organisation for the BWC to monitor compliance among member states and to sanction those who fail to abide by their obligations, thus giving more credibility to the BWC. Without this, the BWC has no clout, with the present CBMs being non-binding and permitting the member states to derogate from their obligations and not take their state responsibilities seriously. Ultimately, the Protocol is still the pinnacle providing accountability and transparency in compliance with the principle of good governance.

7.7.3 The Implementation Support Unit (ISU)

At the Sixth Review Conference of the BWC in 2006, an agreement was reached among member states to establish an ISU, consisting of three full-time staff members within the UNODA (UNOG, 2006, p. 8). The ISU's role is purely administrative and it cannot make any decisions to sanction member states in violation of the BWC. Among the tasks of the ISU include the preparation of documentation for the BWC meetings, functioning as an intermediary between member states, international organisations, scientific and academic institutions as well as NGOs (UNOG, 2006, p. 120). The ISU also serves as a focal point for the submission of information and the implementation of the decisions and recommendations made at the Review Conferences by the member states (UNOG, 2006, p. 120).

The ISU also plays a role in relation to the CBMs. Among some of the ISU's duties is ensuring the national contact points for the CBM submission, developing the electronic format, as well as receiving and distributing CBMs, compiling and generating statistics on the BWC member states' participation pertaining to CBMs, and as an information

exchange point providing assistance to those requesting help to prepare the CBMs (UNOG, 2006, p. 120). Furthermore, the ISU must send reminders with regard to the submission of the CBMs (UNOG, 2006, p. 120). Another role designated for the ISU is to be a receiver of information concerning activities that promote the universalisation of the BWC among the member states (UNOG, 2006, p. 23).

It seems apparent from the analysis of the CBMs, the aborted verification Protocol, and the ISU that the BWC does not have a mandatory mechanism capable of strictly enforcing compliance with the BWC obligations. The implication from this analysis is that currently the CBMs within the BWC itself need to be further developed in order to include verification visits and to make all declarations (as discussed) mandatory because in the long term there is no certainty of reviving the discussion of the aborted Protocol given the continuous objections of the US. In such a manner, it will ensure transparency and accountability in abiding by the BWC, in line with the principle of good governance of the Delhi Declaration relating to sustainable development.

7.8 The Biological Weapons Convention's Connection to Other International Biosecurity Instruments through the Principle of Integration

In this section, the analysis will focus on how the principle of integration within the Delhi Declaration is applicable to the BWC, which could then link this biosecurity agreement to other international agreements and initiatives in other biosecurity sectors. In line with the principle of integration in the Delhi Declaration, the BWC will be examined as to whether environmental protection is considered, and whether it addresses international trade and the aspect of social development within the BWC.

7.8.1 Environmental Considerations in the Biological Weapons Convention

7.8.1.1 Extending Environmental Protection beyond Article II of the Biological Weapons Convention

It has been highlighted that the BWC's concern for the environment has been largely reflected by Article II of the said agreement (BWC, 1972). Willet (2005, p. 22) also

highlighted that the BWC is one of the few arms control treaties that paid attention to the environment as reflected in Article II: "[i]n implementing the provisions of this article all necessary safety precautions shall be observed to protect populations and the environment" (BWC, 1972). This means that any destruction of biological weapons in the disarmament process will have to consider its impact on the environment and population (BWC art. II, 1972). Dhanapala (2001, pp. 48-52) makes a distinction between disarmament and arms control in terms of their meanings. According to Dhanapala (2001, pp. 48-52), disarmament "envisages the physical destruction and elimination of a given weapon system, whereas arms control seeks instead to regulate the conditions of its production and/or use." The word destruction contained in Article II of the BWC (1972) obviously implies disarmament, as a member state to the BWC must destroy or divert for peaceful means any biological agents, weapons, equipment and means of delivery that it possesses no later than nine months after entry into force of the BWC following ratification or acceding to the agreement. On the other hand, Article I of the BWC (1972), regarded as the general purposes criterion, prohibits all classes of weapons and seeks to regulate the conditions of production for biological weapons by stating that "[e]ach State Party to this Convention undertakes never in any circumstance to develop, produce, stock pile or otherwise acquire or retain: Microbiological or other biological agents, or toxins whatever their origin or method of production […]." Thus, it is clear that the BWC is an agreement covering both disarmament and arms control.

Environmental protection should also feature strongly in the BWC in tandem with the Resolution Regarding Observance of Environmental Norms in the Drafting and Implementation of Agreements on Disarmament and Arms Control of 2001 ("Thematic", 2001, p. 3) and in line with Article II of the BWC (1972). This Resolution requires states to consider relevant environmental norms in the process of negotiating arms control and disarmament treaties ("Thematic", 2001, p. 3). Moreover, this Resolution also requires

that states should consider the "advances made in science and technologies to enhance security and facilitate disarmament without adverse impact on the environment or to its effective contribution to the attainment of sustainable development" ("Thematic", 2001, p. 3). Since 2001, this Resolution has undergone some profound changes as its adoption in 2012 requested that states do take into account the agreements of the United Nations Conference on Environment and Development (UNCED), as well as prior relevant agreements to the UNCED in the drafting and implementation of disarmament and arms control agreements ("Resolution on the Observance", 2013, p. 1). This shows that by implementing Article II of the BWC (1972), states may consider provisions from the Convention on Biological Diversity (CBD, 1992) or even principles from the Rio Declaration on Environment and Development (Rio Declaration) ("Report of the United Nations", 1992) which constitute instruments related to the outcome of the UNCED.

This Resolution is indeed a soft law document that complements Article II of the BWC (1972), as the latter seems to be unclear. According to Abe (2015, p. 231), a soft law document can have a "clarifying effect" which can provide further clarification to the member states of the BWC regarding the actions they are supposed to take with regard to Article II. In this case, the Resolution covering disarmament and arms control requires states, as members to the arms control agreements, to consider environmental norms if they choose to complement Article II of the BWC (1972).

In providing further credence for the environmental law principles to be considered, in a paper presented at the Meeting on Military Activities and the Environment in Linköping in 1995, the United Nations Environment Programme (UNEP) conceded that military activities during peacetime would also have repercussions on the environment (UNEP, 1995, pp. 9-10). It was asserted that consideration must be given to some of the principles of the Rio Declaration, such as sustainable development, the precautionary approach, an environmental impact assessment, and the polluters pay principle (UNEP, 1995, pp. 9-

10). During the said meeting, the UNEP also emphasised that "[i]nternational conventions and protocols in the field of environment also provide principles and guidelines in which the military sector could find environmental norms applicable to it" (UNEP, 1995, p. 10). Therefore, this certainly provides an impetus for the BWC to also refer to principles of international environment law as they are contained in the Rio Declaration, the Stockholm Declaration (UNCHE, 1972) and the Delhi Declaration. Since the above Resolution of 2012 and the UNEP in its outcome paper from the meeting in 1995 are supportive of arms control agreements such as the BWC in considering environmental norms, there is no longer an excuse among the member states of the BWC not to consider the principles from the Delhi Declaration of the ISDL. This is also an incentive for this study to analyse how the principles from the Delhi Declaration are relevant to the BWC context, thereby requiring an analysis within this chapter.

Indeed, environmental concerns within the BWC should apply to all stages of biological weapons formulation – from its initiation to destruction and not merely limited to disarmament. Scholars such as Brophy (1990, pp. 63-113), Dhanapala (1999, pp. 1-2), Joffe (2004, p. 1) and even the UNODA (1993, p. 6) have indicated that in cases of manufacturing, storing, testing, training exercises, establishment of military bases, deployment, scraping and destruction of these weapons all have an impact on the environment during peacetime military activities. Thus, environmental considerations should not only be limited to disarmament within Article II of the BWC (1972) but should be reflected in other situations, too.

Additionally, the UNEP has also included accidents as another contributing factor to environmental contamination (UNEP, 1995, p. 3). The forms of environmental damage envisaged by the UNEP as a result of military activities throughout the whole production cycle of weapons include soil contamination, groundwater pollution, air pollution, harm to or destruction of flora, fauna, and their habitats and the destruction of landscapes

(UNEP, 1995, pp. 3-4). As an example of air pollution, the accidental release of anthrax at Sverdlovsk, Soviet Union, back in 1979 which claimed seventy lives, was attributed to failure on the part of the maintenance personnel to replace a critical filter in a vent, thus resulting in anthrax being released as the former Soviet Union was embarking on the production and manufacturing of a biological weapon (Wampler & Blanton, 2001, p. 6). Another form of environmental contamination from air pollution arising from the former Soviet Union's field testing of smallpox on Vozrozhdeniye Island occurred in July, 1971, when a research ship carrying a female technician charged with taking plankton samples from the Aral Sea came within 15 kilometres too close to said island and drove into a plume of smallpox being released by the Soviets (Zelicoff, 2002, pp. 20-21). This technician survived the smallpox as she was vaccinated, but caused an outbreak at Aralsk sickening ten people and killing three (Tucker & Zilinskas, 2002a, p. 7; Zelicoff, 2002, p. 13).

Likewise, the case of anthrax tested by the UK on Gruinard Island off the North West Scottish coast in the 1940s ensured that this island remained uninhabitable for forty-eight years as the anthrax spores contaminated the ground and survived for a long time in the aforementioned environment (McLaguhlin, 2009, p. 61). After a few unsuccessful attempts to decontaminate this island, such efforts finally succeeded in 1987 (McLaughlin, 2009, p. 62). Prior to the decontamination, Gruinard Island was off limits for animal grazing, as anthrax could infect the animals to cause diseases, while all other human habitation, industrial and commercial activities were entirely prohibited (McLaughlin, 2009, p. 62). Gruinard Island illustrates the environmental contamination of the soil, the destruction of the landscape, and the harm caused to the flora and fauna, as identified by the UNEP (UNEP, 1995, pp. 3-4). Hence, it has been shown that the development, manufacturing and testing of biological weapons would indeed result in environmental contamination. This also confirms Brophy's (1990, p. 74) warning that

"[e]ach stage in the development and manufacturing of a weapon system has risks of environmental harm." Brophy (1990, p. 74) further adds, "[i]n the early phase, these are limited to risks of [an] accident", as already shown by the case of anthrax and smallpox in the former Soviet Union discussed above. It is for this reason that the Final Declaration from the Third Review Conference of the BWC in 1991 in connection with Article I of the BWC (1972) indicated that "experimentation involving open-air release of pathogens or toxins harmful to man, animals or plants that has no justification for prophylactic, protective, or other peaceful purposes is inconsistent with […] Article I" (UNOG, 1991, p. 3), hinting at the former Soviet Union's biological weapons manufacturing, development and testing. This same Final Declaration (UNOG, 1991, p. 4) again reiterated that the member states to the BWC must observe all safety precautions in order to protect the population and the environment as evidenced by those who perished and by the environmental contamination caused by the Sverdlovsk and smallpox testing on Vozrozhdeniye Island.

UNEP, too, has emphasised the need "[t]o reduce or mitigate the harmful effects of military activities on the environment and to encourage a positive role for the military sector in environmental protection" (UNEP, 2001b, p. 16). The UNEP had embarked on a survey of the states in order to seek information regarding the extent to which their military complied with international environmental law and domestic law during peacetime (UNEP, 2001b, p. 16). Moreover, the UNEP also sought to "[p]romote laws and policies that encourage consideration, in designing new weapons and military equipment, of their environmental effects throughout their life cycle, i.e., in their production, transport, use and disposal" (UNEP, 2001b, p. 16). Therefore, the military sector in any state should not take environmental considerations lightly. Since biological weapons testing causes environmental degradation, as evidenced by the cases of Gruinard Island (UK) and those of the former Soviet Union, states that are BWC members should

never develop biological weapons as this is against Article I, the general purpose criterion of the BWC (1972). The UNEP has also underlined "the feasibility of developing legal mechanisms for mitigating damage caused by military activities", particularly in removing military hardware and restoring any environmental damage caused by military activities (UNEP, 2001b, pp. 16-17).

7.8.1.2 Linkages with the Cartagena Protocol on Biosafety

(a) ***Learning from the Biosafety Clearing House (BCH)***

It is apparent that Article X (1) (BWC, 1972), which promotes "the fullest possible exchange of equipment, materials and scientific and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes" is the catalyst for the transfer of technology and know-how to promote peaceful uses of biotechnology for agriculture and medicine (Dando & Pearson, 1997, p. 122). In this context, developing states have raised the relevance of the CBD, Agenda 21, the Rio Declaration and the then on-going negotiations on the Cartagena Protocol on Biosafety (CPB) during the period 1996-1997 (Dando & Pearson, 1997, p. 122). In particular, it was stressed that Agenda 21 in Chapter 16 focuses on the Environmentally Sound Management of Biotechnology which covers the usage of biotechnology in order to increase the quantities of food and raw materials, for better health care and protection of the environment (Dando & Pearson, 1997, p. 122; Division for Sustainable Development [DSD], 1992a). Dando and Pearson (1997, p. 122) had identified a range of specific provisions from the CBD which were relevant for the peaceful uses of microbiology and biotechnology such as Article 5 on cooperation, Article 12 on research and training, access to the transfer of technology in Article 16, exchange of information in Article 17, and technical and scientific cooperation in Article 18 (CBD, 1992). Likewise, under the auspices of the NAM and in the course of negotiating for a verification Protocol to the BWC, the developing states also referred

to the CBD concerning the transfer of biotechnology for peaceful purposes in line with Article X (2) of the BWC which promotes economic and technological development (Barnaby, 1997, p. 309; Dando & Pearson, 1997, p. 122).

The reference to the CBD, Agenda 21, the Rio Declaration and the then on-going negotiations for the CPB indeed drew a strong reaction from the developed states at the Fourth Review Conference of the BWC in 1996 (Dando & Pearson, 1997, p. 123). There, the European Union (EU) made a statement about taking note of all these encouraging developments in the aftermath of the UNCED but also asserted that the BWC forum should not digress from its own scope of work and avoid duplication of the work conducted in other forums (Dando & Pearson, 1997, p. 123). This implies that developed states were trying to divert the discussion about biotechnology knowledge transfer and equipment away from the BWC, which would impede the biotechnology development of developing states (Barnaby, 1997, p. 309). Instead, the developed states stressed many existing bilateral and multilateral programmes, whereby some were the outcome of Agenda 21 and that of the CBD in order to avert a discussion of Article X of the BWC (Barnaby, 1997, p. 309). In any case, it is worth mentioning that the Final Declaration emerging from the Fourth Review Conference of the BWC in 1996 did include in one paragraph the significant steps in the biological field taken by the UNCED with the adoption of Agenda 21, the Rio Declaration, and the CBD – complementing the work of the BWC (UNOG, 1996, p. 10).

Indeed, there are some valuable lessons to be drawn from linkages between the CBD, CPB, and BWC. Pearson (1996, p. 5) has suggested that it would be valuable to refer to the CBD, as well as CPB, and particularly to their initiative of clearing-house mechanisms as well as capacity building (Pearson, 2011, pp. 8-10). The existing ISU, formed as part of the outcome of the Sixth Review Conference of the BWC which acts as a clearing-house mechanism, had taken the cue from the clearing-house mechanism of the CBD and

CPB. The present ISU (in the BWC) now acts as a clearing-house mechanism as agreed to in the Report of Meeting of State Parties to the BWC in 2009 (UNOG, 2009, p. 8) so as to facilitate the communication of partnerships for sources of cooperation and assistance among the BWC members. This is in line with having an appropriate mechanism to facilitate the broadest possible transfer and exchange of materials, as well as scientific and technological information, on the use of bacteriological (biological) and toxin agents for peaceful purposes.

The ISU's clearing house mechanism now follows some initiatives of the Biosafety Clearing House (BCH) example from the CPB. This includes useful contact points among national agencies pertaining to biological weapons, and also the relevant laws, regulations and guidelines in this area (Convention on Biological Diversity Secretariat [CBD Secretariat], 2013, p. 11). Pearson also views the BCH as a useful instrument that lists training workshops, internships, study tours, partnerships and a discussion forum that can be emulated by the BWC (Pearson, 2011, p. 9).

(b) ***Learning from Capacity Building Efforts of the Cartagena Protocol on Biosafety***

The BWC has also learned valuable lessons from the CPB's capacity building efforts. The BWC's Intersessional Process (ISP) of 2010 focused on the issue of assistance and coordination with relevant organisations should any member to the BWC request help in the case of alleged use of biological weapons, and to improve national capabilities for disease surveillance, detection and diagnosis for their public health systems (UNOG, 2010b, p. 4). In the section on building national capacity for the BWC members, training to strengthen human resources through frequent seminars, international workshops, courses, along with the dissemination of experiences and best practices were emphasised in the ISP of 2010 (UNOG, 2010b, p. 9). Other collaborative efforts include identifying opportunities for research on detection equipment or in fundamental and transnational

research among the member states (UNOG, 2010b, p. 9). Capacity building has also been identified with regard to the cooperation with developing states on research and development for vaccines and diagnostic reagents, and between International Reference Laboratories and research institutions (UNOG, 2010b, p. 12).

Likewise, the BWC's ISP of 2009 focused on the implementation of Article X concerning international cooperation, assistance and exchange in biological sciences and technology for peaceful purposes, promoting capacity building in the fields of disease surveillance, detection, diagnosis and containment of diseases (UNOG, 2009, p. 2). The ISP of 2009 also addressed the need for assistance and coordination with relevant organisations based on a request from any member over the alleged use of a biological weapon or toxin and to improve disease surveillance, detection and diagnosis (UNOG, 2009, p. 2). For instance, in the area of disease surveillance, detection, diagnosis and containment, capacity building has been reflected in the need to train human resources through workshops, training courses, conferences, computer-based and hands-on training so as to use the necessary equipment for the said purposes or otherwise the medical equipment would become redundant (UNOG, 2009, p. 6). Additionally, the training of human resources for disease surveillance also encourages the promotion of contact and the dissemination of experiences between professional institutions and the relevant personnel (UNOG, 2009, p. 15). Furthermore, hands-on training exercises for biosafety, biosecurity, the use of personal protective equipment and measures for the transport of dangerous goods all make up the crux of the capacity building initiative (UNOG, 2009, p. 15).

Indeed, all of the capacity building efforts from the BWC have certainly taken their cue from the CPB as the latter abides by the Final Document from the Seventh Review Conference of the BWC in 2011 to use any "existing institutional means within the [UN] system and other international organisations, in accordance with their respective

mandates, to promote the objectives of [Article X]" (UNOG, 2011, p. 17). Having benefited from emulating initiatives of the CPB, the Chairman of the Meeting of the States Parties to the BWC in June 2012 invited the CBD Secretariat to its meeting of experts in July 2012 (Delmi, 2012, p. 9). This was in order to enable the CBD Secretariat to share their experience regarding the clearing-house mechanism of the CBD and the BCH of the CPB (Delmi, 2012, p. 9). There was no indication whether the CBD Secretariat accepted this invitation (Delmi, 2012, p. 9). However, the UNEP's representative did attend the BWC's ISP 2008 experts meeting, indicating willingness to share and learn from the CPB's capacity building initiative (Duthie, 2008, pp. 6-7).

Moreover, this mutual cooperation between the UNEP and the CBD Secretariat has continued as the ISU of the BWC in 2013 reported continuous contact (UNOG, 2013a, pp. 2-3). Since contacts exist between the BWC, CBD Secretariat and the CPB, this can be extended further particularly in raising awareness among the CPB members about the misuse of genetic engineering for biological warfare and bioterrorism. This is in view of the fact that these issues have been sidelined even though they have repercussions for the CPB, as elaborated in Chapter 6.

(c) ***Incorporating Risk Assessment***

Another point of relevance of the CPB to the BWC has been observed from Pearson's (2008, p. 3) suggestion to incorporate the risk assessment and risk management processes of the CPB within the BWC's context. In Annex I of the Report of the Meeting of the States Parties to the BWC in 2008, it may be observed that risk assessment has been mentioned whereby the members to the BWC must ensure that "biosafety and biosecurity risk assessments cover risks to humans, animals and plants" (UNOG, 2008b, p. 13). In this same Report, the members of the BWC have been urged to seek "guidance and assistance provided by relevant international organisations" (UNOG, 2008b, p. 13)

wherein Pearson (2008, p. 3) recommends assistance and inputs from the capacity building initiative of the CPB.

Similarly, Nexon (2011, p. 6) stressed that "biorisk assessment and management, tailored to each specific facility, should address both safety and security issues simultaneously, taking into account actual concerns and avoiding redundant and unnecessary measures, in a cost-benefit approach." The *Tri-Valley Cares v. United States Department of Energy (DOE)* (2010) (hereinafter *Tri-Valley Cares*) case illustrates the merger of a risk assessment for biosafety and laboratory biosecurity. The preparation of an Environmental Assessment (EA) in the US pertaining to the construction of a Biosafety Level Three (BSL-3) laboratory handling infectious biological agents harmful and lethal to human health such as the Lawrence Livermore Laboratory (LLNL) in California must consider laboratory biosecurity matters. The EA must consider the environmental impact of a terrorist attack as evidenced by the *Tri-Valley Cares v. Department of Energy* (2006, pp. 6-7) whereby the United States Court of Appeals for the Ninth Circuit indicated there is a need to do so.[7]

Therefore, the risk analysis conducted by the DOE in the US through the EA failed to consider laboratory biosecurity concerning the loss, theft and misuse of biological agents and equipment for bioterrorism. This had prompted the US Court of Appeals for the Ninth Circuit to direct "DOE to consider whether the threat of terrorist activity necessitated the preparation of an environmental impact statement" (*Tri-Valley Cares*, 2006, pp. 1-2). Subsequently, the DOE revised its EA to include potential scenarios of terrorist attacks such as a direct terrorist attack at the LLNL BSL-3 facility resulting in the loss of containment, theft and release of pathogenic material by an LLNL BSL-3

[7] Refer to *Tri-Valley Cares* of 2006 on page 6. The judgment mentioned the following: *"Concerning the [Department of Energy's] DOE's conclusion that consideration of the effects of a terrorist attack is not required in its Environment Assessment [EA], we recently held to the contrary in San Luis Obispo Mothers for Peace v. Nuclear Regulatory Commission, […]. In Mothers for Peace, […] we held that an [EA] that does not consider the possibility of a terrorist attack is inadequate."*

terrorist outsider and insider (*Tri-Valley Cares*, 2012, p. 10). It is apparent that the US court has placed a serious emphasis on the need for a risk assessment in the form of an EA in order to strictly consider laboratory biosecurity measures apart from biosafety. Otherwise, this would not have resulted in the DOE having to redraft its whole EA to include possible scenarios of terrorist attacks, along with their probability and risk management measures.

Another scenario whereby a risk analysis could be useful would be to evaluate the threats associated with scientific advances. In such a scenario, a risk analysis would be useful if only a form of scientific advisory committee be formed first in the BWC since it currently lacks one. This is unlike the CPB which calls for a scientific advisory committee to evaluate the applications of GMOs in every member state to the CPB (CPB art. 16, 2000). Lange and Thränert (2006, p. 22), for instance, propose a scientific advisory committee for the BWC in order to evaluate any threat associated with scientific advances. This could entail risk from genetic engineering, synthetic biology, bioinformatics and other relevant areas of biology if misused. The scientific advisory committee could forewarn states of the misuse of these applications for biological warfare or bioterrorism and the need to withhold relevant information if need be.

The scientific advisory committee can also conduct a risk analysis in the context of reviewing the DURC articles to be published. Indeed, it has to be evaluated whether there is a need for censoring the scientific methods used should these assist terrorists in modifying biological agents to become more virulent, resistant to antibiotics or vaccines for bioterrorism. The opponents of censorship will argue that this will hamper the scientific dissemination of information, as withholding methodology is unethical and non-transparent (Glatter, 2013, p. 3; Lange & Thränert, 2006, p. 22). Opponents also contend that censoring methodology will not matter in that the methods can be easily found in textbooks and practice (Glatter, 2013, p. 4; Lange & Thränert, 2006, p. 24).

Lange and Thränert (2006, p. 24) have contended that students can easily learn the principles of gene technology in order to subsequently work with dangerous biological agents. The supporters of censoring publications cite that more laboratories with less stringent lab biosecurity regulations may be more inclined to work with dangerous biological agents using the available publications and may thus cause an unintentional release (Inglesby, Cicero & Henderson, 2011, pp. 151-152; Osterholm & Henderson, 2012, pp. 801-802). Glatter (2013, p. 6) himself contends that it is not so easy for individuals to create lethal biological agents because this requires tacit knowledge, a skill not readily available through research methodology publications, but one which may be acquired through practical experience over time, as well as consistent observation of peers. Moreover, Glatter (2013, p. 6) highlights despite significant financial means and vast expertise of scientists with different backgrounds in biology, chemistry and engineering in order to design lethal biological agents, it will not be easy for terrorists to develop biological weapons on a large scale. In any case, the Report of the Meeting of the State Parties to the BWC in 2008 has now considered an international scientific advisory panel as an oversight mechanism envisioned to monitor people, resource and knowledge throughout the entire scientific experimental stages, starting from the proposal stage and the request for funding, through to the execution and dissemination of information (UNOG, 2008b, p. 14). It is the dissemination stage that concerns controversial scientific publications needing censorship which requires a risk assessment and management process.

Based on the above discussion, it would seem apparent that the BWC has indeed incorporated environmental considerations within Article II (BWC, 1972) in the context of disarmament. Secondly, the BWC has forged links with the CBD Secretariat in order to learn from the good practices of the CPB initiatives, as already discussed.

7.8.2 International Trade Considerations in the Biological Weapons Convention

The relevant provision dealing with international trade for biological agents, toxins, equipment and means of delivery is found in Article III of the BWC (1972), which specifically addresses export control. In particular, Article III of the BWC (1972) mentions that "[e]ach State Party to this Convention undertakes not to transfer to any recipient whatsoever, directly or indirectly, and not in any way assist, encourage, or induce any state, group of states or international organisations to manufacture or otherwise acquire any of the agents, toxins, weapons, equipment, or means of delivery […]". This provision has been intended for the member states to the BWC in order for them to introduce national laws in the form of export controls that restrain the trade of biological agents, toxins, weapons, equipment or the means of delivery, particularly to hostile states with illicit biological weapons programmes.

Article III of the BWC has its limitations, as it "is directed exclusively at the problem of state-run military programmes involving biological weapons; that non-state actors might develop or use biological weapons is scarcely within the treaty's ambit" (Kellman, 2002a, p. 726). This indicates that the BWC was never meant to target terrorists who develop biological weapons because during its inception in 1972 it was thought that biological weapons can only be developed at the behest of a government, as non-state actors would normally lack the capability to do so (Gronvall, 2012, p. 64). Therefore, terrorists who acquire, retain, produce or develop biological agents and toxins for a biological weapon's attack or transfer and distribute equipment considered to be crucial for the development of biological weapons would have escaped prosecution, as there was no international law making it mandatory for most states to criminalise these terrorist activities (Gronvall, 2012, p. 64). Nevertheless, the BWC is not entirely devoid of any initiative to address terrorist initiatives, particularly with the use of biological agents and toxins for bioterrorism. The Final Declaration from the Fourth Review Conference of the

Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxins Weapons and on their Destruction (December, 1996) does refer to terrorists as subnational groups or individuals that ought to be prevented from acquiring, through transfers, biological agents and toxins for other than peaceful purposes (UNOG, 1996, p. 4).

Prevention in this context requires that the BWC members enact laws that would prevent terrorists from acquiring or transferring biological agents and toxins for bioterrorism. Additionally, the Final Declaration from the Fourth Review Conference of the BWC, in its interpretation of Article IV of the BWC, mentioned the obligation of the members to the BWC "to exclude use of biological and toxin weapons in terrorist or criminal activity" (UNOG, 1996, p. 4). In this sense, Gronvall (2012, p. 64) and Kellman (2002a, p. 726) were right to claim that the BWC has its deficiencies for failing to address the criminalisation of terrorist activities in acquiring, producing, developing, retaining or transferring biological agents and toxins before a biological weapons attack and instead merely addresses the "use" of biological agents by terrorists. Hence, it cannot be said that the BWC has entirely ignored bioterrorism because terrorist use associated with a criminal activity did feature in the Final Declaration of the Fourth Review Conference of the BWC, as already elaborated. Moreover, calls to address bioterrorism within the framework of the BWC have resulted in an acknowledgement of this issue as reflected by paragraph 7 of the Final Declarations of the Sixth and Seventh Review Conferences of the BWC (UNOG, 2006, p. 8; UNOG, 2011, p. 9).[8]

[8] Paragraph 7 from the Sixth and Seventh Review Conferences of the BWC mentions:
"Their conviction that terrorism in all its forms and manifestations and whatever its motivation, is abhorrent and unacceptable to the international community, and that terrorists must be prevented from developing, producing, stockpiling, or otherwise acquiring or retaining, and using under any circumstances, biological agents and toxins, equipment, or means of delivery agents or toxins, for non-peaceful purposes, and their recognition of the contribution of full and effective implementation of United Nations Security Council Resolution 1540 by all states to assist in achieving the objective of this Convention."

Willigen and Bruggen (2012, p. 5) have also indicated that the BWC itself is incapable of addressing bioterrorism as it would have to rely on other binding international initiatives such as Resolution 1540 of the United Nations Security Council (UNSC). As previously discussed, the BWC had implicitly addressed terrorists with reference to the individuals or subnational groups contained in the Final Declaration of the Fourth Review Conference to the BWC – contrary to the views of Willigen and Bruggen. The BWC has also indicated the measures to be taken by the member states through the ISP process of 2007 that deliberated on the "ways and means to enhance national implementation, including enforcement of national legislation, strengthening of national institutions and coordination among national law enforcement institutions" to implement Article III covering export controls and Article IV on national implementation measures (UNOG, 2008a, p. 1). These national measures include actions seeking to deal with biological weapons in a national disaster or to formulate counter terrorism plans, as discussed during the ISP process of 2007 (UNOG, 2008a, p. 12). Other initiatives require the members to the BWC to adopt the appropriate legislative, administrative and regulatory means that would cover all prohibitions to the BWC such as the development, production, stockpiling, acquisition, retention or transfer of agents, toxins, weapons and means of delivery, as stipulated in Article I (UNOG, 2008a, p. 8). Most importantly, the members to the BWC must incorporate in their laws the criminalisation of the use of agents, toxins, weapons, equipment and means of delivery, as contained in Article I because there was no need for such criminalisation up to this stage (UNOG, 2008a, p. 8).

Additionally, the ISP process of 2007 made it very clear for the members to the BWC to impose further export control measures. The members to the BWC had to develop controls on the internal or external transfers of biological agents, toxins and equipment in order to secure a chain of custody between facilities and the authorised personnel through the issuance of licenses upon review of an application (UNOG, 2008a, p. 8). Member

states in their export control law must also have a list of the relevant agents, toxins, and equipment that are of dual use in nature in order to refer them to the enforcement authorities so as to determine whether any of these items can be potentially misused (UNOG, 2008a, p. 8). The export control law would also have to cover the re-exports, transhipment and transit of any biological agents or toxins, equipment or means of delivery transported by rail, road, air, waterways or by sea. The member states to the BWC were also encouraged to have an automatic computer notification system documenting the characteristics of the sender and receiver as a form of database in order to enable the detection of any suspicious transactions that may involve the smuggling of biological agents, toxins and equipment (UNOG, 2008a, pp. 8-9). Therefore, the requirement for export controls to be implemented in national laws and the requirement for counter terrorism plans, as discussed in the 2007 ISP process, certainly do not depict the BWC as being incapable of addressing bioterrorism as claimed by Willigen and Bruggen (2012). With the BWC urging its members to implement export control laws, this complements the Resolution 1540 of the UNSC (S.C. Res. 1540, 2004), which also addresses the transfer and export controls targeting non-state actors, and specifically terrorists.

The deliberation of Resolution 1540 of the UNSC targeting non-state actors is not, however, within the scope of this study and is best discussed elsewhere. In any case, the text interpreting the BWC should be evolutive and should reflect the changes currently being implemented such as the need to address bioterrorism. Revill and Dando (2009, p. 56) have stated that "[w]hile multilateral arms control and partial disarmament agreements have a fixed central text to work from, they are reconstructed and updated through additional understandings which reflect changing concerns based on the perception by States Parties of the evolving geostrategic context." This is precisely the direction the BWC has taken, as reflected by the ISP of 2007 which expanded on Articles

III and IV of the BWC (1972) in order to incorporate the measures taken by the members thereof to address bioterrorism.

Nonetheless, export control measures are not without their limitations. Roberts (1998, p. 241) has indicated that export controls will be ineffective because of the dual use nature of biological agents, equipment and knowledge both for civilian and military purposes, making it hard to distinguish the true intent of importation. Since biological agents can be smuggled in small quantities and easily hidden, export controls may be redundant. Thomas Butler, who was arrested in 2003 in the US for smuggling plague from Tanzania without proper documentation, indicated that the most convenient way for a scientist to smuggle a biological agent is through a vial in a pocket normally practiced among fellow scientists (Alvania, 2004, p. 5; Drennan, 2003, p. 1). This being the case, export control laws may not work well in preventing the smuggling of a biological agent.

Rapid changes in technology through the diffusion of materials and technologies for legitimate medical and commercial biotechnology purposes and the appearance of new suppliers on the market may also render export controls redundant (Roberts, 1998, p. 242). This is the view advocated by Carlson (2003, p. 7), Petro, Plasse and McNulty (2003, p. 165) and Roberts (1998, p. 242) who all reckon that skills such as genetic engineering, equipment that synthesises genes easily, and commercially available kits with simple recipes that permit the transfer of genes from one organism to another will undermine export controls. Their view was challenged by Koblentz (2009, p. 213) who pointed out that the Japanese cult Aum Shinrikyo, despite possessing all the financial means, equipment and scientists from various backgrounds to turn anthrax into a biological weapon, did not succeed in their endeavour. Therefore, the advancements in technology, availability of equipment, and easy dissemination of genetic engineering skills cannot be said to render export controls redundant for the Aum Shinrikyo experience has proven otherwise.

It has also been argued by Roberts (1998, pp. 242-244) that export controls are ineffective because not all states bar the exports of biological agents and equipment to rogue states or perhaps even to terrorists. In countering this argument, Koblentz (2009, pp. 215-216) retorts that states will not supply terrorists with biological weapons because they fear retaliation from other states. Moreover, states sponsoring the biological weapons themselves may fear that terrorists could retaliate against them using the biological weapons (Koblentz, 2009, p. 216). Since there are states that are non-members to the BWC, it is for this reason that Resolution 1540 came into being, as it is binding on all states to impose it under Chapter VII of the UN Charter (S. C. Res. 1540, 2004). The imposition of this Resolution requires that all states of the UN prevent or prohibit the transfer of biological agents, toxins and equipment through their national laws, thereby countering bioterrorism.

Considering that biological agents and toxins can also be found in nature and changed into biological weapons easily, export controls are also ineffective (Lange & Thränert, 2006, p. 25). In countering this argument, Koblentz (2009, p. 213) indicated that Endo, one of the Aum Shinrikyo members, sought to cultivate a lethal strain of botulinum toxin from the wild but was unsuccessful. This shows that it is not an easy process to cultivate biological agents from the wild let alone to turn them into a biological weapon.

The NAM states such as Iran, India, Pakistan and China have also criticised export controls for undermining developing states from obtaining the necessary technology transfer, equipment, biological agents and toxins for their biotechnological development in the sciences, medicine and commercial industries. This is contrary to Article X (1) of the BWC (1972) which promotes the fullest possible exchange of equipment and knowledge for the peaceful use of biotechnology (Ward, 2004, p. 10). In particular, the NAM hardliners have criticised the Australia Group, an exclusive club of developed states that created an informal international arrangement relating to the licensing of transfer of

biological agents, toxins, and equipment (Enemark, 2000, p. 28). The Australia Group also decide whether the necessary technology could be transferred to other states provided they are not suspected of conducting illicit biological weapons programmes (Enemark, 2000, p. 28). The Australia Group also have lists of biological agents, toxins and equipment that are of a dual-use nature, as well as share intelligence concerning the activities of the proliferators, such that they refuse to divulge this information to the errant states of the BWC (Lange & Thränert, 2006, p. 25; Ward, 2004, p. 11). It is for this reason that Iran, India, Pakistan, and China have used the NAM in order to voice their displeasure because these states are suspected of pursuing biological weapons programmes in contravention of the BWC (Ward, 2004, p. 10). As Roberts (1998, p. 244) has indicated, it is not that other NAM states are ignorant of the objectives of their erstwhile co-members, instead they are worried that these rogue states may well be the proliferators they need to be aware of. Hence, if the Australia Group wishes to impose export controls, they should not target all of the NAM states, but merely those selected few with proven records of pursuing biological weapons.

The next subsection will argue that Article X (1) of the BWC, which addresses the mutual cooperation between states and international organisations in order to facilitate scientific discoveries in the area of bacteriology, would cover the international social law of the ISDL, emphasising the initiatives of the WHO.

7.8.3 International Social Law in the Biological Weapons Convention

7.8.3.1 Linkages with the World Health Organisation

Within the BWC, the impetus for collaborating with the WHO is through Article X(1) which encourages the Parties to the BWC "to cooperate in contributing individually or together with other States or international organisations to the further development and application of scientific discoveries in the field of bacteriology (biology) for prevention

of disease […]" (BWC, 1972). It is obvious that the WHO's role complements the BWC in relation to disease surveillance detection, diagnosis and containment of diseases, whether naturally occurring or deliberately inflicted, as is evident from the Report of the Meeting of the States Parties from the ISP of 2009 (UNOG, 2009, p. 4). The WHO itself, for instance, has been given an observer status at the ISP meetings of 2007, 2008, 2009 and 2010 considering that addressing diseases within the BWC's scope of work overlaps with that of the WHO (UNOG, 2008a, p. 4; UNOG, 2008b, p. 3; UNOG, 2009, p. 4; UNOG, 2010b, p. 3).

Indeed, the BWC's ISP of 2009 specifically focused on the implementation of Article X (1) of the BWC (1972), as this meeting provided all the details concerning the actions to be taken by the members at the national, regional and international levels. The ISP of 2009 underlined the need for the members of the BWC to develop an effective infrastructure for disease surveillance, detection, diagnosis and containment by implementing effective surveillance systems for collecting and analysing data from various sources (UNOG, 2009, p. 5). An effective infrastructure for disease surveillance would also require epidemiological response capabilities, the necessary regulatory framework, and quick facilitation for treating diseases, such as diagnostic equipment, vaccines and medicines (UNOG, 2009, pp. 5-6). BWC members are to take advantage of advances in science and technology in order to improve disease detection such as utilising the environmental and climate data collected by satellites (UNOG, 2009, pp. 5-6). Other mechanisms to be implemented include real time information sharing and data management of diseases, as well as developing a national strategic plan for the purpose of monitoring and evaluation by means of standard risk management tools (UNOG, 2009, pp. 5-6). Human resources trained in the use of various items of equipment and types of infrastructure for disease surveillance, detection and diagnosis have also been emphasised (UNOG, 2009, p. 6). As such, those involved in the training would be able to promote

contact and the dissemination of experiences between professional institutions and relevant personnel (UNOG, 2009, p. 15).

Additionally, Article VII of the BWC, which urges the members to the BWC to provide support or assistance to any other state that has been exposed to danger as a result of the violation of the BWC, is another common means shared by the BWC and WHO in favour of mutual cooperation (BWC, 1972). The ISP of 2010 was specifically geared towards providing specific details concerning the implementation of Article VII of the BWC, as the alleged use of biological or toxin weapons can be overcome if the members improve their national capabilities for disease surveillance, detection, diagnosis and public health systems (UNOG, 2010b, p. 2). In particular, it was recognised from the Report of Meeting of the States Parties from the ISP of 2010 that the WHO, FAO, the World Customs Organisation, and the International Criminal Police Organisation all had "to work together more closely, strictly within their respective mandates, to address specific relevant aspects of the threats posed by the use of biological and toxin weapons, and to assist State Parties to build their national capacities" (UNOG, 2010b, p. 6). Moreover, it was also asserted that the "International Health Regulations 2005 [are] important for building capacity to prevent, protect against, control and respond to the international spread of disease" (UNOG, 2010b, p. 6). This being the case, it is quite apparent there are two means for the BWC forum to work very closely with the WHO in combating diseases, as well as on the basis of the IHR 2005 since this falls within the latter's specialised scope of work and is not the BWC's forte.

Indeed, this distinction as to the scope of work of the BWC and WHO has continued for the following reason. Kelle (2007, p. 228) indicated that the UN Secretary General's High-Level Panel on Threats, Challenges and Change Report of December, 2004 had requested the Security Council to consult with the WHO Director General in establishing the necessary procedures for working together in case of a suspicious or overwhelming

outbreak of an infectious disease. This would have made it difficult to draw any distinction between the scope of work of the BWC and that of the WHO. Enemark (2005a, p. 486; 2010, p. 492) has been very critical of the said Report for he argues that "[i]f WHO resources were used to investigate a politically motivated accusation of [biological weapon] BW use, [...] this could tarnish the non-partisan image upon which the Organisation [WHO] relies to work effectively." Enemark (2010, p. 492) further adds that "[s]o much of the access and good will accorded the WHO is dependent on its reputation as a neutral, scientific body. Too close an association with the Security Council, […] might make some countries reluctant to co-operate with WHO investigations." Therefore, the WHO should not be tasked with investigating biological weapons allegations, but should instead work within its mandate in providing relevant data of disease surveillance or otherwise risk losing its neutrality.

Unlike the provisions of the UN Secretary General's Report, the BWC forum merely expected the WHO to work within its mandate as evidenced by the Final Declaration of the Seventh BWC Review Conference of December, 2011, wherein the member states implementing Article VII of the BWC should work with the "appropriate intergovernmental organisation in accordance *with their respective mandates*, such as the [WHO]" (UNOG, 2011, p. 14). Indeed, the relevance of the principle of integration from the Delhi Declaration (ILA, 2002) cannot be denied in the context of Article X (1) and Article VII of the BWC (1972). These two provisions, as mentioned already, have shown the BWC to be highly integrative beyond addressing arms control to include diseases within the ambit of international social law of the ISDL. This has facilitated the collaboration with the WHO.

In preparing for the eventuality that the member states to the BWC could be exposed to diseases arising from biological warfare or bioterrorism, the ISP of 2010 has been instrumental in emphasising national capacity building (UNOG, 2010b, p. 9). These

preparatory initiatives include encouraging collaborative research, such as creating detection equipment for any usage of biological weapons, sharing advanced knowledge concerning the utilisation of portable detectors, protective equipment, means to develop new vaccines, effective drugs and modern decontamination equipment (UNOG, 2010b, p. 9). At the national level, contingency plans detailing the procedures and practices to tackle a biological weapons attack must also be implemented (UNOG, 2010b, p. 9). Other measures include securing water and food supplies, and the ability to operate in contaminated locations (UNOG, 2010b, p. 9). The member states of the BWC must also assume responsibility for the safety and security of all biological materials and facilities within their territory, implying a stringent enforcement of state responsibility and accountability (UNOG, 2010b, p. 9).

As far as disease detection and surveillance are concerned, the ISP 2010 outlined further initiatives to be taken by the member states of the BWC. Chemical and biological detection techniques, whether static or mobile, have been encouraged while BWC member states are incentivised to use modern tools for sampling, epidemiological intelligence and investigation (UNOG, 2010b, p. 10). Disease detection can also be better facilitated if the BWC members develop their own forensic capabilities. This is crucial for providing evidence in the prosecution cases involving the alleged use of a biological or toxin weapon (UNOG, 2010b, p. 10).

Apart from the above, the role and contribution of the WHO to the work of the BWC have been reflected in the area of biosafety and biosecurity. The ISP of 2008 was devoted to a discussion on "national, regional and international measures to improve biosafety and biosecurity, including laboratory safety and security of pathogens and toxins", thereby emphasising the role of the WHO in providing the relevant guidance and standards of biosafety and biosecurity to the BWC (UNOG, 2008b, p. 5). This referred to the WHO's manual for an elaborate biosecurity plan among the states, referred to as Biorisk

Management: Laboratory Biosecurity Guidance (UNOG, 2008b, p. 5; WHO, 2006). The BWC itself does not have the capability to address biosecurity, as this is the attribution of the WHO with which the BWC will have to collaborate. Much more will be elaborated in Chapter 8 on the WHO's Biorisk Management: Laboratory Biosecurity Guidance (WHO, 2006), outlining the measures to be taken by the member states to the BWC in order to ensure safe laboratory biosecurity.

Thus, the findings pertaining to the reflection of the ISDL principles among the provisions of the BWC and its accompanying soft law documents is being summarised in Table 7.1 based on the analysis and elaboration made previously in this chapter.

Table 7.1: Reflection on the International Sustainable Development Law Principles among the Biological Weapons Convention Provisions and Soft Law Documents.

2002 New Delhi Declaration	**Relevant Biological Weapons Convention (BWC) provisions / Soft law documents to the BWC**
The duty of the states to ensure sustainable use of natural resources	• Reflected by Article II, addressing harm to the environment and the population in the context of disarmament such as the decontamination on Vozrozhdeniye Island (Renaissance Island), Fort Sherman, Panama; Zhejiang and Hunan, China.
The principle of equity and the eradication of poverty	• Reflected in Article X (2), stipulating that the BWC be implemented not to hamper the technological or economic development of the member states for peaceful bacteriological activities (biotechnology) especially among developing states (intragenerational equity). Future generations are deprived of their livelihood (intergenerational equity) due to the contaminated land resulting from the testing of biological weapons.
The principle of common but differentiated responsibilities	• Reflected by Article X (1), promoting the fullest possible exchange of equipment, materials, scientific and technological information, perceived to transfer the necessary by developed to developing states in decontamination cases.

'Table 7.1, continued'

2002 New Delhi Declaration	Relevant Biological Weapons Convention (BWC) provisions / Soft law documents to the BWC
The principle of the precautionary approach to human health, natural resources and ecosystems	• Not directly reflected in the BWC but applies in taking preventive measures by having criminal laws in place to prevent and penalise catastrophic bioterrorism (Intersessional Process (ISP) 2007), drafting of biosafety and laboratory biosecurity measures (ISP 2008), and censorship of Dual Use Research of Concern (DURC) publications.
The principle of public participation and access to information and justice	• Although not directly reflected among the BWC provisions, soft law documents indicate participation by the inclusion of bioterrorism and biowarfare experts, Non-Governmental Organisation (NGOs), industry, academia besides states (Meeting of Experts and ISPs). Also reflected by state and non-state actors is the participation of various disciplines in deciding the publication of the DURC in the ISP 2008 meeting documents. Soft law documents to the BWC stress the access to medical, scientific and military textbooks concerning the misuse of biological agents (Second Review Conference, 1986).
The principle of good governance	• Reflected by Article V on Confidence Building Measures (CBM) concerning the compliance with the BWC, yet this is voluntary on behalf of the member states. The ISU is purely administrative. Since the BWC does not have a mandatory enforcement mechanism, it does not fully fulfil the principle of good governance.
The principle of integration	• Reflected by Article X (1) on prevention, protection, control of diseases (WHO and International Health Regulations 2005), Article VII (assistance when exposed to danger), Article III (prevent transfer and export control laws), and Article X (2) in promoting cooperation with the Convention on Biological Diversity (CBD) Secretariat and the CPB.

7.9 Conclusion

This chapter analysed the relevant provisions of the BWC with reference to the principles of international law from the Delhi Declaration, wherever applicable. Upon examining each of these principles, it has been shown that these principles are either reflected explicitly or implicitly despite the BWC or through the soft law documents

emerging from the Meeting of the States Parties through the ISPs of 2007-2009 and 2012-2013 not making sustainable development an objective.

Based on these findings, the BWC is not solely an arms control and disarmament agreement dealing with military matters, but one that incorporates environmental, trade and social issues in a balanced manner in order to achieve sustainable development.

The revelation that the BWC is capable of fulfilling sustainable development as an objective entails an implication for the ISDL. Indeed, doubts can now be raised whether ISDL's jurisdiction should be within the boundaries of international environmental, economic and social law or whether it should be broadened to include other branches of international law equally capable of meeting sustainable development as an objective. This requires a rethinking among the founders of the ISDL, namely the ILA so as to redefine the meaning of the ISDL to accommodate other areas of international law also able to subscribe to sustainable development beyond the existing boundaries.

CHAPTER 8: BIOSECURITY INITIATIVES OF THE WORLD HEALTH ORGANISATION AND INTERNATIONAL SUSTAINABLE DEVELOPMENT LAW

8.1 Introduction

Previously, the analysis of the Biological Weapons Convention (BWC) through the principles of International Sustainable Development Law (ISDL) in Chapter 7 referred to disease detection, diagnosis, prevention and surveillance that were not under the direct purview of the BWC. This would fall under the purview of the World Health Organisation (WHO) as per the International Health Regulations 2005 (IHR 2005). It was also highlighted in Chapter 6 that pharmaceuticals for humans using genetic engineering were not covered by the Cartagena Protocol on Biosafety (CPB), but instead fall within the ambit of the WHO. Similarly, the case of laboratory biosecurity is not within the scope of the CPB or the BWC, but under the preview of the WHO. This present chapter has the objective of analysing the reflection of principles from the New Delhi Declaration of ISDL among the provisions from the IHR 2005 wherever this is applicable. As for the WHO's laboratory biosecurity and biopharming initiatives, the relevant guidelines monitoring these matters will not be subjected to an analysis of the ISDL principles because these are not international agreements with binding provisions. Instead, the linkage of biopharming and laboratory biosecurity will all depend on whether the CPB and BWC have integrative provisions facilitating collaborative work with the WHO in these areas.

In this regard, the analysis in this chapter starts with an elaboration of the IHR 2005 in light of the ISDL principles, which is then followed by the WHO's laboratory biosecurity guidance and dual use issues. Subsequently, an elaboration of the WHO's pharmaceuticals initiative addressed by relevant WHO guidelines will be made and lastly the conclusion to this present chapter will be formulated.

8.2 The International Health Regulations 2005

Tracing back its history to the International Sanitary Regulations of 1951 that were subsequently revised and renamed the International Health Regulations of 1969 (IHR 1969), the present IHR 2005 has certainly had a long past (Hardiman, 2003, p. 208). The current IHR 2005 has the purpose "to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks [while avoiding] unnecessary interference with international traffic and trade" as contained in Article 2 (IHR 2005, 2005). Disease itself has been defined within Article 1 of the IHR 2005 (2005) as "an illness or medical condition, irrespective of origin or source that presents or could present significant harm to humans." Without distinguishing the origin of a disease, the IHR 2005 enables all forms of diseases to be covered, be it communicable or non-communicable, naturally occurring, accidentally caused or intentionally created. It is this broad definition of a disease that permits the IHR 2005 to refer to a disease that stems from a genetically modified biological agent and likely to become more virulent, antibiotic or vaccine resistant and intentionally released into the environment possibly to cause an epidemic. The IHR 2005 now covers all forms of diseases and is not limited to cholera, plague and yellow fever as per the IHR 1969 (Baker & Fidler, 2006, p. 1058).

The present scope of the IHR 2005 has been extended to cover diseases stemming from biological, chemical and radiological threats although this is not directly implied (IHR 2005 art. 1, 2005). In the case of releasing a biological weapon, the latter can be released deliberately from a high containment facility because of inadequate laboratory biosecurity measures or by terrorists through theft and subsequent misuse of bioterrorism. Likewise, the IHR 2005 through its broad definition of the term disease can cover diseases derived from acts of food terrorism that target the food supply chain for human consumption as discussed in Chapter 4 in the German *Escherichia Coli (E. coli)* case (WHO, 2008, p. 34).

For monitoring food borne diseases, the International Food Safety Authorities Network (INFOSAN) receives reports on contaminated food, whether imported or exported, that is thought to endanger human health (WHO, 2008, p. 34). In this sense, the term disease within the IHR 2005 is flexible enough to encompass all forms of diseases regardless of their origin. Indeed, concerns were raised that the IHR 2005 would duplicate the work of other international agreements such as the BWC while the WHO should maintain its neutrality and not be involved in weapons of mass destruction (WMDs) and security (Fidler, 2005, p. 355). As the IHR 2005 would encompass a disease animating from the usage of a biological agent that is accidentally or deliberately released, it is obvious there are linkages with the BWC's work. Moreover, it was also deliberated whether the scope of work of the IHR 2005 would either conflict or overlap with other international agreements and organisations (Fidler, 2005, p. 364).

In resolving this matter, the WHO decided to produce a list of international agreements that the scope of work of the IHR 2005 would overlap, and that would identify the BWC and CPB (WHO, 2004a, p. 426). As it was apparent that the IHR 2005 could be linked with other international agreements and organisations, additional provisions now in the form of Article 14 addressing the cooperation of the WHO with intergovernmental organisations and international bodies, and Article 57 dealing with other international agreements would facilitate a mutual coordination with the CPB and BWC (IHR 2005, 2005). These two provisions mentioned in the IHR 2005 reflect the principle of integration of ISDL enabling the WHO to form linkages with other international agreements.

Furthermore, the principle of integration has been reflected by the IHR 2005 emphasising human rights, and forming part of international social law through Article 32 concerning the treatment of travellers to respect their dignity, human rights and fundamental freedoms should they be subjected to any medical examination, vaccination

or prophylaxis (IHR 2005, 2005). Article 32 of the IHR 2005 (2005) places an emphasis on treating travellers with courtesy and respect, as well as considering their gender, sociocultural, ethnic and religious backgrounds forming the crux of human rights. Additionally, Article 3 of the IHR 2005 (2005) similarly highlights the full respect for the dignity, human rights and fundamental freedoms of persons. In *Kiyutin v. Russia* (2011, p. 9), the European Court of Human Rights (ECHR) referred to the 2006 International Guidelines on Human Immuno Deficiency Syndrome (HIV/AIDS) and Human Rights document that in turn referred to the IHR 1969, which restricted travelling on grounds of yellow fever. The ECHR though could not agree with Mr. Kiyutin being barred as a permanent resident from Russia because of HIV/AIDS, as this constituted a violation of his human rights (*Kiyutin v. Russia*, 2011, p. 9). The case of *Kiyutin v. Russia* (2011, p. 9) indeed emphasises the human rights aspect of the IHR 1969 so as not to perpetuate discrimination.

It is also highlighted that the IHR 2005 also bears a reference to international trade law, as Article 2 elaborating on its purpose and scope "to prevent, protect against, control and provide a public health response to the international spread of disease" must avoid unnecessary interference with international traffic and trade (IHR 2005, 2005). Past negotiations of the IHR 2005 reveal that the actions taken within the ambit of this Agreement must also be streamlined with the measures taken within the Agreement on the Application of Sanitary and Phytosanitary Measures (hereinafter Sanitary and Phytosanitary (SPS) Agreement) of the World Trade Organisation (WTO) (Huei, 2006, p. 515). As stressed by Wilson, Brownstein and Filder (2010, p. 507), "[s]tate Parties applying measures that are more restrictive of trade and intrusive for travellers than recommendations issued by the WHO must provide the WHO with the public health rationale and scientific evidence justifying such measures." It is Article 43(2) addressing the additional health measures of the IHR 2005 that incentivise member states to justify

their stringent actions based on scientific principles (IHR 2005, 2005). Article 43(2) (b) of the IHR 2005 (2005) applies the precautionary approach as it states that "where such [scientific] evidence is insufficient, the available information including from WHO and other relevant intergovernmental organisation and international bodies" will have to be relied on. This is in line with Article 2.2 and Article 5.7 of the SPS Agreement focusing on the precautionary approach to ensure that any health measures taken are not arbitrary nor a disguised restriction on international trade (Huei, 2006, pp. 524-525).

In addition to international trade law, it is observed that the IHR 2005 has also considered the environmental impacts as a consequence of undertaking health measures. Article 22(3) of the IHR 2005 (2005) covering the role of competent authorities in disinsection, derrating, disinfection, decontamination and other sanitary procedures stresses the need to avoid injury to persons, or damage to the environment that impacts public health or causes damage to baggage, cargo, containers, conveyances, goods and postal parcels. Based on the analysis conducted, the view is that the IHR 2005 is highly integrative as it addresses human rights concerns abiding by the international social law, having an environmental component through Article 22(3) and emphasising on international trade law through Article 2 (IHR 2005, 2005). The IHR 2005 (2005) is also highly integrative as it facilitates a possible collaboration with other international organisations and international law agreements, such as the CPB and BWC, as discussed earlier in Article 14 and Article 57, respectively.

The IHR 2005 has also set an unprecedented example in international law, as it no longer exclusively relies on states to report a health related event constituting a Public Health Emergency of International Concern (PHEIC) as reflected by Article 6 and a public health risk to other states through the international spread of a disease (IHR 2005, 2005). This is because the WHO can also collect, analyse and use information from other governments, intergovernmental organisations and Non-Governmental Organisations

(NGOs) as indicated in Article 9 of the IHR 2005 (2005). However, Article 9(1) of the IHR 2005 (2005) requires the WHO to obtain verification from the states as to whether a health related event reported by other non-state actors is indeed true. Additionally, member states must designate a national IHR Focal Point of contact accessible at all times, as reflected by Article 4 to communicate and report a health related event (IHR 2005, 2005). By enabling other non-state actors and governments to report a health related event in another state, this implies that the IHR 2005 complies with the principle of public participation and access to information in conformance with ISDL (ILA, 2002). In this sense, the present IHR 2005 is no longer a traditional international agreement relying on states alone to report on a health related event.

While the inclusion of other non-state actors to report about a health related event is commendable, Fidler (2005, p. 375) has criticised the IHR 2005 as it entails the limitation of having to reveal the non-state actor source to the state affected by the spread of the disease. This may deter the non-state actor from revealing any information for fear of retaliation, particularly from an oppressive or authoritarian state. It is only under certain circumstances that the WHO may be duly justified in hiding the confidentiality of the source (Fidler, 2005, p. 375). The justification for the IHR 2005 to incorporate non-state actors to report a health related event is because some states, such as China that once faced the Severe Acute Respiratory Syndrome (SARS) pandemic in 2003, were reluctant to report this incident to the WHO for fear of jeopardising their economy and foreign trade (Hesketh, 2003, pp. 532-538; Liu, 2004, pp. 532-538). A similar case is that of the plague outbreak in Surat, India back in 1994 whereby Indian officials suppressed the international reporting of this incident (Lakoff, 2010, p. 70). Therefore, the reporting of a health related event by non-state actors certainly promotes transparency and accountability in meeting the principle of good governance of ISDL (ILA, 2002) in the event that states are secretive and choose to hide a spread of disease within their territory.

Related with the above discussion is whether a state is obliged to report a health related event as part of its state responsibility so as not to cause disease contamination in other states. In the case concerning the *Differences between New Zealand and France Concerning the Interpretations or Application of Two Agreements Conducted on 9 July 1986 between the Two States and which related to the Problems Arising from the Rainbow Warrior Affair (N. Z. v. Fr.)* (1986, pp. 215-284) (hereinafter *Rainbow Warrior Arbitration*), it was stated that "[…] any violation by a state of any obligation, of whatever origin, give rise to state responsibility." Going back to the case of SARS in China between 2002 and 2003, the Chinese central authorities were hiding the severity of the outbreak and refused to cooperate with WHO officials to control the disease (Reader, 2006, p. 525). If the present IHR 2005 had been applied then, China could have been implicated for failing to inform the WHO and containing SARS as the present Agreement covers all diseases and not merely those restricted to yellow fever, cholera and plague, unlike the IHR 1969. Fortunately for China, the IHR 1969 still applied during the SARS outbreak of 2002-2003 and this country could not be punished (Fidler, 2003, p. 2). A different scenario is applicable to Indonesia as in 2006-2007, this country stopped providing timely notifications of the bird flu outbreak (H5N1) among humans and refused to share H5N1 isolates with the WHO, since previously the WHO permitted an Australian pharmaceutical company to patent a vaccine from an Indonesian avian flu strain (Holbrooke & Garret, 2008, p. 1; Lakoff, 2010, p. 61). Holbrooke and Garrett (2008, p. 1) accused Indonesia of violation of the IHR 2005 for failing to report the outbreak of bird flu in its territory in a timely manner.

Based on the aforementioned cases, it has to be established whether a customary international law exists that renders states dutifully bound to report to the WHO an outbreak of diseases in their territory. This is tantamount to extrapolating the principle of the duty of states in order to ensure the sustainable use of their natural resources and not

cause damage to other states or areas beyond the limits of their national jurisdiction. Based on the case of SARS in China, plague in India and the bird flu in Indonesia, there is no consistent state practice to indicate a customary international law making states dutifully bound to report the outbreaks of diseases. This leads to the conclusion put forth by Fidler (1997, pp. 61-62) suggesting that states can be accountable for failing to inform about diseases within their territory through state responsibility. However, the IHR 2005 being a binding agreement among the states that have signed and ratified it, commits them to fulfil their obligations in good faith. It should not be discounted that the spread of diseases can affect another state's territory to cause contamination. For example, the transportation of chickens infected with bird flu from one state to another would infect other chickens in the receiving state. If the state of origin fails to inform the receiving state of the chickens infected with bird flu, the state of origin is in breach of the state duty to ensure the sustainable use of its natural resources if contamination occurs in the receiving states as transboundary harm.

Referring back to Indonesia's refusal to share the H5N1 isolates with the WHO, it is asserted that the principle of equity and the eradication of poverty is relevant (ILA, 2002). Inequality exists between developed and developing states, as Indonesia provided influenza virus samples to the WHO but could hardly obtain the necessary vaccine for its impoverished population since the developed states secured most of the vaccine supplies for themselves (Smallman, 2013, p. 22). It is for this reason that the developing states stress upon vaccine development to counter the lack of vaccine supply globally. This is also in line with the WHO's resolution, WHA 55.11 (WHO, 2002b) on health and sustainable development urging member states to provide funds for new drugs and vaccines to prevent diseases caused by poverty. Worse still, upon supplying the avian flu strain, Indonesia was subjected to the case of biopiracy, since an Australian pharmaceutical company had already patented this strain (Lakoff, 2010, p. 61). Moreover,

the cost of such a vaccine would not have been affordable to most Indonesians, with a limited supply being largely provided to developed states (Lakoff, 2010, p. 61). Indonesia's denial in providing the avian flu samples to the WHO was in protest against its mistreatment, as Indonesia wanted to secure its material interest in seeking to ensure equitable access to pharmaceuticals. As implied by Fidler (2010, p 1), "[d]eveloping countries and [the] WHO identified the lack of equity in how developed countries were securing access to the vaccine." There is also no doubt that this issue involved Access and Benefit Sharing (ABS) and was central to the Convention on Biological Diversity (CBD) (Smallman, 2013, pp. 24-25). As indicated by Feldbaum and Michaud (2010, p. 4), "the IHR were adopted because they served powerful state interests, and accordingly some developing countries view the IHR as an instrument of the foreign policy and national security interests of developed countries seeking protection from epidemics emanating abroad." This succinctly reflects Indonesia's position as its grounds for protest were based on equity in the global distribution of medicines.

In furtherance of the above incident, it can be said that Indonesia's reluctance to share the avian flu samples with the WHO has its justification. Indonesia perceived the avian flu strains as coming from its territory and coined the term "viral sovereignty" to demonstrate its sovereignty over the biological samples isolated within its territory (Fidler, 2010, p. 3). This also implies that Indonesia is asserting the duty of states in order to ensure the sustainable use of its natural resources because this state feels it should have control over the avian flu virus that originated from its territory. Indeed, Indonesia's position has been further bolstered considering that the developing states perceiving a threat on behalf of their developed counterparts in philandering their biological resources insisted that the Nagoya Protocol on Access and Benefit-Sharing would include an acknowledgement in its preamble of the IHR 2005 in ensuring access to human biological agents for public health preparedness and response (Greiber et al., 2012, p. 46). Thus,

biopiracy associated with the IHR 2005 is certainly linked with the Nagoya Protocol on Access and Benefit-Sharing, another environment agreement. Indonesia has also been vindicated as its protest led to the WHO in 2011 formulating the Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits (PIPF), a multilateral benefit-sharing arrangement not only seeking to provide equitable access to affordable vaccines among the developing states but also to secure the flow of influenza virus samples to the WHO in order to analyse and assess public health risks as well as to ensure that readily vaccines are available (Greiber et al., 2012, p. 42).

Besides Indonesia, another case in Saudi Arabia in 2013 similarly raised the need to immediately report the discovery of the human betacorona virus 2c EMC (hCoV-EMC), named after the Erasmus Medical Centre (EMC) where Ron Fouchier, a famous virologist who sequenced the unknown coronavirus given by an Egyptian scientist, Ali Mohamed Zaki who in June, 2012 served at the Dr Soliman Fakeeh Hospital in Jeddah (Butler, 2013, pp. 1-2). Since the coronavirus came from a sample in Jeddah, Saudi Arabia, the Saudi authorities raised the alarm of biopiracy considering they had lost biological sovereignty over the coronavirus to the Netherlands (Butler, 2013, p. 2). It was also alleged that the Saudi authorities did not report the new round of coronavirus in a timely manner, as stipulated by Article 7 of the IHR 2005 since the Egyptian scientist allegedly kept his work a secret (Butler, 2013, p. 2). This was denied as the Egyptian scientist reportedly announced his discovery on Pro-MED mal, an on-line surveillance disease reporting system that conforms to the need of disease surveillance and monitoring in accordance with Article 5 of the IHR 2005 (Butler, 2013, p. 2). In any case, researchers now wanting to obtain the new strain of the coronavirus must first sign an EMC Material Transfer Agreement (MTA) as this virus now is patented in the Netherlands (Butler, 2013, p. 2). Based on the case of Indonesia and Saudi Arabia, there is good reason among developing

states in being weary of the IHR 2005, as under the pretext of notifying and giving biological agents to the WHO, abuse is inherent through biopiracy. This is certainly against the principle of equity and the eradication of poverty of the ISDL as already discussed.

In another instance, the principle of common but differentiated responsibilities has been reflected through the building of surveillance infrastructure differentiating capabilities between developed and developing states through Article 5 of the IHR 2005 (2005). Article 5(1) of the IHR 2005 (2005) requires member states to address the surveillance infrastructure and capabilities able to detect, access, notify and report health events. As the IHR 2005 came into force in 2007, Article 5(1) gives a grace period of five years from the execution date for its members to implement their surveillance infrastructure (IHR 2005, 2005). This means that the disease surveillance infrastructure has to be in place by 2012, yet in March 2014 it was reported that only a minority out of 194 states have been able to develop their disease surveillance capacity ("Biomedical Briefing", 2014, p. 226). Switzerland, during the negotiations of the IHR 2005 highlighted capacity building in terms of resources financially and personnel among the developing states in expectation to meet this disease surveillance requirement (Government of Switzerland, 2004, p. 4). Besides this, assistance in building the necessary infrastructure and technical know-how ought to be developed among developing states, requiring member states to the IHR 2005 to collaborate with one another in providing the necessary support (Baker & Fidler, 2006, p. 1060). Article 5(3) of the IHR 2005 (2005), while emphasising that the WHO should assist member states to develop, strengthen and maintain their capacities, does not mention the source of funding for capacity building.

As indicated by Baker and Fidler (2006, p. 1063), since the IHR 2005 does not include any financing mechanism, this leaves member states to bear their own financial costs of improving their own local, intermediate and national surveillance capabilities. Since

developing states face the impediment in meeting their disease surveillance capabilities, it has been suggested by Wilson, Brownstein and Fidler (2010, p. 508) that the WHO should collaborate with other global health partners such as the World Bank and the Group of 20 (G20) affluent states to provide the necessary funding for capacity building. This implies a gap between developing states as the receivers of funding and capacity building, with the affluent states serving as donors directly or indirectly through international organisations or trainers in line with the principle of common but differentiated responsibilities. If developing states have not met their surveillance capabilities by 2012, Article 5(2) of the IHR 2005 (2005) provides an extension of another two years for the implementation thereof with a justified reason and another two years extension until 2016 with the approval from the Director General of the WHO considering the advice of the Review Committee established by Article 50. This importance of disease surveillance received recognition in one WHO resolution referred to as WHA 55.16 whereby its preamble recognised "the most effective methods of preparing for deliberately caused disease is to strengthen public health surveillance and response activities for naturally or accidentally occurring diseases" (WHO, 2002a, p. 2). Therefore, it is also crucial that developing states are given assistance in building their disease surveillance capabilities to prevent an unwarranted incident as indicated by said Resolution WHA 55.16 (WHO, 2002a).

In assessing whether the IHR 2005 abides by the principle of good governance in ISDL, it will be evaluated whether this international agreement has a system of compliance and dispute settlement. Wilson et al. (2010, p. 507) and the WHO itself have acknowledged the weakness of the IHR 2005 as not containing any provision addressing an enforcement mechanism (WHO, 2009 p. 3). By the WHO's own admission, the IHR 2005 relies on peer pressure in order to ensure its enforcement such as reporting about the breakout of a disease and having the capacity for disease surveillance (WHO, 2009, p. 3).

As indicated earlier, the member states to the IHR 2005 are already slacking, as a report from March, 2014 indicated that not all members have their disease surveillance infrastructure in place ("Biomedical Briefing", 2014, p. 226). As for reporting about a disease outbreak, member states who do not want to suffer the embarrassment of a tarnished image, fear of travel and trade restrictions, economic and social disruption, and public outrage will prompt them to abide by the IHR 2005 (WHO, 2009, p. 3). This however did not deter states such as China with SARS and India with plague in the past to succumb to peer pressure, as they still chose to hide the disease breakout in their states. Without an enforcement mechanism similar to the BWC, it is envisioned that the member states to the IHR 2005 will linger to meet their obligations in this Agreement. Therefore, an enforcement mechanism of compliance is needed for the IHR 2005, but this depends whether its member states are willing to agree.

In evaluating whether the IHR 2005 meets the principle of good governance, it is worth to also examine its dispute settlement procedure. Article 56(1) of the IHR 2005 (2005) asserts that member states in the first instant of a dispute are to settle it through negotiations or other peaceful means such as good offices, mediation or conciliation. If the dispute is not settled, this can be referred to the offices of the Director General of the WHO to settle it as per Article 56(2) of the IHR 2005 (2005). Article 56(3) of the IHR 2005 (2005) permits the disputed member states to accept arbitration through the Permanent Court of Arbitration Optional Rules for Arbitrating Disputes between Two States by sending a declaration in writing to the Director General of the WHO. The last option contained in Article 56(4) of the IHR 2005 (2005) enables member states to settle a dispute through any dispute settlement mechanism of other intergovernmental organisations established under any international agreement. Therefore, the IHR 2005 entails several detailed stages of provisions designed to enable a dispute settlement. Based on the above, it is evaluated that the IHR 2005 does not fully fulfil the principle of good

governance as it lacks an enforcement mechanism for compliance but it contains provisions for a dispute settlement.

Indeed, the elaboration of the IHR 2005 against the seven principles of ISDL from the Delhi Declaration have indicated that all of these principles have found a place among the provisions of the IHR 2005 in the attainment of sustainable development as summarised in Table 8.1 below.

Table 8.1: Reflection of International Sustainable Development Law Principles among the International Health Regulations 2005 Provisions and Soft Law Documents

2002 New Delhi Declaration	**Relevant International Health Regulations 2005 (IHR 2005) provisions/ Soft law documents to the IHR 2005**
The duty of states to ensure the sustainable use of natural resources	• Reflected by Article 6 of IHR 2005 to report a Public Health Emergency of International Concern (PHEIC) such as the Severe Acute Respiratory Syndrome (SARS) in China (2003), bird flu (H5N1) in Indonesia (2006-7) and plague in India (1994), whereby the reluctance of states to report a PHEIC spreads diseases and can cause environmental contamination.
The principle of equity and the eradication of poverty	• Not directly reflected in IHR 2005 but the WHO's resolution WHA 55.11 on health and sustainable development classifies funding for new drugs and vaccines as relevant. Indonesia's reluctance to provide bird flu strains to a pharmaceutical company is because of patents, access and benefit sharing and its inability to purchase vaccines with inflated prices for its poor.
The principle of common but differentiated responsibilities	• Reflected by Article 5 (3) seeking to develop, strengthen and maintain diseases surveillance capabilities but no funding and technical support is mentioned directly in IHR 2005 thus needing assistance from the World Bank and affluent G20 countries to assist developing states.
The principle of the precautionary approach to human health, natural resources and ecosystems	• Reflected by Article 43 (2) (b) that stringent health measures have to be based on scientific principles.

'Table 8.1 continued'

2002 New Delhi Declaration	Relevant IHR 2005 provisions/ Soft law documents to the IHR 2005
The principle of public participation and access to information and justice	• Reflected by Article 9 permitting the WHO to collect, analyse and use information from Non-Governmental (NGOs) and intergovernmental organisations for reporting diseases of a Public Health Emergency of International Concern (PHEIC).
The principle of good governance	• Reflected by Article 9 on the NGOs ability to report diseases promoting transparency and accountability, while the IHR 2005 implementation based on peer pressure for enforcement is ineffective governance. Article 56 (1) on dispute settlement mechanisms reflects good governance.
The principle of integration	• Reflected by Article 14 (WHO cooperation with intergovernmental organisations and international bodies), Article 57 (dealing with other international agreements), Article 3 and Article 32 (respect for human rights of travellers, their dignity and freedom), Article 2 and Article 17 (d) covering international traffic and trade shall not be hampered by a public health response, and Article 22 (3) addressing environment and health.

8.3 Laboratory Biosecurity and Dual Use Initiatives of the World Health Organisation

Earlier in Chapter 7, it was emphasised that the BWC had stressed upon the WHO's laboratory biosecurity initiative as a guide of safe practices to ensure the security of laboratories against bioterrorism. The Biorisk Management: Laboratory Biosecurity Guidance (2006), a non-binding guideline underlines a biorisk management approach based on biosafety, laboratory biosecurity and ethical responsibility among states to handle and store valuable biological materials (VBMs) and emphasises on the legal framework of the states holding and supporting these laboratories. Laboratory biosecurity goes beyond the containment principles, technologies and practices to prevent the unintentional exposure to biological agents and toxins as emphasised by biosafety. Laboratory biosecurity stresses whether there are security actions to be taken in order to

ensure that VBMs are sufficiently protected to prevent their intentional and accidental release into the environment (WHO, 2006, p. 7). In achieving this goal, a biorisk management approach underlines the inputs from various representatives of an institution handling VBMs, combining scientific directors, principal investigators, biosafety officers, laboratory scientific staff, maintenance staff, administrators, information technology staff, law enforcement agencies and security staff (WHO, 2006, p. 7). All of them have their own roles to play in preventing the unauthorised access, loss, theft, misuse, diversion or intentional release of biological agents and dual use equipment for malicious intent (WHO, 2006, p. 7).

In achieving the above goal, a comprehensive laboratory biosecurity plan has been implemented to include physical biosecurity, covering security personnel, control and document access to these laboratories, restriction to the restricted areas only for authorised personnel and monitoring the traffic in and out of these restricted areas (WHO, 2006, p. 26). Zaki (2010, p. S73) also argues that physical biosecurity should additionally have a security camera system and an intrusion alarm system, while Jonsson, Cole, Roy, Perlin and Byrne (2013, p. 3) stress the importance of a multi-layered security system, with each layer acting as a barrier preventing an intruder with malicious intent from stealing VBMs from the hidden area in which they are located. Jonsson et al. (2013, p. 3) describe the multi-layered physical security system of a laboratory as (1) having a perimeter with fences and ballards with controlled access points, (2) a building with electronic access controls or a biometric system capable of identifying whether an individual should be permitted into the restricted areas, (3) another additional access control system in the laboratory environment, and (4) having secured locks among the biological agent storage units for the freezers storing these biological agents. Moreover, the physical security of a building housing the laboratory which handles the select agents with Biosafety Level 3 (BSL-3) and 4 (BSL-4) should benefit from emergency power

combining both the centralised and backup power sources in order to ensure that critical systems continue to function for an additional duration of time until the arrival of the law enforcement and emergency response personnel (Jonsson et al., 2013, p. 4). The WHO's Biorisk Management: Laboratory Biosecurity Guidance (WHO, 2006, pp. 24-25) also underlines the crucial need of emergency response protocols in the event that an emergency occurs, be it through fire, natural risks such as earthquakes, hurricanes, floods, tsunamis or those intentionally caused events such as arson. Law enforcement officials and laboratory personnel have to undergo relevant trainings, briefings and tabletop exercises in order to be aware about the safety issues of the site and the procedures to be followed when an incident occurs (Jonsson et al., 2013, p. 6).

Secondly, personnel management is being stressed by the WHO in assuring that laboratory staff members have the necessary training, experience, competency, technical qualifications, skills, and sustainability requirements to handle VBMs (WHO, 2006, p. 26). The WHO also emphasises the professional and bioethical eligibility of the individuals handling these VBMs (WHO, 2006, p. 26). Zaki (2013, p. S73) provides further details about personnel management to laboratories, including actions of security clearance such as screening, identity verification, educational, professional or credential verification, military service verification, national criminal checks, financial standing checks and security interviews. More important is for the laboratory personnel to be screened psychologically for abnormal patterns of behaviour such as aggressiveness, violence, depression, high stress or suspicious behaviour leading to unethical behaviours such as substance abuse in the risky environment of handling VBMs (Jonsson et al., 2013, p. 5).

Apparently, the anthrax mail attacks of 2001 in the United States (US) were attributed to Bruce Irvins, a disgruntled laboratory staff member serving at the United States Army Medical Research Institute (USAMRIID) in Fort Detrick, Baltimore, who was someone

pictured as having a mental illness and suffering from alcoholism (Klotz, 2009, p. 111). In *United States v. Maureen Stevens* (2008, pp. 1064-1065), the Supreme Court of Florida determined that Maureen Stevens could certainly pursue a case against the US Government and the Battelle Memorial Institute (Battelle), Fort Detrick as they owed a duty of care under Section 302B of the Restatement (Second) of Torts (1965) for failing to employ adequate security procedures. In particular, Battelle was negligent in its hiring practices for failing to conduct background investigations prior to hiring individuals (in this case Bruce Irvins) who had access to anthrax. Irvins subsequently disseminated anthrax by mail causing the death of Robert Stevens, the spouse of Maureen Stevens then working at American Media, Incorporated ('American Media') (*United States v. Maureen Stevens*, 2008, pp. 1064-1065). In this case, the Supreme Court of Florida determined that negligence was involved on the part of the Battelle Memorial Institute because it failed to prevent Irvins from having access to anthrax and subsequently misusing this select agent (*United States v. Maureen Stevens*, 2008, pp. 1069-1070).[1]

The US Government and Battelle Memorial Institute were also negligent with their security, as they failed to thoroughly screen the mental state of mind of Bruce Irvins, who was handling the anthrax at that time. Gaudioso, Gribble and Solerno (2009, p. 144) have underlined that the factors to be considered for personnel security should also include mental health. However, it is not known how often the US authorities and the Battelle Memorial Institute conduct psychological tests on their scientists handling select agents in order to identify whether they are fit to handle said agents. As emphasised by Gaudioso et al. (2009, p. 145), "an incident where a pathogen or toxin accidentally escapes from a

[1] In United States v. Maureen Stevens (2008, pp.1069-1070), the judgment indicated:

[T]he government and Battelle are required to contemplate a countless variety of situations in which a reasonable laboratory in their position must anticipate and guard against the unauthorised interception and dissemination of the dangerous substance. Given the allegations of negligent security of the ultrahazardous material and the virtual impossibility of potential victims to protect themselves once this substance is at large, this is obviously one of those cases […], where the risk of injury is great and the corresponding duty of the lab is heightened. In a very real sense, it is this inability to measure the extent of this risk that merits giving the claimants an opportunity to go forward.

facility or is misused and can be traced back to a specific institution could be liable if it has not implemented best practices in biosafety and biosecurity." This perfectly fits Maureen Stevens bringing a case against the US authorities for failing to implement personnel security, part of the laboratory biosecurity. In the end, the US Justice Department agreed to settle a wrongful death lawsuit amounting to US$ 2.5 million in 2011 so that Maureen Stevens would not pursue the case further (McGowan & Felder, 2011, p. 1).

Additionally, the WHO underscores the need of information security encompassing the knowledge of log books regarding which laboratory staff member handles particular biological agents, where these biological agents are being transferred, and the storage location (WHO, 2006, p. 27). Therefore, information security seeks to ensure that there is an appropriate level of confidentiality preserved by the system being used in order to acquire, store, manipulate and manage information to limit the access for the individuals seeking to gain access to this information for malevolent intentions (WHO, 2006, p. 27). The WHO recommends appropriate action to preserve this confidentiality by focusing on the marking and handling of information, documenting how the information was gathered, maintained, distributed, accessed, shared and stored within a laboratory facility (WHO, 2006, p. 27). Besides log books, Jonsson et al. (2013, p. 4) recommend that laboratories implement software tracking programmes using a secured database and bar codes capable of tracking all select agent samples and ancillary data. Furthermore, the laboratory facilities handling select agents must have protocols in place to enable their staff to produce documentation for the transfer and accountability of inventories should a principal investigator change employment, retire, die or leave for other reasons or no longer have an active role in the laboratory (Jonsson et al., 2013, p. 4). All of the aforementioned measures are imperative for the accountability stressed by the WHO (WHO, 2006, p. 19). By having such measures in place, it is envisaged that the moral

obligation of accountability can be instilled among laboratory staff so as to know the identity, source, date of receipt, number of vials and volumes of stocks of the select agents at particular sites. This in essence abides by the principle of good governance promoting transparency and accountability in accordance with ISDL within the context of laboratory biosecurity.

Related with accountability and information security is the need to assure the secure transportation of the select agents, whether domestically within a state or across borders internationally (WHO, 2006, p. 22). As emphasised by the WHO, "[t]ransport security applies to biological materials within a single institution and between institutions" (WHO, 2006, p. 22). This includes crucial documentation, accountability over the select agents moving between the secured areas of a facility and internal delivery of the select agents through shipping and the receiving process (WHO, 2006, p. 22). Similarly, the WHO has urged states to follow the guidelines of the United Nations (UN) Model Regulations for the Transport of Dangerous Goods in enabling states to develop national and international transport regulations covering the handling of dangerous goods, such as infectious select agents in all modes of transportation (WHO, 2006, p. 22). Additionally, the WHO has also stressed that states implement import and export permits for these select agents prior to the transfer and authorisation across borders (WHO, 2006, p. 22). This implies that the WHO is actually addressing the need to implement a criminalised approach for the unauthorised transfer of select agents posing a danger to human health in line with the state control laws regulating the distribution of contagious biological agents across state borders (Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction) (hereinafter Biological Weapons Convention (BWC) art. III, 1972). In *United States v. Thomas Campbell Butler* (2005, p. 144), Butler was convicted of three account for the illegal exportation of plague (*Yersinia pestis*) to Tanzania and making a false statement

on the waybill accompanying the plague vials to Tanzania in violation of the US export control law. As stressed by Jonsson et al. (2013, pp. 4-5), accountability also includes the Standard Operation Procedure (SOP) concerning the process of obtaining a permit for the transfer of import and export, proper shipment packaging and documentation practice that the case of Thomas Campbell Butler had violated.

Another aspect emphasised by the WHO regarding laboratory biosecurity concerns training, whereby laboratory staff should be trained in line with both biosafety and biosecurity measures (WHO, 2006, p. 29). The WHO prescribes the roles and responsibilities of the personnel and not only of those working within the facility, but of those operating externally such as the police, fire brigade and medical emergency personnel who are required to familiarise themselves with the methods deployed for emergency preparedness and response readiness of unexpected events (WHO, 2006, p. 29). This form of training should be conducted regularly in order to facilitate communication skills and improve coordination among all the stakeholders of the laboratory facility (WHO, 2006, p. 29). As asserted by the WHO, training should also familiarise laboratory personnel with the codes of conduct for scientists especially regarding the forms of research acceptable and the ethical issues of the Dual Use Research of Concern (DURC) pertaining to select agents (WHO, 2006, p. 29).

Complementing the measures of laboratory biosecurity, another document, namely Responsible Life Sciences Research for Global Health Security: A Guidance Document (WHO, 2010), acknowledges the potential misuse of bioscience entailing a dual use requiring for an overseeing body to be established among research institutions, universities and other institutions dealing with contagious select agents in order to evaluate whether the form of research could raise any ethical controversies. Both WHO documents have likewise stressed upon the formulation of a code of conduct for scientists to evaluate the purpose of their research with regard to select agents, considerations of its

impact to affect funding and the censoring of the publication of the research methods and results that are of dual use in nature (WHO, 2006, p. 21; WHO, 2010, pp. 14-16). Thus, it can be argued that laboratory biosecurity as underlined by the WHO requires different sets of actions to be implemented by the states.

Noticeably though, the WHO documents prescribing states to implement laboratory biosecurity measures are mere guidelines that are non-binding and the implementation thereof remains voluntary. The same applies to the BWC soft law documents as an outcome of the Intersessional Processes (ISPs) that are similarly non-binding but also address laboratory biosecurity and the misuse of biotechnology through dual use requiring codes of conduct. This being the case, states have the discretion either to implement laboratory biosecurity measures or to omit doing so. Nevertheless, soft law documents such as in the case of the ISPs of the BWC and the guidelines of the WHO on laboratory biosecurity are not without legal reference. This is because the states having come together in the first place and presumably agreed with these soft law documents in good faith during international discussions can be assumed as willing to act on the basis of these non-binding documents, in whole or to some extent, or at least are reluctant to directly violate these commitments as it all relies on the nature of the intent (Shelton, 2000, p. 1). This being the case, it can be assumed that the soft law documents of the WHO guiding laboratory biosecurity may have some clout after all.

Notably, Gaudioso et al. (2009, p. 146) have been critical of the fact that laboratory biosecurity measures have been merely implemented by more affluent states, while those failing to do so will enable actors with malicious intent to obtain select agents, equipment and expertise. This defeats laboratory biosecurity altogether, as bioterrorism can still be perpetuated through the acquisition of the necessary resources under lax laboratory measures. For this reason, developed states should provide financial and technical

assistance to the developing states so that they can all ensure that terrorists will find it very difficult to obtain the select agents and equipment facilitating bioterrorism.

Lastly, Gaudioso et al. (2009, p. 145) have raised the extent that laboratory biosecurity measures will be relevant in the future considering the advances in biotechnology, such as synthetic biology enabling the artificial synthesis of biological agents which make it irrelevant to steal from laboratories. For the time being, genetic engineering still makes laboratory biosecurity relevant, but for advanced synthetic biology, this may require a different set of guidelines that the WHO will have to work on.

8.4 Pharmaceuticals within the World Health Organisation

Previously in Chapter 6, it has been mentioned that the CPB did not cover pharmaceuticals for humans. It has also been indicated in Chapter 6, that the concern for pharmaceuticals within the CPB was aroused because the developing states were concerned that the medical substances produced through the molecular farming of plants and animals through genetic engineering would endanger human health when consumed. As these aspects are supposed to be dealt with by the WHO, this sub-section of the present chapter will explore the initiative of the WHO in addressing molecular farming or biopharming among plants and animals through the elaboration of relevant guidelines.

8.4.1 Biopharming among Plants

While the plants and animals used for biopharming would be subjected to a risk assessment within the scope of the CPB, it is obvious that the medicinal substances they produce cannot be consumed or used directly by humans unless they have undergone further processing. This introduces the WHO, as it is also the international organisation responsible for International Biological Reference Preparations (IBRPs) in order to standardise vaccines and other biological preparations, updating the WHO guidelines and recommendations, known as the written standards for the production, control, nonclinical

and clinical evaluation of biological products (Shin, Connrad, Knezevic & Wood, 2011, p. 165). All of these documents guiding the biological standardisation have undergone international consultations in ensuring the quality, efficacy and safety of biological medicines and *in vitro* biological diagnostic tests worldwide (Shin et al., 2011, p. 165). This is being accomplished through the WHO's biological programme, the WHO Collaborating Centres and its Expert Committee on Biological Standardisation (ECBS) (Shin et al., 2011, p. 165). The WHO guidelines in particular provide general guidance on a range of topics to the National Regulatory Authorities (NRAs) and manufacturers, whilst recommendations set the technical specifications for manufacturing and quality control of specific products (Shin et al., 2011, p. 165).

Against this background, the WHO convened an informal consultation in 2005 in order to determine whether any specific guidance will be needed for the plant-derived vaccines which are yet to be regulated internationally (WHO, 2005, p. 2). It emerged from this informal consultation "that existing guidelines for the development, evaluation, and use of vaccines made by traditional methods can be applied to plant-derived vaccines" (WHO, 2005, p. 2). Basically, this meant that the WHO reached a consensus there was no need to draft a specific guideline for the biopharming of plants since guidance could be obtained from a few established guidelines already existing within the WHO's circulation.

The informal consultations from 2005 described above agreed there was a need to refer to the good manufacturing practices (GMPs) for the early parts of manufacturing in the case of transgenic plants, either for vaccines or other biologics through the WHO's Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants (WHO, 2003a). Additionally, there was also the need to refer to the WHO's document, Quality Control Methods for Medicinal Plant Materials (WHO, 1998).

The WHO's Guidelines of GACP for Medicinal Plants (WHO, 2003a), as mentioned earlier, provide good agricultural practices (GAPs) for medicinal plants and prescribe general principles and technical details for the cultivation of medicinal plants. Some considerations to be taken with reference to the GAP include selecting the appropriate species or botanical variety of the plant based on the reference material referred to as the national pharmacopoeia or those within a particular region while its scientific name (genus, species, subspecies/variety, author and family) should be verified and recorded (WHO, 2003a, p. 7). If there are doubts about a botanical species as it may be an unknown species, this needs to be verified by a regional or national herbarium for identification (WHO, 2003a, pp. 8-9). As for the seeds supplied for cultivation, suppliers need to provide information of its identity, quality and performance of their products and breeding history (WHO, 2003a, p. 8). Cultivation practices such as rotation, tillage and specific site selection are to be considered. Other factors such as the climate and soil must also be taken into account (WHO, 2003a, pp. 8-9). This WHO Guideline also recommends measures for separating the plants of indigenous and non-indigenous species for fear of genetic contamination relevant to the Recombinant Deoxyribonucleic Acid (rDNA) biopharming plants produced through genetic engineering (WHO, 2003a, p. 9). Climatic changes such as rainfall, the length of day, frost, field temperature and soil attributes such as the usage of chemical and organic fertilisers are to be considered as GAP (WHO, 2003a, p. 10). Irrigation and drainage, the optimal period for harvesting, plant maintenance and protection as well as the knowledge of the personnel concerning the botanical identification, cultivation characteristics, soil fertility, plant spacing and light requirements all pertain to the GAP and must be considered (WHO, 2003a, pp. 11-12).

As for good collection practices (GCP), the WHO's Guidelines on GACP for Medicinal Plants (WHO, 2003a, pp. 11-12) require that necessary permits be obtained prior to the collection of plants and that endangered species should not be collected.

Knowledge of their taxonomy, phenology, genetic diversity and ethnology is also to be accounted for (WHO, 2003a, p. 13). The GCP also emphasises the safe transportation of these plants and of their harvesting during an appropriate season in order to ensure the consistency of biologically active constituents that vary during plant growth and development (WHO, 2003a, p. 15). Besides this, the emphasis on non-destructive systems of plant collection plants free from herbicides, pesticides and other contaminants from elsewhere have been stressed (WHO, 2003a, p. 15). Additionally, the collection of plants should be free from insects, rodents, birds, pests and has to be sun dried prior to transportation (WHO, 2003a, p. 16). As for personnel, they should have a background in plant sciences in order to be able to recognise medicinal plants and document at all stages of their work (WHO, 2003a, p. 16). Moreover, the occupational safety and health standards of personnel serve as the uppermost measures to protect them from toxic and dermatitis causing plants, poisonous animals and disease carrying insects to be implemented (WHO, 2003a, p. 16). As for the technical aspects of the GAP and GCP, the inspection for cross contamination, foreign matter, changes in appearance, damage, size, colour, odour and taste are to be enforced (WHO, 2003a, p. 17). The drying process of plants should minimise their moisture content to reduce the damage from mould and other microbial infestations (WHO, 2003a, p. 18).

Other technical aspects include the sanitation and hygiene of the processing plant, its temperature and humidity, specifications concerning the construction of walls, floors, ceilings and other structures suitable for processing medicinal plants (WHO, 2003a, pp. 20-21). The personal hygiene of the personnel and being free from certain diseases that can contaminate the processing of plants has been stressed as well (WHO, 2003, pp. 26-27). The labelling of the processed product indicating the place of origin of the plant, cultivation and collection date, the names of the grower/collector, processor and batch number should be displayed on the end product in order to enable traceability should any

contamination or illness be associated with the product (WHO, 2003a, p. 23). Furthermore, the said WHO Guideline on the GACP for Medical Plants has a multitude of other recommendations.

Most importantly, the WHO Guidelines on the GACP for Medicinal Plants addresses social justice issues, going beyond the conventional norm covering ABS and compensation, especially if a medicinal plant comes from the traditional knowledge of a particular indigenous community (WHO, 2003a, p. 29). Appropriate documentation from national authorities certifying that the medicinal plants were not collected from the wild and Intellectual Property Rights (IPRs) matters such as patents need to be resolved if these involve rDNA plants prior to the collection and research of these plants (WHO, 2003a, pp. 29-30).

As for the WHO's Quality Control Methods for Medicinal Plant Materials, this document prescribes all kinds of technical test procedures supporting the development of national standards for testing medicinal plants (WHO, 1998). For instance, the macroscopic and microscopic examination of plants based on a monograph provides the description, illustration and photographic images, while the microscopic examination functions as an initial screening for impurities and assures the identity of plants (Kunle, Egharevba & Ahmadu, 2012, p. 104). Chromatography, the science studying the separation of molecules based on the differences of their structure and composition has also been emphasised by the WHO (WHO, 1998). Other tests being referenced include the determination of ash through the incineration of the medicinal plant subsequently treated with hydrochloric acid producing acid-insoluble ash composed of the silica used to measure the soil present (WHO, 1998). There is also the need to determine the accumulated pesticide residue contaminating medicinal plants such as Dichlorodiphenyltrichloroethane (DDT), chlorinated hydrocarbons, organophosphates, carbamates or polychlorinated biphenyls (WHO, 1998). The identification of arsenic and

other metals such as lead, cadmium, mercury, and thallium among medicinal plants must also be undertaken (WHO, 1998). Checking for microbial contamination especially among medicinal plants with increased starch content for enterobacter, enterococcus, clostridium, shigella and streptococcus is also crucial (WHO, 1998). Furthermore, medicinal plants must also be checked for radioactive contamination in the event there is a radioactive nuclear plant nearby or contaminants resulting from an accident (WHO, 1998). Other tests to be performed include those seeking to determine extractable matter, water and volatile oils, the bitterness value, tannins, the haemolytic activity, and the swelling and foaming index (WHO, 1998).

Apart from the two WHO Guidelines involving biopharming with plants, the WHO Guidelines on Nonclinical Evaluation of Vaccines have been cited as being relevant (WHO, 2003b; WHO, 2005, p. 12). These involve tests on animals namely on species closely resembling the human illness when exposed to this pathogen to check for innate immunity, humoral and cellular immunity (Laan, Minor, Mahaney, Arntzen, Shin & Wood, 2006, p. 4277). A nonclinical evaluation may also consider toxicity studies to indicate immunogenicity but may be less relevant because of a low dose of proteinous material through the oral dose (Laan et al., 2006, p. 4277). Tests for allergenicity should likewise be conducted if parts of the plants, animals and microorganisms used have the propensity to cause an allergic reaction, while soluble proteins inducing immunotolerance have to be avoided (Laan et al., 2006, p. 4277). Considering that the insertion of the transgene may influence the expression of plant toxins or host proteins, this ought to be checked through toxicity studies (Laan et al., 2006, p. 4277).

The biopharming of plants likewise relies on the WHO's Guidelines on Clinical Evaluation of Vaccines: Regulatory Expectations (WHO, 2004b). An emphasis has been placed on the need to define and control the dose for an orally delivered inactivated vaccine to test its potency and stability (Laan et al., 2006, p. 4277). The tests conducted

on patients should also consider the site of trial that may be influenced by the intestinal environment such as flora (Laan et al., 2006, p. 4277). Additionally, the WHO Guideline for clinical trial highlights the consistency of production for the vaccine since there is not much evidence on the vaccine quality at the clinical trial stage for verification (Laan et al., 2006, p. 4273). It has also been asserted that genetic stability and a strong justification for plant derived vaccine needs to be made given that the safety of the new plant substance is unknown and that the tools for the safety assessment at the pre-licensing stage are limited (Laan et al., 2006, p. 4274). Overall, the said WHO Guideline provides useful guidance outlining the data that must be obtained at the different production stages of the vaccine in order to gain marketing approval (Laan et al., 2006, p. 4273).

Moreover, the WHO has underlined the importance of referring to the Guidelines on the Quality, Safety, and Efficacy of Biotherapeutic Protein Products Prepared by Recombinant DNA Technology (WHO, 2013). This Guideline applies to all biologically active protein products for the treatment of human diseases prepared by rDNA and protein products for diagnosis purposes, such as monoclonal antibody products covering the *in vivo* diagnosis and the *ex vivo* treatment, those modified by pegglation, conjugation with a cytoxic drug, or modification of the rDNA sequences (WHO, 2013, p. 11). Nevertheless, this WHO Guideline excludes the *in vitro* diagnosis (Ruini, 2013, p. 1), yet some parts of its application may apply to transgenic plants and animals (WHO, 2013, p. 11). Additionally, this WHO Guideline does not apply to recombinant viral vectors or live attenuated vaccines or to gene transfers for humans (Ruini, 2013, p. 1). In this regard, the previous WHO Guidelines on Nonclinical Evaluation of Vaccines elaborated earlier should also be referred to (WHO, 2013, p. 11). Part A of the Guidelines on the Quality, Safety, and Efficacy of Biotherapeutic Protein Products Prepared by Recombinant DNA Technology considers the effects of manufacturing changes and devices used in the delivery and stability of the product (WHO, 2013, p. 11). Furthermore, this same

Guideline contains new sections, namely on nonclinical and clinical evaluation of the rDNA-derived biotherapeutics, that have to be evaluated so as to determine whether they apply to biopharming plants (WHO, 2013, p. 11).

Lastly, the WHO informal consultation concerning human vaccines derived from plants in 2005 also recommended that a banking system be established, with the formation thereof depending on the method of production, whether sexual or vegetative (Laan et al., 2006, p. 4276). Besides this, existing GMPs for drugs/biologics should also apply, while it has been recommended that greenhouse cultivation be implemented for the production of vaccines from plants (Laan et al., 2006, p. 4276). Overall, the above analysis has shown that human health concerns associated with vaccines and other biologics derived from plants through molecular farming or biopharming are indeed regulated internationally by the WHO using various guidelines that are non-binding, as these are soft law documents. Therefore, it all depends on the goodwill of the states and pharmaceutical manufacturers whether they would apply these guidelines. However, this study asserts that it is to the advantage of these pharmaceutical companies to follow these guidelines as a form of quality assurance should they want their pharmaceutical products to be received by other states. It is also acknowledged that these products have undergone a rigorous safety process deservable of acceptance.

8.4.2 Pharmaceuticals Derived from Animals

In 2008, after much deliberation among the member states, the Codex Alimentarius Commission finally passed the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals (Food and Agriculture Organisation of the United Nations [FAO], 2008). During the negotiations of this Guideline, states such as Australia, Canada, the United States (US) and one NGO, namely Consumers International, were very explicit in stating that biopharming or gene farming among

animals for the production of pharmaceutically/therapeutically relevant proteins in the animal system to be harvested from their serum, urine or milk went beyond the scope of the said Guideline (FAO, 2005, p. 9). The reason for this exclusion being that the Codex Alimentarius Commission merely deals with food safety matters and not pharmaceuticals (FAO, 2005, p. 9).

As Schmatberger and Schultz (2008, p. 23) have remarked, the said Guideline "deliberately avoids the questions of whether this risk assessment can/ should also apply to genetically modified animals which serve purposes other than food, e.g., in the field of gene-pharming." Instead, the Ad Hoc Intergovernmental Task Force on Foods derived from Biotechnology responsible for preparing this Guideline noted it was left to member states to select the most appropriate approach in deciding whether or not this Guideline will apply to the substance produced by animals through biopharming (Schmatberger & Schultz, 2008, p. 23). For Schmatberger and Schultz (2008, p. 23), it was a grave mistake for the Guideline not to address biopharming among animals, as these animals could accidentally contaminate the food chain through disposal routes, as in the case of transgenic pigs in Canada in 2002 or through the processing of animal waste as feedstuffs. Notably, this Guideline requires an assessment of possible toxicity or bioactivity for new substances derived from animals such as proteins, fats, carbohydrates, vitamins and new metabolites (FAO, 2008, p. 7). Apart from this, the Guideline also recommends for allergenicity tests and the presence of any antibiotic resistance marker genes to be considered (FAO, 2008, pp. 8-10). During the deliberation of the Guideline, Australia indicated that bioactive substances like phytosterols and omega-3 fatty acids would rightly fall within the scope of this Guideline (FAO, 2005, p. 8). Since there is uncertainty that this Guideline cannot address human health concerns from biopharming substances derived from animals, there is obviously a gap in this aspect that the WHO will have to address in due course.

8.5 Conclusion

This chapter intended to analyse the relevant provisions from the IHR 2005 and whether these provisions were reflective of the principles of international law from the Delhi Declaration of ISDL. Overall, the IHR 2005 reflects all seven principles from the Delhi Declaration of the ISDL in their own unique way which is context specific to the IHR 2005. The findings pertaining to the IHR 2005 are not unusual, as it is expected that an international health law agreement would fulfil the international social law aspect of ISDL. It is also clear from the findings of the IHR 2005 that it is not solely concentrated on health or else the seven principles of the ISDL would not find a place among its provisions. Thus, the IHR 2005 is a well-balanced international health law agreement that considers the environmental, economic and social development aspects of sustainable development as proven by the reflection of the principles of ISDL among its provisions.

This chapter has also shown the detailed requirements to be met for laboratory biosecurity through relevant WHO documents that the CPB in Chapter 6 has to consider, as it closely relates to biosafety, while the same goes for the BWC to tap on the WHO's expertise on laboratory biosecurity and the IHR 2005 because their scope of work intersects with the WHO. The WHO elaborated in this chapter also have a few guidelines in ensuring that the medicinal substances generated for humans are to meet certain safety and health requirements so as to complement the work of the CPB that merely involves a risk assessment to the plants and animals of biopharming. For the CPB and BWC to consider the WHO guidelines for laboratory biosecurity and biopharming, this can merely be done through their provisions reflecting the principle of integration of ISDL because those guidelines are devoid of the provisions that permit the ISDL principles to be applied considering their status as non-binding documents.

CHAPTER 9: FINDINGS AND DISCUSSION

9.1 Introduction

This chapter serves to integrate and synthesise the various issues raised within Chapters 4, 5, 6, 7 and 8. The purpose of this study is to analyse whether principles of international law from the New Delhi Declaration (hereinafter Delhi Declaration) of International Sustainable Development Law (ISDL) (International Law Association [ILA], 2002) holds the solution in linking different biosecurity sectors and their respective international agreements and initiatives together in the context of genetically modified organisms (GMOs) for coherent management among international organisations.

In subsequent sections, this chapter serves to answer the research questions posed in this study by combining the findings and the discussion together. As such, this chapter will cover (i) the scope, and limitations as well as to suggest relevant recommendations and risk management practices to harmonise various biosecurity sectors and their respective international instruments, (ii) identify the principles of international law from the New Delhi Declaration of Principles of International Law Relating to Sustainable Development and (iii) the analysis of relevant provisions from selected international biosecurity agreements and initiatives that reflect the principles of international law in the Delhi Declaration whenever applicable.

9.2 The Scope of Biosecurity Sectors, Limitations and Recommendations for Harmonisation

This section presents the **finding statement** with a subsequent discussion pertaining to the first research question, which is:

(i) *What are the scope, limitations, relevant recommendations and risk management practices that would be needed to harmonise the various biosecurity sectors and their respective international instruments?*

The biosecurity sectors are the biosecurity of biotechnology, laboratory biosecurity and agricultural biosecurity whereby their specialisation limits their ability to recognise connections among them to require an integrated biosecurity definition to change existing mindset and practice that is enhanced by a proposed coordinating United Nations (UN) mechanism bringing various biosecurity international organisations and agencies to cooperate in forming interlinkages among respective international instruments.

9.2.1 The Biosecurity of Biotechnology

The biosecurity of biotechnology is the form of "security against the inadvertent, inappropriate, or intentional malicious or malevolent use of potentially dangerous biological weapons as well as natural outbreaks of newly emergent and epidemic diseases", a definition provided by the United States National Academy of Sciences (USNAS) (N. R. C. Committee, 2006, p. 32). The biosecurity of biotechnology has been associated with biological warfare and bioterrorism. This form of biosecurity is also concerned with the dual use issues of biological agents, knowledge and technology pertaining to the means of delivery of biological weapons that can be utilised for good or bad intentions in the life sciences. Chapter 4 introduced biological warfare as the wartime use of biological agents through the example of the former Soviet Union that utilised genetic engineering to create numerous, virulent biological agents in anticipation of its use against its arch enemy, the United States (US) (Ainscough, 2002, p. 3; Gilsdorf & Zilinskas, 2005, p. 1160). Bioterrorism as the "deliberate release of viruses, bacteria, or other germs (agents) used to cause illness or death to people, animals or plants" (Centres for Disease Control and Prevention [CDC], 2015) also constitutes an aspect of the biosecurity of biotechnology. Cases of terrorist groups such as Aum Shinrikyo and Al-Qaeda that were able to create biological weapons and weaponisation on a large scale have not been successful because doing so requires a whole range of capabilities. These

include such capabilities as technical expertise, large financial backing, and other factors that these terrorists do not possess (Cole, 2011; Koblentz, 2009, p. 213). Small scale bioterrorism is likely to be perpetuated through food contamination, water and voluntary suicide missions by terrorists willing to infect themselves so that they may subsequently infect others (Cole, 2011, p. 55). Advances in the life sciences in generating new knowledge and techniques to reduce the level of expertise in creating biological weapons may make it easier in the future for terrorist to create biological weapons. Terrorists are unlikely to utilise genetic engineering because this technique is too complicated for them and they have not perfected the rudimentary means of creating biological weapons (Cole, 2011, p. 209). Detecting the creation of biological weapons is complicated because of the dual use nature of the equipment; it may be used for legitimate civilian purposes or for malign intent.

The biosecurity of biotechnology has limitations in addressing biological warfare and bioterrorism. This form of biosecurity fails to address the protection and accountability of biological agents in laboratories and the environmental impacts from the deliberate release of biological agents. This form of biosecurity is associated with the 1925 Geneva Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare (1925 Geneva Protocol), the Convention on the Prohibition of the Development, Protection and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, in short the Biological Weapons Convention (BWC, 1972), the International Health Regulations 2005 (IHR 2005) and the United Nations Security Council Resolution 1540 (UNSCR 1540).

9.2.2 Laboratory biosecurity

Laboratory biosecurity as a sector has a scope that is limited to "the protection, control and accountability for valuable biological materials (VBMs) within laboratories, in order to prevent their unauthorised access, loss, theft, misuse, diversion or intentional release"

(World Health Organisation [WHO], 2006, p. iv). This form of biosecurity does not consider the negative environmental impacts from the release of VBMs nor does it address the misuse of knowledge that can generate biological weapons. The Lawrence Livermore Laboratory (LLNL) court case, *Tri-Valley Cares v. United States Department of Energy* (2010, p. 7) (hereinafter *Tri-Valley Cares*) and *United States v. Maureen Stevens* (2008, p. 3) case laws have shown laboratory biosecurity being breached via inappropriate record keeping of pathogens within laboratories, the failure to consider scenarios of terrorist breaching high containment laboratories and inadequate security in the handling and shipping of pathogens. These have led to ordinary US citizens bringing lawsuits against US authorities because they want accountability and better laboratory biosecurity practices. The WHO's Biorisk Management Laboratory Biosecurity Guidance (WHO, 2006) provides detailed measures in meeting laboratory biosecurity requirements.

9.2.3 Agricultural Biosecurity

Agricultural biosecurity is "a strategic and integrated approach that encompass the policy and regulatory frameworks (including instruments and activities) for analysing and managing relevant risks to human, animal and plant life and health, and associated risks to the environment" (Food and Agriculture Organisation of the United Nations [FAO], 2007, p. 3). This biosecurity's scope covers food safety, zoonoses, the introduction of animal and plant diseases and pests, the introduction and release of GMOs and their products and invasive alien species (FAO, 2007, p. 3). Based on its scope, this form of biosecurity is concerned with the impacts on biological diversity and the environment. The FAO's understanding of agricultural biosecurity has its own deficiencies. These include failing to address diseases that are man-made and produced intentionally through bioterrorism and biological warfare harming humans, plants and animals.

9.2.4 Limitations of Biosecurity Sectors Require Complementary Actions

The German *Escherichia coli (E. coli)* 0104: H4 contaminated sprouts case of 2011 in Hamburg, Germany ("E. coli Outbreak: EU", 2011) discussed in Chapter 4 not only illustrates food safety (agricultural biosecurity) and bioterrorism (biosecurity of biotechnology) but also laboratory biosecurity could be involved. The sectorial approach to biosecurity in that case caused the German authorities to approach the outbreak of the disease resulting from the *E. coli* as a natural outbreak to merely involve health and agricultural authorities. This failure of making a connection between food safety and bioterrorism is a result of biosecurity practiced according to segmented sectors without interlinkages with one another. The bigger picture is that practicing biosecurity segregation will not occur unless there is a precedent set at the international level, as reflected by different definitions of biosecurity provided by USNAS, the WHO and FAO.

Therefore, there is a need for biosecurity sectors to complement each other's role and to create an approach characterised by cooperation and coordination in realising holistic biosecurity management internationally. Accompanying the linkages among biosecurity sectors is a need for a holistic biosecurity definition that combines the biosecurity definitions from the USNAS, WHO and FAO. As indicated in Chapter 2, Al-Rodhan, Nazaruk, Finaud and Mackby (2008, p. 28) provided their own comprehensive definition of biosecurity in the spirit of merging disparate biosecurity sectors and their respective international agreements and initiatives together, but biological warfare is not mentioned. Therefore, an alternative definition of biosecurity needs to be provided starting from Al-Rodhan et al.'s proposal. A changed mindset of viewing biosecurity holistically can only start with a changed definition and understanding of biosecurity. This must simultaneously be mirrored by the integration of international biosecurity agreements and initiatives initiated through a proposed UN coordinating mechanism that is able to bring members of international organisations and agencies to cooperate together. It is hoped

that this will lead to a shared perspective among international organisations to combine these international instruments to resolve a biosecurity issue that arises synergistically.

This study's idea of integrating diverging biosecurity sectors together is consistent with Meyerson and Reaser's (2002a, p. 44; 2002b, pp. 593-600) idea of an expanded scope of biosecurity to cover public health, biological weapons, infectious diseases and aspects of agricultural biosecurity. The extended form of biosecurity put forth in this study is also consistent with Koblentz's (2009, p. 108) rationale that such an approach can create an umbrella framework bringing scholars and practitioners together from a wide range of disciplines, agencies, sectors, organisations and states to form strategies that prevent, prepare and spontaneously respond to naturally occurring or man-made diseases. Moreover, the approach taken in this study coincides with Koblentz's (2009, p. 108) proposition that an extension of biosecurity beyond that which is sector specific can offer a framework to assess and compare the dangers inflicted by different biological threats. It is anticipated that if there is a changed understanding of biosecurity toward a definition that is more holistic, the result will facilitate integration and cooperation among international organisations and agencies. The result will be that these administrators of biosecurity international instruments and states will manage biosecurity more coherently at the international level.

9.3 The Principles of International Law from the New Delhi Declaration of Principles of International Law Relating to Sustainable Development

This section presents the **finding statement** and discussion pertaining to the second research question, which is:

(ii) *What principles of international law can be gleaned from the New Delhi Declaration of Principles of International Law Relating to Sustainable Development?*

Seven principles of international law form the crux of ISDL within the Delhi Declaration that can build linkages among disparate biosecurity sectors and their associated international agreements and initiatives.

9.3.1 The History of International Sustainable Development Law and Its Seven Principles

In Chapter 1, Stannard, Graaf, Randell, Lallas and Kenmore (2004, p. 398) emphasised the integrative role of sustainable development in merging environmental protection, economic and social development together to enable varying agriculture, trade and environmental agreements of biosecurity to complement each other's role. This has been confined though to the convergence of these international agreements in the agricultural biosecurity sector. Rhodes (2007, pp. 24-32) then identified key principles from the World Commission on Environment and Development (WCED) Report, the Rio Declaration on Environment and Development (Rio Declaration), Agenda 21, the Johannesburg Plan of Implementation from the World Summit of Sustainable Development (WSSD) and the Millennium Development Goals (MDGs) of the UN, which can be used to assess whether these international agreements of biosecurity can attain sustainable development through locating these principles within them.

The idea of identifying relevant principles from these key sustainable development documents is certainly not new within the realm of international law. The WCED Report previously called for changes at the legal and institutional levels, promoting the integration between environment and development concerns that led to twenty two Proposed Legal Principles for Environmental Protection and Sustainable Development that was annexed to this Report (WCED, 1987, p. 87). This led to the next milestone in the formation of international law pertaining to sustainable development at the United Nations Conference on Environment and Development (UNCED) held in 1992, whereby its outcome document, Agenda 21 in Chapter 39, reiterated the need of "further

development of international law on sustainable development giving special attention to the delicate balance between environmental and development concerns" (Division for Sustainable Development [DSD], 1992b, p. 1).

After UNCED, the United Nations Division for Sustainable Development in 1994 produced the Report of the Expert Group Meeting on Identification of Principles of International Law for Sustainable Development (Goepel, 2010, pp. 1694-1718). There were nineteen principles and concepts in this Report related to the international law of sustainable development taken from the Rio Declaration, Agenda 21 and other environmental agreements (Goepel, 2010, pp. 1694-1718).

Concurrently, the ILA Committee on the Legal Aspects of Sustainable Development build upon the above Report and issued the New Delhi ILA Declaration on Principles of International Law relating to Sustainable Development, otherwise known as the Delhi Declaration of ISDL as a resolution for the 70th Conference of the ILA held in New Delhi, India from 2-6 April, 2002 (ILA, 2002). Segger and Khalfan (2004a, p. 103) defined ISDL as "the area of intersection between three fields of international economic, environmental and social laws".

The Delhi Declaration contained seven principles. These are the duty of states to ensure sustainable use of natural resources, the principle of equity and the eradication of poverty, the principle of common but differentiated responsibilities, and the principle of the precautionary approach to human health, natural resources and ecosystems (ILA, 2002). Other principles include the principle of public participation and access to information and justice, the principle of good governance and the principle of integration (ILA, 2002). Except for the duty of states to ensure sustainable use of natural resources achieving the status of customary international law (French, 2005), all the other principles did not achieve such a status. The principles of ISDL from the Delhi Declaration had also received international recognition by being published as a UN document under the theme

of "Environment and Sustainable Development" at the 57th General Assembly and the World Summit for Sustainable Development (WSSD) of 2002 ("Report of the Second Committee", 2002; "World Summit on Sustainable Development", 2002b). As for its implementation, the World Future Council (WFC), together with the United Nations Office for Disarmament Affairs (UNODA), held a competition on the theme of disarmament in 2013 by utilising ISDL principles in gauging treaties, laws and policies. This was held in conformance with the Delhi Declaration and to encourage states to utilise those principles as benchmarking disarmament policies (Riet & Bywaters, 2013, p. 4). Similarly, this study also situated the principles of ISDL among biosecurity international agreements such as the BWC (1972) in disarmament and other initiatives that benefited from the WFC's effort to encourage the implementation of those principles in assessing whether these international instruments can make sustainable development an objective. This has been done through analysing provisions of the biosecurity international agreements and subsequent documents to these agreements whether these principles are directly or indirectly being reflected among them.

9.4 The Reflection of Principles of International Law from the Delhi Declaration of International Sustainable Development Law among the Selected International Biosecurity Agreements and Initiatives

This section presents the finding statement and discussion pertaining to the third research question, which is:

(iii) *How are the principles of international law in the Delhi Declaration of ISDL being reflected in the selected international biosecurity agreements and initiatives?*

9.4.1 The Cartagena Protocol on Biosafety

The reflection of principles from the Delhi Declaration of ISDL in the Cartagena Protocol on Biosafety (CPB) generated the following **finding statement:**

The principles of international law from the Delhi Declaration of ISDL are directly reflected within the CPB, which refers to sustainable development explicitly to be able to link disparate biosecurity areas within and among other biosecurity international agreements and initiatives in other sectors.

The results of this study indicate that the CPB directly fulfils the principles of ISDL. The CPB is a highly integrated international environmental agreement, as attested by Segger and Khalfan (2004a, p. 109) when they point out that the agreement not merely addresses environmental matters solely but covers international social law. International social law is reflected through the public health aspect of GMOs by Article 2(5) of the CPB (2000) covering the expertise, instruments and work undertaken by other international forums concerning risks to human health, implying a need of collaboration with the WHO. Other provisions referring to the protection of human health include Articles 1, 4 and Article 5 of the CPB (2000) referring to pharmaceuticals for humans covered by other international forums.

The aspect of international economic law also finds a place within the CPB. For instance, the preamble explicitly states that trade and environmental agreements should be mutually supportive to achieve sustainable development (CPB, 2000). Moreover, Article 26 of the CPB (2000) covers the socio-economic considerations of GMOs on the conservation and sustainable use of biological diversity regarding indigenous and local communities encompassing the social and economic impacts of introducing GMOs in agriculture.

Besides this, other provisions within the CPB permit linkages with other international organisations and international agreements and initiatives. This is indicated by Article 2(4) whereby more protective actions taken than required by the CPB (2000) must be consistent with the members' states' other international obligations and international law. Another example includes Article 29 (8) of the CPB (2000) that permits invitees from

other UN agencies to attend CPB meetings. Likewise, Article 22(1) of the CPB (2000) covering capacity building for human resources development and institutional capacity building for biosafety permits cooperation with other global, regional, sub-regional and national organisations. This shows that the principle of integration is truly reflected in the CPB. These integrative provisions can function as a catalyst for the CPB (2000) to build relationships with other international organisations such as the Implementation Support Unit (ISU) of the BWC to address biological warfare, and with the WHO covering laboratory biosecurity and biopharming initiatives.

Impeding the CPB from building relations with other international organisations and international agreements is the attitude of member states deciding issues being put on the CPB's agenda, as highlighted by Rhodes (2008a, p. 45). This study found that were member states to the CPB that felt that biological warfare should not be raised within the CPB's ambit, and doing so being beyond its scope of work. This matter would be better addressed by the BWC as indicated at the Fifth Meeting of the Intergovernmental Committee in 2001 and the First Meeting of the Intergovernmental Committee for the CPB (ICCPB) (United Nations Environment Programme [UNEP], 2001a, p. 16). Therefore, it is true, as indicated by Rhodes (2008a, p. 45) and discussed in Chapter 1 that parties to biosecurity international agreements are drivers in determining the issues put on the agenda of international organisations and their unwillingness to consider that an issue stems from their reluctance to encroach into the jurisdiction of other biosecurity organisations.

In this regard, it is also true according to Rhodes (2008a, pp. 165-166) that biosecurity international agreements being segmented with their own specialisation creates a lack of clarity concerning which international agreement will apply, in this case either the CPB or BWC. As a remedy on the lack of coherence concerning which international agreements would apply when there are overlaps of issues, Rhodes (2008a, p. 172)

suggests cooperation among international organisations to rectify the ambiguity. Indeed, Article 22 (1) on capacity building, Article 29 (4) (c) in seeking the services and cooperation of other intergovernmental and international organisations and Article 29(8) of the CPB (2000) covering its ability to invite other UN agencies to participate in meetings can be utilised to facilitate cooperation with the ISU's BWC (1972). These resolve the ambiguity whether the CPB (2000) or BWC (1972) should address the environmental contamination of GMOs in the environment and biological diversity resulting from biological warfare because both international agreements prescribe different actions in solving the problem. As shown by the attitude of some member states to the CPB, while biosecurity international agreements may contain provisions facilitating collaboration with other international instruments, this may not necessary lead to cooperation at all because it takes political will among member states signatory to these agreements to permit this mutual cooperation.

The second principle, the duty of states to ensure sustainable use of natural resources, is not directly mentioned in the CPB. The imposition of the Advanced Informed Agreement (AIA) in seeking the permission of importing states for GMOs released into the environment was reflected by Articles 7 and 8 of the CPB (2000). In Chapter 6, this study highlighted that GMOs imported for pharmaceuticals meant for human consumption under Article 5 of the CPB (2000) are not subjected to the AIA but merely requires notification to the Biosafety Clearing House (BCH). Terrorists can abuse this provision by establishing legitimate medical front companies on the pretext of importing GMOs meant for pharmaceuticals but later channelled to bioterrorism. Release of these GMOs then by terrorists to cause environmental contamination in the importing state can trigger the principle of the duty of states to ensure sustainable use of natural resources and not to pollute the environment of other states. This is when the exporting state did not

stringently check the background of the exporting company prior to permitting the exportation of GMOs to the receiving country to trigger state responsibility.

This study also related Article 5 of the CPB (2000) in the context of the biopharming of plants and animals. Although the CPB will impose a risk assessment on the plant and animals, especially if they are being imported to be planted in a receiving state, the substance produced by the pharmaplants and animals for human consumption or usage and its safety measures are within the WHO's purview through guidelines highlighted in Chapter 8. These substances can trigger Article 6(1) and Article 6(2) of the CPB (2000) covering GMOs in transit and contained use when they are further processed in other states' pharmaceutical laboratories and facilities as the substance are not directly consumed or used. While in transit, these GMO substances may be stolen and diverted by terrorists if they have the means and capabilities to change these substances into deadlier organisms for bioterrorism. Environmental contamination can occur in the state's territory where these GMO substances are being processed. This situation can trigger the principle of the duty of states to ensure sustainable use of natural resources and not to pollute the environment of other states. This condition exists when the state of origin fails to detect any plans among terrorists within its state and their counterparts in the transit states that have the intention of releasing the GMO substances for bioterrorism to trigger state responsibility.

As indicated by Vöneky (2015, pp. 122-123), Article 25 concerning illegal transboundary movement of GMOs can be misused by terrorists to illegally smuggle biological agents into a country. Terrorists may illegally smuggle GMO biological agents acquired on a black market or from less stringent pharmaceutical companies to subsequently appear unintentionally in another state to trigger Article 17 of the CPB (2000). This can also trigger the principle of the duty of states to ensure sustainable use of natural resources and not to pollute the environment of other states. The state of origin

that fails to take preventive and enforcement measures to prevent terrorists from smuggling GMO biological agents to another state can incur state responsibility when these biological agents appear illegally in the receiving state and subsequently are released to cause environmental contamination. Thus, this study analysed the principle of the duty of states to ensure sustainable use of natural resources in light of Article 5 covering pharmaceuticals, Article 6 encompassing GMOs in transit and contained use and Article 25 of the CPB (2000) encompassing illegal transboundary movement of GMOs from the angle of bioterrorism. This differs from Segger, Welch and Frison (2013, p. 8) who interpret the aforementioned principle in light of Article 2 (2) covering the CPB's (2000) general provisions.

As for the principle of equity and the eradication of poverty, this is directly reflected in Article 26 of the CPB (2000) addressing the socio-economic considerations of GMOs, namely the socio-economic effects of introducing GMO crops on indigenous and local communities. This study asserted that Article 26 of the CPB (2000) can be viewed in light of the outcome of biological warfare to cause environmental contamination for future generations that deprives communities from farming land. This also deprives other economic activities like oil exploration evident from the Vozrozhdeniye Island case of the former Soviet Union. The Soviet Union, as highlighted in Chapter 7, used genetic engineering to develop and test biological weapons on this island (Ainscough, 2002, p. 3; Gilsdorf & Zilinskas, 2005, p. 1160). Unable to generate a livelihood from contaminated land from the testing of biological agents can cause a community to be deprived of an income and exacerbate their poverty. While Segger, Welch and Frison (2013, p. 9) highlighted the relevance of this principle to the impacts of biotechnology on poor populations in rural areas for GMOs in agriculture, this study has analysed the principle and Article 26 of the CPB (2000) in light of the socio-economic consequences wrought from biological warfare.

With regard to the principle of common but differentiated responsibilities, this study indicated that more affluent states can share their knowledge and biosensor technology with developing states in the detection of illegal transboundary movement of GMOs. This study also indicated that developed states have a role to play in educating developing states about the potential misuse of GMOs for bioterrorism and biological warfare. This is because developing states need guidance from developed states that have the knowledge and technology to deal with cases of bioterrorism and biological warfare to share their expertise. Through knowledge and technology transfer by developed states, this can help developing states to deal with future incidents of bioterrorism that can cause environmental contamination. Both developed and developing states have differentiated roles to play to minimise incidents of bioterrorism that can cause environmental contamination and degradation as the giver and receiver of knowledge and technology. This is consistent with Segger, Welch and Frison (2013, pp. 9-10) indicating that capacity building measures such as those indicated in this study are associated with the principle of common but differentiated responsibilities.

This study also associated the precautionary approach addressed in the preamble and Article 10 (6) of the CPB (2000), not only with GMOs in agriculture and for food, feed and processing, but also its relevancy to the environmental consequences of biological warfare. Because the lethality and survivability of genetically modified biological agents used for biological warfare causes more severe environmental contamination than GMOs in agriculture, the precautionary approach should apply. Moreover, this study also asserted the relevance of the precautionary approach in making a risk assessment of a likelihood of bioterrorism attack occurring as a preventive measure to prevent a bigger catastrophe. Thus, this study has extended Hill's (2013, p. 76) application of the precautionary approach in food, feed and processing as well as to human health, natural resources and ecosystems of GMOs in agriculture to one related with biological warfare.

Regarding the principle of public participation and access to information and justice, this is reflected in Article 23 of the CPB (2000) covering public opinion concerning the growth and suitability of GMO crops in a particular location. This study highlighted that education and awareness in having access to information must not be restricted to the knowledge of GMO crops alone. Knowledge and awareness of GMOs should be broadened to encompass the misuse of GMOs for bioterrorism and biological warfare. This is in view that GMO crops can be targeted for biological warfare and bioterrorism while an informed public of these issues will enable them to notify authorities for timely action.

The principle of good governance though is not explicitly mentioned in the CPB but is indirectly implied through Article 34 concerning CPB member states' compliance in meeting all biosafety requirements stipulated by its provisions. A compliance mechanism within the CPB assures transparency, which is a feature of good governance. This study indicated that a verification procedure of on-site visits utilising Institutional Biosafety Committees (IBCs) at the national level with regard to inspection of contained facilities is needed to verify whether GMOs are truly used for their intended purpose or diverted for bioterrorism as a form of compliance.

Article 27 of the CPB (2000) addressing liability and redress also fulfils good governance in the context of when states fail to implement and enforce their laws in preventing terrorists from acquiring GMO biological agents within their borders that is subsequently released into another state to cause damage. While it is true that states may not be accountable for the actions of private actors (in this case terrorists) to invoke state responsibility and liability, states are still accountable if proven to have failed to enforce their laws related to terrorism. While Segger, Welch and Frison (2013, p. 13) discussed the principle of good governance in light of compliance procedures to the CPB (2000) in Article 34, the AIA in Article 7(1) and other legal and administrative measures to be

followed by member states, this study extended the understanding of good governance concerning the need for a verification procedure and the invocation of liability and redress in the context of illegal acquisition of biological agents meant for bioterrorism. Thus, this study assessed the CPB from the perspective of the biosecurity of biotechnology being misused for bioterrorism and biological warfare. In view that sparse literature exists to link the CPB and BWC together, and to analyse CPB provisions in light of bioterrorism and biological warfare, this study contributed to a grey area that has been given scant attention.

9.4.2 The Biological Weapons Convention

The reflection of principles from the Delhi Declaration of ISDL in the BWC generated the following **finding statement**:

> *The principles from the Delhi Declaration of ISDL are indirectly reflected in the BWC to connect disparate areas and sectors of biosecurity within and among other international agreements and initiatives despite sustainable development not being mentioned explicitly.*

There are no provisions within the BWC that directly mention sustainable development. That said, one UN non-binding Resolution on the Observance of Environmental Norms in the Drafting and Implementation of Agreements on Disarmament and Arms Control (2013) (hereinafter "Resolution on the Observance of Environmental Norms") stresses that science and technological advancement in enhancing security and facilitating disarmament should not cause adverse impact on the environment nor limit the attainment of sustainable development. This same UN Resolution also recommends that arms control agreements also adopt environmental norms, making it plausible to interpret BWC provisions in light of ISDL principles from the Delhi Declaration ("Resolution on the Observance of Environmental Norms", 2013). This study highlighted that Article II of the BWC (1972) covering disarmament and harm

to the environment resulting from the destruction of biological weapons must be read together with the aforementioned Resolution. Thus, the BWC abides by the principle of integration in integrating environmental concerns in the disarmament context and is not fully focused on international arms control alone.

The second manner in which the principle of integration is reflected within the BWC (1972) is through Article X (1), which promotes the exchange of equipment, materials, scientific and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes. The BWC forum has referred to the CPB and the Convention on Biological Diversity (CBD) Secretariat to emulate how the clearing-house mechanism can be replicated in the BWC context through the Implementation Support Unit (ISU) in facilitating partnerships of cooperation and assistance among BWC states (Delmi, 2012, p. 9; United Nations Office at Geneva [UNOG], 2009, p. 8).

Similarly, reference to the CPB is made in learning from the latter's capacity-building efforts and is likewise implemented within the BWC through the organisation of workshops, courses, training, sharing of experiences and best practices. These include for instance, the Intersessional Process (ISP) of the BWC in 2010 covering requests for assistance in the alleged use of biological weapons (UNOG, 2010b, p. 9), the ISP 2009 in facilitating cooperation, assistance and exchange for disease surveillance, detection, diagnosis and containment of diseases (UNOG, 2009, p. 2). This study found that collaborative efforts with the CPB was largely initiated by the BWC forum. Instances of this include the United Nations Environment Programme (UNEP) attending the BWC's ISP 2008 to share the CPB's capacity-building efforts while the CBD Secretariat was invited to the BWC's expert meeting in July, 2012 (Delmi, 2012, p. 9; Duthie, 2008, pp. 6-7). As asserted by Anuradha (1999, p. 133), Mauro (2000, p. 122), and Pearson (2000 p. 8), by the BWC learning from the CPB's BCH mechanism and capacity building initiatives, this highlights that both international agreements share a commonality in these

areas. Existing linkages between the CPB and BWC should be extended further. This study proposed for the CPB forum to learn how bioterrorism and biological warfare is relevant in the CPB's context.

This study also found that developing states attempt to bring the relevance of the then on-going negotiations of the CPB during the period of 1996-1997 had encountered a rebuff by developed states (Dando & Pearson, 1997, p. 123). The European Union (EU) at the Fourth Review Conference of the BWC in 1996 took note of on-going negotiations of the CPB as being encouraging but asserted that the BWC forum should not digress from its own scope of work and should avoid duplication of work conducted by other international organisations (Dando & Pearson, 1997, p. 123). This is consistent with Rhodes (2008a, pp. 45-48) who highlighted the unwillingness of certain international organisation and member states deciding not to encroach into the jurisdiction of other organisations scope of work that hampers an integrative and cooperative relationship, in this case the CPB and BWC.

The BWC also addressed international social law of ISDL by emphasising health and diseases under the tutelage of the WHO in promoting collaboration. Article X(1) of the BWC (1972) promoting cooperation individually, together with other states or international organisations for further development and application in bacteriology (biology) for prevention of diseases is the catalyst for cooperation with the WHO with the latter being invited to certain BWC meetings as an observer as in Chapter 7. Article VII of the BWC (1972) emphasises that assistance be provided to BWC Parties exposed to a danger in violation of the BWC is another trigger mechanism for collaboration with the WHO and the International Health Regulations 2005 (IHR 2005) in preventing, protecting, control and responding to international spread of diseases. The BWC's cooperation with the WHO is also through the ISP of 2008 regarding laboratory biosecurity, which is the competency of the WHO through its manual, Biorisk

Management: Laboratory Biosecurity Guidance (WHO, 2006) while laboratory biosecurity is relevant to the CPB (2000) through Article 6(2) covering contained use.

In this regard, it would seem that the BWC administrators and states under its scope seem more willing to build a more cooperative relationship with other international organisations managing the CPB and WHO. As indicated by Rhodes (2008a, p. 45), this could be due to the fact that states within the BWC forum have a vested interest for international cooperation and perhaps the attitude of individuals holding key positions in administering the BWC are willing to facilitate this integrative relationship. This also shows that the BWC representing the biosecurity of biotechnology sector not only links with the WHO in the same sector but can relate with the CPB in the agricultural biosecurity sector too.

As for the international trade law element in the BWC, this is embedded within Article III (BWC, 1972) regarding prohibiting transfer of any biological agents, toxins, weapons, equipment or means of delivery in the form of export controls to be implemented at the national level among states. This provision is not applicable to non-state actors like terrorists acquiring, producing, developing, retaining or transferring biological agents for bioterrorism, which is best addressed by UNSCR 1540 (S. C. Res. 1540, 2004).

As for the duty of states to ensure sustainable use of natural resources, this is indirectly implied in the BWC through Article II concerning environmental contamination and disarmament (BWC, 1972). This study highlighted that the principle is applicable to successor states that have inherited land environmentally contaminated through biological weapons testing and incomplete decontamination during the disarmament process by predecessor states. This is exemplified by the case of Vozrozhdeniye Island of the former Soviet Union, Fort Sherman in Panama, and Zhejiang and Hunan provinces in

China (Ainscough, 2002; Gilsdorf & Zilinskas, 2005; Power, 2005, p. 1; "The horrors", 2001, p. 3).

With regard to the principle of equity and eradication of poverty, this has been directly implied by Article X (2) of the BWC (1972) stressing that this international agreement be implemented in a manner to avoid hampering the technological or economic development of BWC Parties or international cooperation in the peaceful bacteriological (biological) activities. This means the transfer of biotechnological knowledge to developing states for peaceful purposes like agriculture and medicine should not be curtailed for their development. Article X (2) is contrary to Article III of the BWC (1972) because the imposition of export controls of biological agents, weapons, equipment and means of delivery as an obstruction to bioterrorism and biological warfare will curtail developing states biotechnological development for peaceful purposes because the very same items are dual use in nature and can be used for malicious or peaceful intentions. Intergenerational equity in the BWC was reflected in the case of environmentally contaminated land by the testing of biological agents and incomplete decontamination in the disarmament process preventing future generations from utilising land for agriculture and other economic activities, raising equity as a concern.

Referring to the principle of common but differentiated responsibilities, this principle is not explicitly mentioned in the BWC. This principle though is relevant to Article X of the BWC (1972) promoting the fullest possible exchange of equipment, materials and scientific and technological information for peaceful purposes whereby the Non-Aligned Movement (NAM) states views this provision as a legal obligation for developed states to transfer the necessary training of human resources (Barnaby, 1997, p. 309; Dando & Pearson, 1997, p. 122). This shows the distinctive roles between developing states as receivers of biotechnological knowledge and equipment and the giver of assistance among developed states indicating the relevance of the said principle of ISDL.

Concerning the principle of the precautionary approach to human health, natural resources and ecosystems, this principle does not find expression directly in the BWC. The precautionary approach though can be interpreted in the BWC context as taking preventive measures through criminal law to prevent bioterrorism by penalising, preventing and prosecuting prohibited activities stipulated in the BWC (Borgers & Sliedregt, 2009, p. 187; Kittelsen, 2009, p. 64). Additionally, the BWC's ISP 2007 requires criminal laws that prohibit assisting, encouraging, including others to breach the BWC and implementing export control laws in tandem with Articles III and IV (BWC, 1972). Requiring BWC Parties to draft national laws to implement biosafety and laboratory biosecurity measures, introducing codes of conduct for scientists internationally and nationally, including publication censorship for Dual Use Research of Concern (DURC), in preventing misuse and having a national regulatory framework and infrastructure for disease surveillance in line with the ISP of 2008 and 2009 are also precautionary measures against bioterrorism and biological warfare (UNOG, 2008b, p. 6; UNOG, 2009, pp. 4-6).

As to the principle of public participation and access to information and justice, no BWC provision directly bears reference to this principle. Nevertheless, public participation indirectly features within the BWC forum because non-state actors have increasingly been invited to give their feedback within their areas of competency at the BWC meeting of experts and side events of panel discussions (Ijssel, 2011, pp. 14-15). Public participation was also featured in the ISP 2008 in highlighting the participation of both state and non-state actors from the sciences and social sciences as overseers in approving DURC research and publications (UNOG, 2008b, p. 1). This depicts a multidisciplinary approach to be implemented at the national and international levels (UNOG, 2008b, p. 1). Regarding access to information about the misuse of biological agents, the Second Review Conference of the BWC in 1986 asserted that textbooks in

medical, scientific and military educational programmes should convey to the readers at large the misuse of biological agents (UNOG, 1986, p. 4). Similarly, the BWC's ISP 2008 stressed upon oversight, education, awareness raising and the adoption of codes of conduct to prevent the misuse of the biosciences and biotechnology (UNOG, 2008b, p. 1).

In referring to the principle of good governance, similarly there is no provision in the BWC that explicitly refers to this principle. This study found that the BWC lacks a binding compliance mechanism but has a non-binding mechanism in the form of Confidence Building Measures (CBMs) requiring parties to report annually their high containment research centres and laboratories, outbreak of infectious diseases and toxins, their publication of results in scientific journals of DURC, declaring laws and regulations in line with the BWC, past offensive and defensive research, and defence programmes and vaccine facilities (UNOG, 1986, p. 6). A past verification protocol to the BWC that would have made all the requirements listed under the CBM compulsory was ultimately rejected because there was no agreement for on-site visits with regard to biotechnological development sites of parties (Bailey, 2002, pp. 15-16). CBMs are the only means now of assuring compliance, although voluntary reports from member states have not met the mark. The ISU is purely administrative as a receiver of BWC Parties CBMs, a facilitator of information exchange among parties and it cannot make any decisions or punish parties in violation of the BWC (UNOG, 2006, p. 120). Thus, it can be said the BWC does not have an effective compliance mechanism in assuring transparency and accountability in making it mandatory for all member states to report how they have complied with the BWC provisions and cannot fully fulfil the principle of good governance.

Overall, the findings concerning the BWC is indeed consistent with that of Rhodes (2008a, p. 45) who asserts that while the BWC does not incorporate sustainable development principles explicitly, some of its provisions do indeed meet the criteria for

sustainable development. Rhodes (2008a, p. 45) cited the criteria of technology transfer and the requirement of financial resources between developing and developed states, poverty and inequality among developing states as the equivalent to the principle of common but differentiated responsibilities and the principle of equity and eradication of poverty of ISDL. The difference is that this study used the broader remaining principles of ISDL to evaluate whether the BWC can subscribe to sustainable development, which has not been addressed by Rhodes. While the BWC itself does not refer to sustainable development, this should not obliterate this agreement from achieving sustainable development because the United Nations General Assembly (UNGA) Resolution on the Observance of Environmental Norms in the Drafting and Implementation of Agreements on Disarmament and Arms Control (2013) urges all BWC Parties to consider all relevant environmental norms in ensuring that scientific and technological progress within the ambit of international security, disarmament and other areas would not harm the environment and contribute towards sustainable development despite being non-binding. This being the case, the findings of this study is consistent with the earlier assertion made by Tladi (2007, p. 107) and Weiss (2000, p. 348) that international arms control law, as demonstrated by the BWC's case, can similarly attain sustainable development too.

Therefore, this study's analysis of the BWC linked with the attainment of sustainable development contributes towards the sparse literature of international arms control law and sustainable development law. This also requires a re-examination of the definition of ISDL by Segger and Khalfan (2004a, p. 103), which is merely confined to international environmental, economic and social law; the definition can be extended to international arms control law too.

9.4.3 The International Health Regulations 2005

The reflection of principles from the Delhi Declaration of ISDL in the IHR 2005 generated the following **finding statement**:

The principles of international law from the Delhi Declaration of ISDL are fully reflected in the IHR 2005 in connecting disparate areas and sectors of biosecurity within and among other international agreements and initiatives despite not explicitly referring to sustainable development.

Within the IHR 2005, none of its provisions explicitly mention sustainable development as an objective. However, the WHO subscribes to sustainable development as evident by resolution WHA 55.11 on health and sustainable development stressing that WHO Parties provide funding for new drugs and vaccines to prevent diseases of poverty (WHO, 2002b).

Provisions of the IHR 2005 were found to incorporate the principle of integration of ISDL. This study referred to Articles 3 and 32 of the IHR 2005 (2005) concerning the respect of human rights for travellers, their dignity and the fundamental freedoms of persons complying with the international social law aspect of ISDL as implied by Fidler (2005, p. 367). In addition to Article 17 (d) of the IHR 2005 being identified by Fidler (2005, p. 383) as stressing that health measures must not be more restrictive of international traffic and trade, this study also cited Article 2 (IHR 2005, 2005) on the same capacity. This shows that international trade law is also considered in the IHR 2005, implying that it is a highly integrative international agreement. This study found that the environmental aspect of the IHR 2005 (2005) is covered by Article 22 (3) concerning the role of competent authorities in disinsection, derrating, disinfection, decontamination and other sanitary procedures avoiding injury to persons, damage to the environment and public health not mentioned previously by scholars. As for the IHR 2005 cooperating with other international agreements and intergovernmental organisations, this is reflected by Article 14, as highlighted by Fidler (2005, p. 364). Additionally, this study found that Article 57 of the IHR 2005 (2005) concerning its relationship with other international

agreements also makes it possible to form linkages with the CPB and BWC in the agricultural biosecurity and the biosecurity of biotechnology sectors.

This study found there was some form of awareness about existing linkages between the IHR 2005 and CPB within the WHO forum because in the drafting process of the IHR 2005 there was a document referring to a list of international agreements prepared, highlighting any overlap or conflict in areas of the CPB and BWC (WHO, 2004a, p. 426). This seems to be consistent with Rhodes' (2010, p. 178) previous findings indicating that some external awareness among negotiating states and international organisations regarding the connection between disparate biotechnology international instruments known as a "common identity" as in Chapter 2. The building of linkages between the CPB and IHR 2005 also seeks to contribute towards this least emphasised relationship relating GMOs and infectious diseases covering the interface of health and environment that has received scant attention, as highlighted by Mariani (2007, pp. xii-xiv). Therefore, there is nothing to impede the IHR 2005 to form linkages with the CPB and BWC. Doing so is a matter of political will among state parties and international organisations toward facilitating a collaborative relationship.

Other principles of ISDL also find its relevance within the IHR 2005. This study found the relevancy of the duty of states to ensure sustainable use of natural resources is applicable in the IHR 2005 when states fail to notify the WHO and other states of the outbreak of diseases within their territory. There is risk in such cases for the spread of outbreaks into the jurisdiction of other states, causing harm to health and environmental contamination. This is exemplified by the case of a plague outbreak in Surat, India back in 1994 (Lakoff, 2010, p. 70) and when Indonesia failed to provide notification of a bird flu outbreak (H5N1) in 2006-2007 (Holbrooke & Garrett, 2008, p. 1). This is consistent with the findings of Fidler (2003, p. 2) and Reader (2006, p. 525) that related the same principle to the Severe Acute Respiratory Syndrome (SARS) from 2002-2003 in China

when Chinese officials failed to inform the WHO of this disease outbreak (Holbrooke & Garrett, 2008, p. 1; Lakoff, 2010, pp. 61-70).

Fidler (2004) and Gostin (2004, p. 2626) earlier interpreted the principle of good governance in the IHR 2005 as referring to the participation of non-governmental sources of disease surveillance to obtain information about infectious diseases that promotes transparency. This study interprets the principle of good governance differently, whether provisions of the IHR 2005 (2005) have a binding system of compliance and a dispute settlement mechanism to promote accountability. A dispute settlement through Article 56 (1) of the IHR 2005 (2005) emphasises negotiations in settling disputes is also a contributor towards good governance.

Likewise, this study similarly identifies Article 9 of the IHR 2005 (2005) that the participation of Intergovernmental and Non-Governmental Organisations (NGOs) in providing information about infectious diseases that constitute a Public Health Emergency of International Concern (PHEIC) abides by the principle of public participation and access to information and justice. This finding is similar to the interpretation of Abbot and Gartner (2012, p. 3).

The remaining principles of ISDL have not been interpreted in light of the IHR 2005. As such, this study equated the principle of equity and the eradication of poverty with the case of Indonesia being reluctant to provide influenza virus samples to the WHO because developed states that create vaccines do not necessarily share them with impoverished developing states, reflecting an intragenerational equity issue (Smallman, 2013, p. 22).

As for the principle of common but differentiated responsibilities, this has been implied by Article 5 (3) of the IHR 2005 (2005) concerning the WHO's assistance to member states in developing, strengthening and maintaining their capacities without mentioning funding. This provision implies assistance from developed states and

intergovernmental organisations as givers to developing states as receivers in making a distinction of their roles. This study's findings are indeed consistent with Rhodes's (2004b, pp. 763-765) assumption earlier that while the IHR 2005 does not refer to sustainable development directly, it does contain supportive provisions like Article 5 (3) (IHR 2005, 2005) concerning assistance in building capacities that indirectly support sustainable development.

The precautionary approach is the last principle identified in Article 43 (2) (b) of the IHR 2005 (2005) that encourages member states to justify their stringent health measures based on scientific evidence obtained either through the WHO or other intergovernmental organisations and international bodies. This completes the analysis of the whole seven principles of ISDL embedded in the IHR 2005.

The findings pertaining to the IHR 2005 is indeed consistent with Segger and Khalfan (2004a, p. 103), indicating that ISDL covers health law under international social law. By analysing the IHR 2005 in light of all seven principles of ISDL that have earlier been left incomplete, this enriches international health law and ISDL, which Prabhu (2004, p. 323) indicates is an underexplored area.

9.4.4 The World Health Organisation's Laboratory Biosecurity Initiative

The principles from the Delhi Declaration of ISDL cannot be reflected within the WHO's laboratory biosecurity initiative because it is devoid of provisions featured in a binding international agreement. The **finding statement** is presented below:

> *The WHO's laboratory biosecurity initiative can be linked with the CPB and BWC through these international agreements containing provisions reflecting the principle of integration as a catalyst of collaboration with the WHO.*

In the context of laboratory biosecurity, the WHO's non-binding document, Biorisk Management: Laboratory Biosecurity Guidance (WHO, 2006) provides a biorisk management approach based on biosafety, laboratory biosecurity and ethical responsibility in guiding states to handle and store VBMs.

Indeed, the said guideline is relevant to the CPB that addresses contained use through Article 6 (2) (CPB, 2000) and Article X (1) of the BWC (1972), which promotes existing cooperation with the WHO including laboratory biosecurity in line with the ISP 2008. Article 29 (8) permitting the CPB to work with other UN agencies and Article 22 (1) covering capacity building (CPB, 2000) are regarded to be integrative provisions that can form a catalyst in building a relationship with the WHO that addresses laboratory biosecurity under its purview. This being the case, the principle of integration of ISDL is the main facilitator for collaboration between the CPB, BWC and WHO in the area of laboratory biosecurity. Together with the WHO's Responsible Life Sciences Research for Global Health Security: A Guidance Document (WHO, 2010, p. 13) urging the creation of an oversight body among research institutions and universities to screen DURC research and publications, laboratory biosecurity encompass a combination of measures that deserves due attention.

9.4.5 The World Health Organisation's Biopharming Initiative

The principles from the Delhi Declaration of ISDL cannot be reflected within the WHO's biopharming initiative because it is devoid of provisions featured in a binding international agreement. The **finding statement** is presented below:

> *The WHO's biopharming initiative can be connected to the CPB through provisions within this international agreement reflecting the principle of integration.*

Because the CPB does not address the health safety aspect of pharmaceuticals such as vaccines for humans within the scope of the WHO derived from pharmaplants and

biopharming of animals, forming linkages with the WHO is crucial as this organisation has a few technical guidelines addressing the health safety aspect of plants and substances derived from biopharming. Since pharmaplants are used to obtain vaccines, some relevant guidelines such as the WHO's Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants (WHO, 2003a), the Quality Control Methods for Medicinal Plants Materials (WHO, 1998), the WHO Guidelines on Nonclinical Evaluation of Vaccines: Regulatory Expectations (WHO, 2004b) and the Guidelines on the Quality, Safety and Efficacy of Biotherapeutic Protein Products Prepared by Recombinant DNA Technology (WHO, 2013) are relevant in providing guidance, which have been discussed in detail in Chapter 8.

As for the biopharming of animals, Chapter 8 highlighted that it was disputable that the Food and Agriculture Organisation of the United Nations' (FAO) Guideline for the Conduct of Food Safety, Assessment of Foods Derived from Recombinant – DNA Animals (FAO, 2008) applies to the production of pharmaceutically/therapeutically relevant proteins derived from animals. This is because the Guideline applies in the context of food. However, the Ad Hoc Intergovernmental Task Force on Foods derived from biotechnology of the Codex Alimentarius Commission (FAO, 2005, p. 9) has left the issue to member countries in deciding whether or not this Guideline applies to substances produced by animals through biopharming. If this Guideline is not applicable, there exists a gap in this area that the WHO, together with the FAO in due course, will have to address.

Indeed, for the health safety aspect affecting humans concerning substances for vaccines derived from the biopharming of plants and animals, the principle of integration of ISDL reflected by Articles 29 (8) concerning cooperation with UN agencies and Article 22 (1) on capacity building of the CPB (2000) can form a catalyst in building a relationship between the CPB and the WHO. Such a relationship will enable CPB states

to familiarise themselves with the various technical guidelines mentioned not under the CPB's purview. As the generation of vaccines also raises a biosecurity of biotechnology concern like its misuse for biological warfare and bioterrorism, it is crucial that all safety precautions recommended by the WHO among the various guidelines be adhered to.

Indeed, the analysis of linking the WHO's laboratory biosecurity and biopharming initiatives with the CPB and BWC through the principle of integration in ISDL has further enriched international health law and ISDL, which as Prabhu (2004, p. 323) has indicated, sparse literature exists in this area.

Therefore, this study's significant contribution to the literature through theory and policy wise based on the earlier extensive elaboration made in this chapter can be summarised in Table 9.1 as below.

Table 9.1: The significant contribution of this study to the literature

Theoretical/ Policy Contribution	**Explanation**
1) To propose a new biosecurity definition merging that of the Food and Agriculture Organisation of the United Nations (FAO), World Health Organisation (WHO) and United States National Academy of Sciences (USNAS)	• A changed approach to biosecurity starts with a holistic definition combining the three biosecurity sectors together followed by the collaboration among biosecurity international agreements and initiatives managed through a United Nations (UN) coordinating mechanism.
2) This study used a different approach especially the principle of integration in International Sustainable Development Law (ISDL) to facilitate cooperation among varying biosecurity international agreements and initiatives	• Previous approaches used multilateralism, global governance and global policy networks within international relations (Al-Rodhan et al, 2008) and epistemic communities (Mariani, 2007).
3) This study proposed to expand the existing ISDL definition to accommodate international arms control law.	• Findings from the Biological Weapons Convention (BWC) indicating its objective of sustainable development shows the need to extend ISDL beyond international environmental, economic and social law.

'Table 9.1, continued'

Theoretical/ Policy Contribution	Explanation
4) The analysis of the International Health Regulations (IHR 2005) in light of the seven principles of ISDL from the angle of biosecurity enriches international health law and sustainable development law in line with Prabhu's (2004) assertion.	• Scholars such as Abbot and Gartner (2012), Fidler (2003, 2004, 2005), Gostin (2004) and Reader (2006), before this have analysed the seven principles in piecemeal while this study has analysed all seven principles of ISDL as a whole.
5) The analysis of the Cartagena Protocol on Biosafety (CPB) from the angle of bioterrorism and biological warfare utilising the seven principles of ISDL contributes to the sparse literature which have barely elaborated on these aspects.	• Previous analysis of the CPB in light of the seven principles of ISDL have mainly focused on GMOs in agriculture.
6) The analysis on relevant WHO guidelines in relation to biopharming have contributed to a grey area of which little was known of their existence and how they would complement the CPB in addressing biopharming.	• Previous analysis did not go beyond indicating that pharmaceuticals would fall under the purview of the WHO but no further elaboration was made to identify which WHO guidelines would specifically cover biopharming.
7) Contribution to Policy and Law	• International organisations as administrators and states as members to international biosecurity agreements and its non-binding initiatives should embrace ISDL principles to bring disparate biosecurity sectors and areas together for the betterment of biosecurity governance internationally.

9.5 Conclusion

This chapter provided interpretations to the findings whether principles of international law from the Delhi Declaration of ISDL holds the solution in linking different biosecurity sectors and their respective international agreements and initiatives together in the context of GMOs for coherent management among international organisations. Overall, all three international agreements, namely the CPB, BWC and

IHR 2005 have directly or indirectly reflected the seven principles of ISDL among their provisions. Since the principle of integration was reflected among provisions of all three international agreements enabling interlinkages of cooperation to be formed among international organisations managing these biosecurity international agreements, the main impediment this study found was the lack of political will among member states and administrators of international organisations to coordinate work among one another causing continued fragmentation among biosecurity sectors. Minimal awareness and interaction exists among biosecurity international organisations to cooperate in some aspects of their interest as in the case of the ISU of the BWC learning some useful administrative actions of the CPB through interaction with the CBD Secretariat. This needs to be intensified further though.

As for the remaining principles of ISDL, this study showed they were fully reflected within the three biosecurity international agreements, both directly and indirectly. By these biosecurity international agreements reflecting the remaining principles of ISDL, this indicates that it is not solely focused on its specialisation but considers other issues affecting its effectiveness. These included the need to consider the principle of the duty of states to ensure sustainable use of natural resources, and the principle of equity and the eradication of poverty. Other principles of ISDL considered include the principle of common but differentiated responsibilities, the principle of the precautionary approach to human health, natural resources and the ecosystems, the principle of public participation and access to information and justice as well as the principle of good governance.

The surprising findings pertaining to the BWC as an international disarmament and arms control agreement, especially regarding fulfilling most principles of ISDL challenges Segger and Khalfan's (2004a, p. 103) assumption that ISDL is limited to international environmental, economic and social law. The findings pertaining to the

BWC indeed extended Tladi (2007) and Weiss's (2000) assumption that international arms control law agreements can similarly attain sustainable development as an objective, which is particularly true.

As for the CPB and IHR 2005, the findings pertaining to these biosecurity international agreements reflecting all principles of ISDL conforms to Segger and Khalfan's (2004a, p. 103) definition of ISDL that international environmental and health agreements are within the scope of ISDL. As this study showed, the difference was analysing CPB provisions using ISDL principles from the angle of bioterrorism and biological warfare. As for the IHR 2005, this study covered ground in analysing remaining principles of ISDL not covered fully by other scholars in the context of infectious diseases.

CHAPTER 10: CONCLUSIONS AND RECOMMENDATIONS

10.1 Introduction

This study analyses whether the introduction or present existence of principles of international law from the New Delhi Declaration of Principles of International Law Relating to Sustainable Development (Delhi Declaration) can connect different biosecurity sectors to recognise the interrelationship within and among selected biosecurity international agreements and initiatives in order to facilitate better cooperation. The following conclusions are drawn from the findings and will cover the following areas: (a) Biosecurity Sectors and Their Limitations; (b) The Prospect of Sustainable Development Linking Disparate Biosecurity Sectors, Associated International Agreements and Initiatives; and (c) A Need to Extend International Sustainable Development Law (ISDL) Beyond Existing Boundaries. Subsequently, the following recommendations are made: (a) Theoretical Recommendations and (b) Policy Recommendations. This is then followed by the direction of future research and the conclusion to the study.

10.2 Biosecurity Sectors and Their Limitations

The biosecurity of biotechnology, laboratory biosecurity and agricultural biosecurity, constituting sectors with associated international agreements and initiatives, are restricted in their scope of work, thereby limiting their ability to recognise connections between sectors for better management.

While it has been apparent that each biosecurity sector is specialised in their own area, their specialisation is also their limitation in their inability to overcome a biosecurity issue that encroaches into all three sectors. A conclusion is drawn that, to overcome this limitation, there is a need for these biosecurity sectors and their associated international

agreements and initiatives to form interlinkages between them to complement each other's scope of work.

A second conclusion is that, if biosecurity sectors and their associated international agreements and initiatives are to dispense with the current sectorial approach, there is a need to discard the existing sectorial definitions of biosecurity propounded by the United States National Academy of Sciences (USNAS), the World Health Organisation (WHO) and the Food and Agricultural Organisation of the United Nations (FAO). A changed mindset of approaching biosecurity sectorially among administrators of international organisations and the member states that are parties to them can be brought about if the definition of biosecurity itself merges all three sectors as a first point of reference. There will also be a need for a coordinating mechanism at the international level which is able to bring various members of existing biosecurity international organisations together in interlinking international agreements and initiatives for the betterment of biosecurity.

10.3 The Prospect of Sustainable Development Linking Disparate Biosecurity Sectors, Associated International Agreements and Initiatives

The second major finding to this study is that the seven principles of international law that form the crux of ISDL within the Delhi Declaration can build linkages among disparate biosecurity sectors and their associated international agreements and initiatives. The integrative nature of sustainable development that seeks to reconcile environmental protection, economic and social development provides a suitable means in bringing disparate biosecurity sectors together. Within the realm of international law, in particular the Delhi Declaration of Principles of ISDL, seven principles have been shown in this study to be capable of linking together disparate biosecurity sectors within and among their associated international agreements and initiatives; provided that provisions among the biosecurity international agreements, namely the Cartagena Protocol on Biosafety (CPB), Biological Weapons Convention (BWC) and International Health Regulations

2005 (IHR 2005), reflect the ISDL's seven principles. The CPB refers to sustainable development directly within its text, while other non-binding United Nations (UN) documents that concurrently exist within the BWC and IHR 2005 address these international agreements to sustainable development and recommend the adoption of environmental norms, which directly refer to the ISDL principles that member states to the BWC and IHR 2005 can choose to adopt. Thus, it can be concluded that ISDL holds the potential for bringing disparate biosecurity international agreements and initiatives together.

10.4 A Need to Extend International Sustainable Development Law (ISDL) Beyond Existing Boundaries

While the findings pertaining to the biosecurity international agreements all indicated that principles of ISDL have been reflected, directly or indirectly among them, the definition of ISDL indicating its scope as being restricted to international environmental, economic and social law also needs to be reviewed. There was nothing unusual in that, the CPB, being an international environmental law agreement, and the IHR 2005, an international health law agreement constituting part of international social law, would have conformed to ISDL. The unusual finding relates to the BWC, an international arms control agreement, being able to reflect the principles of ISDL despite none of its provisions explicitly mentioning sustainable development. Regardless, the United Nations General Assembly (UNGA) Resolution on the Observance of Environmental Norms in the Drafting and Implementation of Agreements on Disarmament and Arms Control has prescribed that environmental norms be adopted among arms control agreements. As for the WHO's guidelines pertaining to laboratory biosecurity and biopharming initiatives, the findings indicated that CPB and BWC provisions reflecting the principle of integration of ISDL are a facilitator in forming linkages with the WHO. This is because the WHO guidelines on laboratory biosecurity and biopharming do not

contain provisions of a binding international agreement reflecting the principle of integration as being able to be linked with other biosecurity international instruments.

Based on the findings pertaining to the BWC especially, it can be concluded that ISDL's definition and scope needs to be reviewed, as it should not merely be restricted to international environmental, economic and social law, but incorporate other branches of international law, such as arms control law and other areas not covered by ISDL.

10.5 Recommendations

10.5.1 Theoretical Recommendations

10.5.1.1 The Need for a Holistic Biosecurity Definition and Coordinating Mechanism

Consistent with the findings of this study, some changes at the international level regarding how states and international organisations approach biosecurity as disparate sectors will have to be made to the one that merges all three biosecurity sectors as addressed in this study. It is recommended that states, the UN and its agencies, intergovernmental organisations and a whole host of other stakeholders adopt a holistic biosecurity definition merging all three sectors of biosecurity, as proposed below:

> *Biosecurity is an integrative overarching concept addressing the overlap between different sectorial aspects of biosecurity, ranging from biosafety and laboratory biosecurity; agricultural biosecurity protection from biological harm occurring naturally or artificially (diseases, pests, food safety and agroterrorism); the unintentional and intentional misuse of select biological agents, toxins, biotechnological knowledge and equipment for benevolent or malevolent purposes, such as bioterrorism and biological warfare, requiring risk*

management practices, both binding and non-binding initiatives, as forms of defence to prevent, reduce or eliminate biological threats.

As indicated by the term integrative in the biosecurity definition above, it covers the three sectors of biosecurity as it addresses laboratory biosecurity, agricultural biosecurity and the biosecurity of biotechnology regarding the intentional misuse of select biological agents for malevolent purposes. Dual use of biotechnology is also recognised, as this also covers benevolent usage. The last part of the proposed biosecurity definition encompasses the risk management practices for biosecurity, covering binding and non-binding actions referring to the relevant policies, laws and administrative actions already in existence or to be newly formulated and implemented. These risk management practices will be designed to prevent, reduce or eliminate any biological threat endangering the national security of a particular state. The rationale is that a changed mind set concerning biosecurity starts with a changed understanding of its definition to one that is holistic, merging the definitions of the FAO, WHO and USNAS, as described above. Complementing this holistic biosecurity definition is a recommendation to form a UN coordinating mechanism able to bring together related international organisations and agencies to cooperate in complementing their scope of work involving international agreements and initiatives to avoid duplication.

10.5.1.2 Broadening International Sustainable Development Law (ISDL) to Accommodate Other Branches of International Law

This study also suggests that the International Law Association (ILA), the founders of ISDL from the Delhi Declaration, need to broaden the existing ISDL definition to accommodate an international arms control law that equally subscribes to sustainable development. This study proposes a new definition of ISDL to be adopted by the ILA as:

ISDL encompasses all branches of international law that equally subscribe to environmental protection, economic development and social development in the attainment of sustainable development.

This newly proposed ISDL definition is not biased to any branches of international law, but able to accommodate other branches of international law as long as they have features that subscribe to environmental protection, economic and social development. In this way, ISDL is no longer confined to international environmental law, international economic law or international social law, but extended to other branches of international law.

10.5.2 Adhering by Principles of International Sustainable Development Law (ISDL) among Biosecurity International Agreements and Initiatives

Matching the holistic definition of biosecurity proposed earlier is equally a need for all stakeholders, be they administrators of UN agencies managing biosecurity, member states or other stakeholders, so as to be fully aware and embrace ISDL principles. A coordinating mechanism proposed at the UN level and able to unite existing biosecurity international organisations and agencies to cooperate with one another so that their scope of work among international agreements complements rather than duplicates efforts, can also be tasked with introducing ISDL principles among stakeholders to put these principles into practice. It is recommended that the UN coordinating mechanism for biosecurity works closely together with the World Future Council (WFC), which is already embarking on educating international organisations, states and other stakeholders about ISDL principles and evaluating whether treaties, national policies and laws abide by these principles as a form of benchmarking. Once these principles of ISDL are being put into practice, these stakeholders will be able to bring disparate biosecurity sectors together, provided they discard their existing sectorial view of disassociating one biosecurity international agreement or initiative from another.

Most importantly, member states and UN agencies need a strong political will to bring about this coordinated effort of linking biosecurity sectors and their associated international agreements and initiatives together. Therefore, it is recommended for states which are members to the CPB, BWC, IHR 2005 and the WHO's laboratory biosecurity and biopharming initiatives and the administrators of these international instruments to cooperate among themselves in building bridges between biosecurity sectors. As no single biosecurity international agreement and initiative can address diverse biosecurity issues, coordinated work and a division of labour is crucial to save on manpower resources.

While the BWC itself has not explicitly referred to sustainable development and the principles of ISDL, member states can still choose to adopt the Delhi Declaration of ISDL. After all, the UNGA Resolution on the Observance of Environmental Norms in the Drafting and Implementation of Agreements on Disarmament and Arms Control has recommended that states which are members to arms control agreements adopt environmental norms. Thus, a full adoption of the Delhi Declaration of Principles of ISDL among all international instruments is envisaged to merge disparate sectors together to complement the holistic biosecurity definition proposed and to be further strengthened with a UN coordinating mechanism monitoring this implementation process.

10.6 Recommendations for Future Research

Given that the BWC merely addressed biological warfare among states and not specifically bioterrorism, it is recommended that further research be conducted in the direction of bioterrorism, not only together with the United Nations Security Council Resolution 1540 (UNSCR 1540), but other counter-terrorism documents of the UN, through the lens of ISDL. This is a grey area needing further clarification regarding how

ISDL can be used as a benchmark in gauging the extent to which the terrorism documents of the UN are able to fulfil ISDL principles.

This study limits itself to the analysis of the CPB, BWC, the IHR 2005 and the WHO's laboratory biosecurity and biopharming initiatives using principles from the Delhi Declaration of ISDL whenever applicable. Since the number of international instruments used in this study is small, it is hard to make a generalisation that ISDL can be useful in merging disparate biosecurity sectors and its associated international agreements together. It would certainly be useful to test the ISDL principles against other biosecurity international agreements, for instance the International Plant Protection Convention (IPPC) and other non-binding initiatives. With a much larger sample of international instruments, this will then ascertain whether ISDL can be a facilitator in bringing together segmented biosecurity sectors by embracing sustainable development.

10.7 Conclusion

This study highlighted that biosecurity and its associated international agreements and initiatives are in piecemeal form and that this is not effective in dealing with complex biosecurity matters. Thus, a multidisciplinary approach to biosecurity is needed in bringing segregated biosecurity sectors to a point of convergence. International organisations as administrators and states as parties to these international instruments must pave the way for facilitating changes in the current biosecurity practice in order to make a difference.

This study offered some suggestions in bringing the fragmented biosecurity international agreements and initiatives together, first by proposing a holistic biosecurity definition to change the existing mindset of practising biosecurity disparately and in employing a UN coordinating mechanism to facilitate the integration process. This has to be accompanied by embracing the principles from the Delhi Declaration of ISDL.

Political will is needed among administrators of international organisations and member states to these biosecurity international instruments to seriously adhere to the ISDL principles. Through fully adopting the principles from the Delhi Declaration of ISDL, this will also be a benchmark in ascertaining whether states have actually met their commitment to sustainable development in international law too.

Biosecurity international agreements such as the CPB and IHR 2005 contain embedded provisions reflecting the principles of ISDL. It only takes states that are already signatories and which have ratified these international agreements of biosecurity to adopt and fully apply these principles of ISDL in making the connectivity among biosecurity sectors a reality. As for the BWC, it is time for the member states to adopt the principles from the Delhi Declaration of ISDL, as this has been prescribed by the UNGA Resolution mentioned earlier. Therefore, the time is ripe for states, UN agencies and other stakeholders to usher in a new era of biosecurity governance that is more coherent in terms of management.

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LIST OF PUBLICATIONS AND PAPERS PRESENTED

The list of publications below is in fulfilment of the University of Malaya's requirements for 2 ISI indexed journals and related proceedings.

(a) List of Conference Proceedings presented and published from this thesis:-

i) Abdul Majid, M. (2012). Meeting the biosecurity concerns of genetically modified organisms (GMOs) through Malaysia's Strategic Trade Act 2010 and Biosafety Act 2007. In Brebbia, CA and Chon, T-S (Eds.), *Proceedings from Ravage Planet III: Third International Conference on Management of Natural Resources, Sustainable Development and Ecological Hazards* (pp. 325–338). Ashurst: Wessex Institute of Technology (WIT) Press. (Scopus Indexed Conference)

ii) Abdul Majid, M. (2012). Malaysia: Bioethics as a biosecurity measure for monitoring genetic engineering activities against the threat of bioterrorism. In Z. Ismail, M. K. Hamzah, & H. Hashim (Eds.), *2012 IEEE Colloquium on Humanities, Science & Engineering Research* (pp. 1–9). Kota Kinabalu, Sabah, Malaysia: IEEE, NJ, United States. (ISI & Scopus Indexed Conference)

iii) Abdul Majid, M. (2013). Addressing the exportation of genetically modified organism (GMO) samples through Malaysia's Strategic Trade Act 2010. In A. S. Hadi et al. (Eds.), *International Conference Challenges of Extended Mega Urban Regions: The Changing Face of South East Asia and the World* (p. 134). Putrajaya: National University of Malaysia (UKM).

iv) Abdul Majid, M. (2013). Addressing potential smuggling of genetically modified organisms (GMOs) for bioterrorism in Malaysia through the Biosafety Act 2007 as environmental governance. In A. S. Hadi et al. (Eds.), *International Conference Challenges of Extended Mega Urban Regions: The Changing Face of South East Asia and the World* (p. 148). Putrajaya: National University of Malaysia (UKM).

v) Abdul Majid, Marina and Abdullah, N. A. (2015). An ethical code of conduct for the non-proliferation of biological agents among Malaysian businesses. In H. A. Sulaiman (Ed.), *International Symposium on Technology Management and Emerging Technologies (ISTMET)* (pp. 285–290). Langkawi: IEEE, NJ, United States. (ISI/ Scopus Indexed Conference)

(b) List of Journal papers published from this thesis:

i) Abdul Majid, M. (2012). An inclusion of bioethics for a unified biosecurity definition in Malaysia: Genetic engineering as a case study. *Eubios Journal of Asian and International Bioethics*, *22*(5), 171. (ERA indexed, abstract published)

ii) Abdul Majid, Marina, Baharuddin, Azizan and Lee, W. C. (2016). Preventing Intangible Technology Transfer (ITT) on the internet and telecommunications for bioterrorism through Malaysia's Strategic Trade Act 2010 (STA 2010). *Computer Law and Security Review: The International Journal of Technology Law and Practice*, *32*(3), 495–512. (ISI indexed)

iii) Abdul Majid, Marina, Abdullah, Nor Anita, Noor, Siti Nurani M. and Chan, K. G. (2016). The principle of integration in International Sustainable Development Law (ISDL) with reference to the Biological Weapons Convention (BWC). *Sustainability*, *8*(2), 166. (ISI indexed)