SCIENCE ETHICS AND SOCIETY

International Governance of Biotechnology

Needs, Problems and Potential

Catherine Rhodes

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Science Ethics & Society

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Series Editors' Preface

John Harris and John Sulston

Science ethics is an emerging field in which the ethical and policy dimensions of science are perceived to be and are treated with an importance and urgency commensurate with the significance of the science and the benefits that flow from it.

It is at last being recognised that 'science doing good' and 'doing good science' are not only equally important but mutually supportive and even necessary, and that ethics is fundamental to achieving both. In science, perhaps more than any other field, the public interest cannot be subordinated to the pursuit of corporate profit or personal prestige.

The purpose of this series is to explore the ways in which science ethics broadly conceived must constitute a constructive and reassuring thread in the process from discovery, through proof of principle and innovation, to products in the clinic and the marketplace; and to propose positive measures to ensure that the highest standards of moral awareness and ethical conduct go hand in hand with the best science and the most useful technology. In doing so we will be commissioning work from the brightest and the best in this new field, aiming to encourage new work and young scholars as well as to showcase and bring to the widest possible public the very best of thinking in this field. To this end we are particularly pleased that as well as publishing books in the traditional way all work in this series will also be published open access online through Creative Commons. This will ensure that not only will everything we publish reach the widest possible audience but also that access to all our work will literally be freely available in every sense.

Two big questions are coming to dominate early work in science ethics; they are 'Who owns science?' and 'What is the good of science?'. The first phase of the work of the Institute for Science, Ethics and Innovation (iSEI), established at the University of Manchester (http://www.isei.manchester.ac.uk/) and working in collaboration with a new iSEI Wellcome Trust Programme in The Human Body: Its Scope, Limits and Future, is devoted to these questions. Alongside work on these very fundamental ethical questions must go more detailed analysis of how ethical principles designed to protect individuals and ensure that science works for and in harmony with the public interest can be translated into the national and international processes of law and regulation that govern science and innovation and without which anarchy would reign. The present book by Catherine Rhodes is therefore particularly welcome.

This, the first book in our new series, outlines regulatory needs at the international level for a key area of science governance – the applications and impacts of biotechnology. It provides core information on the thirty-seven

international regulations that are currently applicable to biotechnology and highlights a key problem for effective governance efforts caused by their fragmentation. It ends by pointing to possible routes forward.

Other topics on our urgent agenda include:

- Global justice
- Public health
- Technological governance
- Intellectual property
- The scope, limits and future of humanity
- Chronic poverty
- Climate change
- Environment
- Human enhancement.

Finally, we hope that study of these important issues will prove both interesting and useful and we welcome both suggestions for further work and proposals for new book projects.

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Abbreviations

AAHC	Aquatic Animal Health Code
BCH	Biosafety Clearing House (of the Cartagena Protocol on Biosafety)
BSL	biosafety level
Bt	*Bacillus thuringiensis*
BWC	Biological Weapons Convention
CAC	Codex Alimentarius Commission
CBD	Convention on Biodiversity
CGRFA	Commission on Genetic Resources for Food and Agriculture
COP	Conference of the Parties
COP-MOP	Conference of the Parties serving as the Meeting of the Parties
CPM	Commission on Phytosanitary Measures
CWC	Chemical Weapons Convention
DNA	deoxyribonucleic acid
DSU	Dispute Settlement Understanding (of the World Trade Organisation)
EnMod	Environmental Modification Convention
EU	European Union
FAO	Food and Agriculture Organisation
FAS	Federation of American Scientists
GE	genetically engineered
GM	genetically modified
GMO	genetically modified organism
HEPA	high-efficiency particulate air
HFEA	Human Fertilisation and Embryology Authority
HGC	Human Genetics Commission
HGP	Human Genome Project
ICADS	International Convention against Doping in Sport
ICRC	International Committee of the Red Cross
IDA	International Depositary Authority (under the Budapest Treaty)
IDHGD	International Declaration on Human Genetic Data
IHL	international humanitarian law
IHR	International Health Regulations
INCB	International Narcotics Control Board
IPFSAPH	International Portal on Food Safety, Animal and Plant Health
IPPC	International Plant Protection Convention
IPRs	intellectual property rights

ISA	International Search Authority (under the Patent Cooperation Treaty)
ISAAA	International Service for the Acquisition of Agri-biotech Applications
ITPGR	International Treaty on Plant Genetic Resources
LBM	Laboratory Biosafety Manual
LMO	living modified organism
LMOFFP	living modified organism for food, feed or food processing
MOP	Meeting of the Parties
mRNA	messenger ribonucleic acid
NASS	National Agricultural Statistics Service
NIAID	National Institute of Allergy and Infectious Disease
NIH	National Institutes of Health
OECD	Organisation for Economic Cooperation and Development
OIE	Office International des Epizooties
OPCW	Organisation for the Prohibition of Chemical Weapons
PCR	polymerase chain reaction
PCT	Patent Cooperation Treaty
PGD	pre-implantation genetic diagnosis
PGR	plant genetic resources
PLT	Patent Law Treaty
rDNA	recombinant deoxyribonucleic acid
RNA	ribonucleic acid
rRNA	ribosomal ribonucleic acid
RPPO	Regional Plant Protection Organisation
SCID	severe combined immunodeficiency disorder
SPS	Sanitary and Phytosanitary (Agreement)
TAHC	Terrestrial Animal Health Code
TBT	Technical Barriers to Trade (Agreement)
TRIPS	Trade Related Aspects of Intellectual Property Rights (Agreement)
tRNA	transfer ribonucleic acid
UCS	Union of Concerned Scientists
UDBEHR	Universal Declaration on Bioethics and Human Rights
UDHGHR	Universal Declaration on the Human Genome and Human Rights
UN	United Nations
UNDHC	United Nations Declaration on Human Cloning
UNESCO	United Nations Educational, Scientific and Cultural Organisation
UNGA	United Nations General Assembly
UNODC	United Nations Office on Drugs and Crime

UPOV	Union for the Protection of New Varieties of Plants (Union Internationale Pour la Protection des Obtentions Végétales)
VBM	valuable biological materials
WADA	World Anti-doping Association
WADC	World Anti-doping Code
WHO	World Health Organisation
WIPO	World Intellectual Property Organisation
WTO	World Trade Organisation

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1. Introduction

A series of scientific advances, particularly from the mid-twentieth century onwards, combined to produce a major scientific and technological revolution – the biotechnology revolution. The rapid and widespread application of these scientific and technological developments in agriculture, health care and a range of other industries has led to a socio-economic revolution that is still in its infancy, but is already having significant impacts.

A key aspect of the biotechnology revolution is that, as with all technological revolutions, it will have negative as well as positive impacts. The unprecedented potential for interference in basic life processes enabled by its new technologies and techniques means that some of these impacts could be severe and irreversible. While the impacts of the revolution are global, they are unlikely to be evenly distributed, which may well result in widening disparities between rich and poor, a significant negative impact itself.

The global context in which the revolution is taking place is highly significant in terms of outcomes. The situation of complex interdependence caused by various globalising influences means that the impacts of the revolution will not and cannot be contained within national boundaries; it also makes common international action necessary in a variety of issue areas. International regulation is, therefore, an essential part of any attempt to effectively control the biotechnology revolution.

International regulation helps to coordinate state action through the performance of certain key functions. Where there are sets of regulations addressing a particular matter, coherence among the regulations is important in enabling them to fulfil those functions. Regulatory sets which, on the other hand, lack coherence present various problems for the effective coordination of state action. In this book a model of coherent international regulation is constructed in order to enable a detailed assessment of the coherence of the thirty-seven international regulations that are applicable to the control of biotechnology. The implications of this assessment for their effective functioning will also be addressed.

Aims of the Book

There is limited awareness – for example among national and international policy-makers and those involved in researching, developing and implementing relevant international rules – of the full range of international regulations that are applicable to the control of the biotechnology revolution, and this book aims to address this by examining their operation as a whole. It is not generally known whether they are coherent and able to function well or fragmented and unable to appropriately manage the challenges and opportunities presented by modern biotechnology. The book will, therefore,

explore the issue of regulatory coherence and the implications of the current situation. This is done in a series of steps which involve:

- examining the course and impacts of the biotechnology revolution in order to establish what needs there are for regulatory control;
- identifying the issue areas in which the impacts of the revolution coincide with a need for coordinated action by states – i.e. the issue areas that require international regulation of biotechnology;
- identifying the functions of international regulation and exploring how they relate to coherence;
- establishing a model of coherent international regulation;
- identifying the existing international regulations that are applicable to the control of the biotechnology revolution, within the issue areas;
- assessing whether these regulations match the model of coherence; and
- drawing out the implications of this.

Concepts/Use of Terms

Biotechnology

Technology can be defined as the practical application of scientific developments. Biotechnology can, therefore, be defined at a basic level as the practical application of the biological sciences. It can also be defined as the use of living organisms to create useful products and processes, and within this definition traditional and modern biotechnology can be differentiated. Traditional biotechnology refers to uses of biotechnology that have a long history – such as fermentation in the production of beer and bread – and do not require a detailed understanding of the biological processes involved. Traditional forms of biotechnology are still in widespread use in various industries.

A fundamental shift in the science behind biotechnology occurred in the mid-twentieth century, as the structure of deoxyribonucleic acid (DNA) was discovered and it was realised that it carried heritable information. (Chapter 2 explores the scientific origins of the biotechnology revolution.) Genetic interventions and other tools and techniques based on these scientific breakthroughs are referred to as modern biotechnology. When the term biotechnology is used in this book, it is referring primarily to modern biotechnology. In the literature the term is often used interchangeably with genetic engineering, which is one of its primary techniques, but the term is broader and incorporates other tools and techniques such as cloning, genomics, proteomics and stem-cell research. The biotechnology revolution is based on the development and application of modern biotechnology.

International Regulation

The use of this term is discussed in more detail in Chapter 4, including its relationship to the term international law. International regulation is used in this book to cover a range of written rules, including voluntary standards,

guidelines, codes and legally binding treaties. It refers to regulations made between states, which any state may consent to or make use of, with no geographical restrictions. It therefore excludes regional and bilateral regulations.

The emphasis on states in this definition is not meant to indicate that other international actors do not have important influence on the biotechnology revolution and its governance, but states are the dominant actors in the international system and the main subjects of international regulation. Nor does the emphasis on regulation mean that there are not other options for governance of biotechnology; it is focused on because it is a core method used by states to address areas of common concern.

Impacts/Consequences

These terms are used interchangeably to refer to the outcomes of the biotechnology revolution. Positive impacts/consequences are sometimes referred to as benefits. Negative impacts/consequences are distinguished from risks – which refer to the possibility of negative outcomes occurring. Negative impacts may be thought of as costs, but they are generally not referred to in that sense in this book.

Structure of the Book

The book is divided into three main sections. The first section (Chapters 2–4) provides context, outlining the development of the revolution and the range of socio-economic impacts that can be expected, and explains the need for regulation. Chapters 5 and 6 form the second part, presenting the model of coherent international regulation and the thirty-seven international regulations that are relevant to the governance of the applications and impacts of biotechnology. The third part (Chapters 7–11) provides the central analysis that compares the identified regulations to the model, giving a detailed assessment on each of its sixteen characteristics; this section ends with a summary of the findings and discussion of their implications for effective governance of modern biotechnology.

Context

To understand the significance of the biotechnology revolution it is useful to have knowledge about its development as both an established scientific and technological revolution and as a socio-economic revolution that is in its infancy. From this basis regulatory needs can be established.

Knowledge from two major scientific strands – chemistry and genetics – converged in the early 1950s as connections were made between the molecular structure of DNA and its role in inheritance. Since then, advances in biotechnological tools and techniques have given scientists an extremely detailed understanding of life processes and have enabled deliberate manipulation of life forms at the genetic level. So, having outlined the

scientific developments that led up to the discovery of the molecular structure of DNA and to identification of its key role in inheritance, Chapter 2 moves on to look at how this knowledge expanded and was applied through genetic engineering and genomics. The new tools and techniques were rapidly applied to a range of sectors, and illustrative examples from health care, agriculture, food and drink, mining and environmental management are provided. Examining this history establishes that there has been a scientific and technological revolution in biotechnology, based on new understanding and knowledge of genetics and new tools and techniques to apply this knowledge, that has been rapidly and extensively applied.

Considerable uncertainty remains about what the outcomes of the biotechnology revolution will be in the long term, but from past experience it is clear that all major technological change has significant socio-economic impacts, not all of which are positive. Various factors which can influence the speed and direction of technological change are outlined in Chapter 3. Important factors include public opinion, government policy and – in an era where climate change is stated to be the greatest threat to humanity – environmental necessity.

The extensive range of biotechnology applications and their potential impacts cannot all be covered in this book. Instead some examples are provided of positive and negative impacts of certain applications for the environment, health, development and (protection against) misuse. Some more general economic and political challenges are also outlined. Complex ethical dilemmas are raised by the new technologies and the possibilities they bring, particularly in the field of human genetics, where the decisions made have significant implications for social relations. Therefore, Chapter 3 also addresses some of the major issues of concern in this area: eugenic outcomes; new forms of discrimination; and new social divisions.

In addition to there being both positive and negative consequences to the revolution, it is also clear that – due to the unequal global context in which the revolution is situated – the outcomes will not be evenly distributed. As a result, the revolution could contribute to entrenchment and widening of global and national gaps between rich and poor. Chapter 3 outlines how this may lead to resistance that could slow the progress of the revolution, and could impede some important benefits – for example enhanced food security – from reaching those who need them most.

This study of the revolution's impacts demonstrates that, despite some uncertainty about long-term impacts, important trends can be identified, and this provides the background for identification of regulatory needs.

Drawing on the discussion of consequences and highlighting again the importance of the global context, it is argued in Chapter 4 that there is a clear need for regulation of biotechnology. Four key roles are outlined: promotion of benefits; identification, assessment and management of risks;

minimisation of negative impacts; and promotion of capacity-building. The next stage of the argument establishes that, for those areas in which there is high interdependence and a need for coordinated state action and in which the revolution has significant applications and impacts, an essential part of this regulation must take place at the international level. Seven issue areas are identified in which these two factors are present: arms control; health and disease control; environmental protection; trade; drugs control; development; and social and ethical impacts.

Chapter 4 also reflects on how international regulation is conceptualised in the book, outlines key functions of international regulation and explains how coherence will be an important influence on whether sets of regulation can effectively fulfil these functions. Thus the contextual section provides the reader with an understanding of what the biotechnology revolution is, its socio-economic significance and the need for its international regulation. It also establishes what is required from this regulation, and that regulatory coherence will be important for effective control of the biotechnology revolution.

Those familiar with the literature on the biotechnology revolution's origins, significance, applications and impacts may prefer to focus primarily on the second and third sections of the book; however, it is recommended that at least Chapter 4 of the first section is read – it is here that the motivations for examining coherence in international biotechnology regulation are established.

Model and Data

To enable assessment of the coherence of international regulation of biotechnology, a framework is needed, along with identification of the applicable regulations. Both tasks are accomplished in the second part of the book.

Development of the model starts with formulation of key characteristics indicative of coherence, based on an examination of established coherent regulatory sets. There are sixteen characteristics, each of which is defined in Chapter 5. They are:

- Common (primary) purpose
- Common principles
- Common historical development
- Common identity
- Self-referencing
- Shared definitions
- Unifying provisions
- Complementary provisions
- Common structure
- Common administration and review procedures
- Common enforcement and dispute settlement mechanisms

- Same strength of force
- Single international organisation
- Self-contained
- Clear issue focus
- Comprehensive coverage of the issue

Chapter 5 demonstrates the applicability of the model through an analysis of the Geneva Conventions and Protocols. A table at the end of the chapter demonstrates that the model is applicable to other sets of international regulations.

Within the seven international areas in which regulation of biotechnology is required, thirty-seven relevant international regulations are identified as applicable to its control. Chapter 6 introduces each regulation, outlining its development and key features, and reflects on why the regulation is relevant to control of biotechnology.

The relevant arms control regulations are those designed to prevent the hostile application of biology and chemistry. They also have the corresponding role of promoting peaceful use of science. In the health area, three main types of regulation are applicable: regulations that aim to prevent the transboundary spread of human, animal and plant diseases; regulations which promote biosafety and biosecurity in laboratories and during the transport of infectious substances; and food safety regulations. In the environment area, the key regulations are those concerned with protection of biodiversity.

There are three main trade-related regulatory areas of relevance: promotion of free trade; protection of intellectual property rights; and facilitation of access to genetic resources. Relevant drugs control rules are those designed to end the illicit international trade in narcotics and psychotropic substances and rules against doping in sport. The relevant provisions on development are not contained in separate regulations, but instead are located within several of the regulations from the other issue areas. Finally, for social and ethical impacts there are four international declarations on human genetics issues, which have a basis in human rights principles.

Analysis

In order to examine the extent to which the international biotechnology regulations form a coherent regulatory set, in the third part of the book they are assessed against each of the model's characteristics. Chapters 7, 8, 9 and 10 each address four of the characteristics. They contain definitions of the characteristics and an explanation of the basis used for the assessment. In the majority of cases the biotechnology regulations fail to match the characteristics, which clearly indicates a lack of coherence. There are, however, some interesting cases of interconnection both within and between issue areas and some patterns also start to emerge, for example where there

are complementary provisions there are likely to be common principles too (although no causal relationships are established).

Reflecting back on the importance of coherence to the functionality of regulatory sets, the implications of the current regulatory situation for the effective control of biotechnology are highlighted in Chapter 11. Significant difficulties appear to be presented for the effective regulation of biotechnology by the lack of coherence in the regulatory set and some suggestions are made for routes to improving this situation.

Given the importance of effectively governing biotechnology if its benefits are to be maximised and negative impacts limited, this book raises significant concerns about whether the current regulations that affect its control can effectively coordinate state action. The international community cannot, however, simply get rid of the current regulations and start from scratch, and must move forward from where it currently stands. Adaptation of the regulations to improve coherence is likely to be a complex and long-term task. It is worth noting, therefore, that many of the international organisations involved appear to be gaining awareness of areas of interconnection in the regulation of biotechnology and several cooperative initiatives are underway, which may clarify regulatory relationships and improve coherence at least at the stage of implementation.

2. The History of the Biotechnology Revolution

The biotechnology revolution is based on massive scientific advances that have been made over the last sixty years. These advances have given scientists an extremely detailed understanding of life processes, have allowed life forms to be deliberately manipulated at the genetic level and enabled the creation of novel organisms containing genes from other species. To understand the history of the biotechnology revolution, it is useful to look at the development of the science that has helped to create it. There was a significant merging of chemistry and biology (still seen by many as two distinct strands of science) in the early 1950s as connections were made between the molecular structure of deoxyribonucleic acid (DNA) and its role in inheritance. The revolutionary techniques of genetic engineering and genome sequencing stem from this convergence.

This chapter studies the history of chemistry and the history of genetics separately until 1953 (but this is not to suggest that there was no earlier interaction between the two), before looking at the development of genetic engineering and of genome sequencing from then until the present day. The scientific advances have rapidly and often quite directly found applications in a variety of products and processes since the mid-1970s. This chapter, therefore, also looks briefly at the history of biotechnology applications. A glossary is provided towards the end of the book for readers unfamiliar with some of the scientific and technical terms used within this chapter.

Chemistry 1770–1953

The links between the development of modern chemistry and modern biotechnology may not be immediately apparent. However, new discoveries and techniques in chemistry have been vitally important to the development of modern biotechnology and the two areas continue to be connected. Of greatest importance was the discovery of the molecular structure (and from this the chemical properties) of DNA. The structure of DNA was discovered by James Watson and Francis Crick in 1953. At this point the fields of chemistry and biology merged in significant ways to produce the tools, techniques and knowledge that drive the biotechnology revolution. A lot of important steps had to be taken in the field of chemistry before scientists were able to define complex molecular structures like DNA, and these will be looked at briefly in this section.

Modern chemistry is usually dated as emerging in the 1770s with the discrediting of the established phlogiston theory. One scientist in particular is considered to have been instrumental in this move to modern chemistry – Lavoisier, who, using the newly refined concept of elements,

came up with the chemical atomic theory that 'different elements have fundamentally different atoms' (Hudson, 1992, p. 77). He and others then worked on identifying as many of these elements as possible. Lavoisier listed thirty-one elements in his 1789 book *Elements of Chemistry* (another chemist, Berzelius, listed forty-nine in 1826). However, the chemical atomic theory was not widely taken up or much used until the periodic table was established – Mendeleev first published his periodic table in 1869 – and this was not to be achieved until there had been some agreement between chemists on atomic and molecular weights. An international congress of chemists was called in 1860 seeking to clarify issues on the establishment of atomic and molecular weights. Although no agreement was reached at the congress it did provide the impetus for the resolution of these issues, which occurred during the following decade.

The study of chemistry split between organic and inorganic chemistry around 1860. Organic chemistry concerns compounds containing carbon, whereas inorganic chemistry concerns those that do not. This was a split more in the focus of research than in techniques and the two areas remain connected. The establishment of atomic weights brought progress to both areas, allowing the periodic table to be formed and also enabling molecular formulae to be deduced. The formulae of molecules are important in identifying their structure. Knowledge of the atomic weights of elements allowed their proportions within molecules to be worked out.

The discovery of further elements continued well into the twentieth century. Mendeleev had left gaps in his periodic table at points where he had predicted these elements would fall. Two techniques aided the discovery of new elements. The first, developed in 1860, used a spectroscope that could be used to analyse light produced from burning materials (Hudson, 1992, p. 125). Several elements were discovered in this way that had previously been hard to identify due to them being present only in tiny amounts mixed up with other materials. The second and better known technique was developed in 1898 by Marie and Pierre Curie, who made use of radioactivity to discover new elements including radium and polonium, through their radioactive isotopes.

Increasing knowledge of relatively simple molecular structures enabled increased work to take place on the synthesis of organic compounds from inorganic elements. This had first been shown to be possible in 1828 with the synthesis of urea, but knowledge of molecular structure enabled it to take place more systematically. Soon chemists were also 'producing compounds that had no natural counterparts' (Hudson, 1992, p. 144), particularly dyes and drugs.

As more was discovered about the structure of simple molecules, chemists were able to progress to working out the more complicated structures of some of the larger, complex molecules that existed in nature. It was work in this area that was to lead to the discovery of the structure of DNA.

A new technique of X-ray crystallography, developed in 1913, was to enable the identification of the structures of much larger molecules. This technique essentially allowed a photograph of a molecule to be produced from its crystalline form, by making use of X-ray diffraction, i.e. the way X-rays are deflected from their original course when they hit the molecule. This technique was refined over the following decades, allowing sharper images to be produced. Such a picture of DNA, produced by Rosalind Franklin in 1952, gave Watson and Crick significant clues about its structure.

There was also an obstacle of how to deal with the large amounts of information that would be produced when dealing with more complex molecules containing thousands of atoms. The invention of electronic computers helped to overcome this obstacle (Hudson, 1992, p. 224).

Other discoveries about the chemistry of DNA had also assisted Watson and Crick, particularly the discovery by Erwin Chargraff that the number of adenine bases was equal to the number of thymine bases and the number of guanine bases was equal to the number of cytosine bases. Franklin also suggested (based on her photograph) that the sugar-phosphate 'backbone' of DNA ran along its outside. Further discoveries about the chemical properties of DNA and how it functions followed. Those are dealt with later in this chapter.

Developments in modern chemistry from the late eighteenth century onward enabled the structure of DNA to be worked out in 1953. Knowledge of the structure, properties and functions of DNA, combined with the realisation in the field of genetics that DNA carried hereditary information, allowed new techniques of genetic engineering to be rapidly developed, and these techniques underpin the biotechnology revolution.

Genetics 1900–53

Many of the modern developments in biotechnology are based on a detailed knowledge of genes and genetics. This knowledge has been built up over the past century.

Modern genetics study is said to have begun in 1900 with the rediscovery of Mendel's work on the inheritance of factors in pea plants (factors later to be termed genes). Mendel had published his work in 1866, but it attracted little attention until the same principles were independently discovered by three scientists (Carl Correns, Hugo de Vries and Erich Von Tschermark) in 1900. Study of cells (cytology), aided by improvements in the clarity and magnification of microscopes, had led to the observation of chromosomes in 1879, and by 1900 it had also been shown that protein and nucleic acid were present within cells. Through experimentation in the early twentieth century it was established that genes were located on the chromosomes. However, it was not until 1952 that it was widely accepted amongst geneticists that DNA carried genetic information; the proteins in cells had seemed better candidates for this role.

Acceptance of the role of DNA combined with the new knowledge of its molecular structure (announced by Watson and Crick in 1953) was to bring about the rapid development of new tools and techniques in genetic engineering, which in turn brought huge advances in biotechnology.

Following Darwin's work on evolution (*Origin of Species* was published in 1859) many people sought to discover how characteristics could be passed on from parents to offspring. These were suggested to be 'material factors' and were recognised by Hugo de Vries (writing in 1910) to be 'the units which the science of heredity has to investigate. Just as physics and chemistry go back to molecules and atoms, the biological sciences have to penetrate these units in order to explain, by means of their combinations, the phenomena of the living world' (Fruton, 1972, p. 225). (The units in fact turned out to be molecules of DNA.)

By the end of the nineteenth century cytologists studying the behaviour of chromosomes had observed the processes of mitosis and meiosis, different types of cell division, providing good evidence that these parts of the cell could carry genetic information. There was a mechanism for duplication which occurred during routine cell division (mitosis) and there was also a mechanism which allowed for the inheritance of both parents' genes in the reduction in the number of chromosomes by half in meiosis (cell division in the germ cells), which then combined with the other parent's half set during reproduction.

Studies of genetic changes (mutations) in the early twentieth century provided further evidence about the role and functions of chromosomes, and also of the location of genes upon them. Significant work was done with the fruit fly *Drosophila melanogaster*. This fly breeds quickly and that meant that mutations could be studied through many generations. Experiments with mutations reinforced Mendel's theory that some characteristics were inherited separately from one another, but also showed that some were linked in inheritance. The phenomenon of 'crossing-over' was also observed (and named) by Thomas Hunt Morgan. This is where sections of a pair of chromosomes swap with each other during meiosis causing mutations to occur. Morgan realised that this might allow the locations of genes to be established and A. H. Sturtevant used statistical study of mutations and the frequency of crossing-over to establish the relative positions of six genes on one of *Drosophila's* chromosomes in 1913. He then produced the first chromosome or linkage map based on this. By 1925 Morgan's team had located 100 genes on *Drosophila's* four chromosomes.

Mutations are very significant to the study of genetics and methods were later developed to increase mutation rates through radiation and chemical means. The early work on chromosome mapping helped to lay the basis for later, more complex, mapping of the genomes, including the Human Genome Project (HGP).

By the 1920s the concept of the gene as the unit of heredity had been established, the study of genetics was well underway and it was understood that gene expression and inheritance relied on processes occurring within the chromosomes. There had also been some suggestion that mutations might occur due to interference in the production of enzymes.

The puzzles remained of how the cell used the genetic information, where the genetic instructions came from and why the information was expressed differently in different cells despite the same chromosomes being present. The theory was that proteins were responsible. Proteins are present in the cell, and enzymes (which are a form of protein) are used in many cytological processes.

There had been a suggestion as early as 1884 by the scientist Oskar Hartwig that 'Nuclein is the substance that is responsible ... for the transmission of hereditary characteristics' (Aldridge, 1996, p. 7). But this view was largely ignored until the early 1950s, partly because of a theory called the 'tetranucleotide hypothesis' put forward by Phoebus Levene in the 1930s. This held that the four nucleotides of DNA (adenine, thymine, guanine and cytosine) made up a string of repetitive code and were therefore incapable of carrying the complex code that would be needed for holding the genetic instructions. Proteins did not have this problem. Proteins are a type of complex molecule known because of its structure as a 'polypeptide chain'. They are made up of amino acids and 'there are 20 amino acids commonly found in proteins' (Aldridge, 1996, p. 13), allowing the variation necessary to hold a long and complicated code.

It was also decided in the 1920s that genes (and therefore what they were made of) had to be autocatalytic, that is able to make themselves replicate. Geneticists tried, but failed, to come up with a satisfactory theory as to how proteins achieved this. Once the molecular structure of DNA was established its autocatalytic properties were self-evident as Watson and Crick noted: 'It has not escaped our notice that the specific pairing we have postulated immediately suggests a possible copying mechanism for the genetic material' (Hudson, 1992, p. 225).

Further evidence of mutations being linked to a lack of a particular enzyme led to another theory (by Beadle and Tatum) that also hindered the recognition of the significance of DNA. The 'one-gene, one-enzyme' hypothesis, while not essentially wrong, did lead some to the erroneous conclusion that enzymes were genes. The theory has since been revised to the 'one-gene, one-polypeptide' hypothesis, but it was along the right lines, genes do code for enzymes.

It was not until the tetranucleotide hypothesis was disproved by Erwin Chargraff in 1948 that the possibility of DNA carrying genetic information was taken seriously. He showed through paper chromatography that the nucleotides did not form a repetitive sequence, and so it was possible for DNA to be carrying a code. Experiments on pneumococci bacteria by

Oswald Avery in 1944 had shown that DNA was likely to be the 'transforming principle' exchanged between bacteria and led to the statement that: 'nucleic acids of this type must be regarded not merely as structurally important but as functionally active in determining the biochemical activities and specific characteristics of pneumococcal cells' (Fruton, 1972, p. 248, quoting Avery, McLeod and McCarty in 1944).

Yet it seems to have been experiments on bacteriophages by Hershey and Chase (who published their findings in Hershey and Chase, 1952) that finally convinced geneticists that DNA was the molecule of heredity. Using radioactive tags (one that attached only to DNA and one that attached only to protein) they showed that it was through the transference of DNA that bacteriophages attack bacteria.

Cytology combined with genetics to lead in just over half a century to the crucial discovery of the role of DNA in inheritance and its importance in the functioning of cells. Coupled with new knowledge about the molecular structure of DNA, this led to rapid development of new genetic engineering tools and techniques which underpin the biotechnology revolution.

Genetic Engineering from 1953 Onwards

By 1953 there was widespread acceptance among geneticists that DNA carried genetic information and its molecular structure had been discovered. This opened up the possibility that genes could be manipulated at the molecular level, their function understood and possibly corrected or controlled. First scientists had to work out how genes are expressed, that is how DNA codes for proteins.

Within twenty years the possibility of working with DNA at the molecular level had been realised. One of the most important steps was the development of recombinant-DNA (rDNA) techniques. rDNA involves the insertion of one piece of DNA into another, including between unrelated organisms. rDNA was immediately recognised to be an extremely powerful technology, and fears about its use soon emerged, leading to a temporary halt in rDNA experiments. The experiments restarted a couple of years later. The technology was soon applied to a range of new biotechnological products including pharmaceuticals and transgenic organisms.

Erwin Chargraff had shown that the four bases of DNA, adenine (A), thymine (T), guanine (G) and cytosine (C), did not form a repetitive sequence and could therefore be capable of carrying the genetic code. It remained to be shown how this code functioned and how the information from the code could be transferred to enable the building of proteins.

In 1957 it was suggested by Frances Crick and George Gamow that the genetic code referred to the sequence of the amino acids that make up proteins. There are twenty amino acids to code for and four bases to code for them. This meant that it was most likely for the bases to code for amino acids in groups of three, because this would produce sufficient variations in

the code. The bases separately could code for only four amino acids, in pairs for sixteen, while triplets gave sixty-four possibilities. The triplets of bases are referred to as codons.

Marshall Nirenberg made the first link between a codon and the amino acid it specified in 1961. This corresponded to an AAA codon on a strand of DNA and specified the amino acid lysine. Nirenberg's team had worked out the rest of the codon 'dictionary' by 1966. In some cases two or more codons specify the same amino acid and three codons do not specify an amino acid, but instead a point in the code at which translation (the reading and converting of the code) should stop – they are therefore referred to as stop codons.

It was known that DNA would have a replication mechanism and the process of replication was observed in 1957. It was later discovered how ribonucleic acid (RNA) carried sections of the genetic code out of the nucleus to build proteins. RNA is similar to DNA although it is normally single stranded and the base thymine of DNA is replaced by the base uracil (U) in RNA, so it has the bases A, U, G and C. In studies of the cell, RNA had been shown to be present both in the nucleus and in the cytoplasm (the part of the cell surrounding the nucleus).

There are three types of RNA in cells and each has a different function. The only one present in the nucleus of cells is messenger ribonucleic acid (mRNA) and it is this that carries the genetic code from the DNA out into the cytoplasm where the proteins are built. It was observed that certain sections of DNA will unravel temporarily and the mRNA will match up to one side of the strand and by matching the nucleotide bases A to T, U to A, C to G and G to C can then carry the code away while the DNA rewinds. Back in the cytoplasm the mRNA is then translated into amino acids which the transfer ribonucleic acid (tRNA) collects and the ribosomal ribonucleic acid (rRNA) builds into proteins.

The discovery of how genes code for proteins was an important step towards the development of rDNA techniques. Also important were the discovery of restriction enzymes and DNA ligase. Restriction enzymes can 'cut' DNA at specific points in the base sequence and were discovered by Hamilton Smith and David Nathans in 1971. Such enzymes are used by viruses to insert their RNA into a host's DNA. DNA ligase is an enzyme that can 'stick' two strands of DNA together. In 1972 the biochemist Paul Berg used a restriction enzyme to cut strands of DNA and used ligase to stick two strands together in a novel way. This created the first rDNA molecule.

With this new technique it became possible to transfer genetic information across species boundaries and to manipulate DNA in a controlled manner 'to modify genes or to design new ones, to insert them into bacterial cells … and thus to form cells with new biochemical properties' (Asimov, 1987, p. 591). Concerns were soon raised within the scientific community about the safety of rDNA experiments, with particular fears about accidental release

of genetically altered bacteria or viruses. This led to a halt in experiments following discussion at the 1975 Asilomar Conference, until guidelines had been introduced. The United States National Institutes of Health (NIH) issued guidelines the following year and research continued.

rDNA gave scientists 'methods of participating directly in gene activity' (Asimov, 1987, p. 591), and the ability to create entirely new products from biological processes brought about many biotechnological applications. Early examples include the production of human insulin (1978) and human growth hormone (first cloned in 1979), transgenic mice (1981) and later genetically modified crops (first field trials in 1985) and gene therapies (1990).

Genome Sequencing

Another important development in genetic engineering has been the sequencing of genomes. This developed from the early work of geneticists on locating and mapping genes on chromosomes. Current techniques and knowledge now allow much more sophisticated mapping to be done and sequencing is a first step in the mapping process. Advances in sequencing tools, and particularly the increased speed at which the information produced can be processed, meant that it was possible to begin sequencing the human genome in 1990 and a full draft of the human genome was published in April 2003. Sequencing of genomes has greatly increased the amount of genetic information available to scientists, and this will, among other things, enable them to gain increased knowledge of human diseases – 'When we have a detailed genetic map we will be able to identify whole sets of genes that influence general aspects of how the body grows or how the body fails to function' (Kevles and Hood, 1992, p. 94).

Mapping of genes is the 'Determination of the relative positions of genes on a DNA molecule (chromosome or plasmid) and of the distance, in linkage units or physical units, between them' (Kevles and Hood, 1992, p. 379). The first linkage or chromosome map was created by A. H. Sturtevant in 1913 and mapped the relative locations of six genes on one chromosome of the fruit fly *Drosophila melanogaster*. Early mapping used mutations (genetic changes) to establish the location of genes on particular chromosomes. Mutations can be studied relatively easily in fruit flies as they breed rapidly, allowing genetic changes to be followed through many generations, but it was difficult to do this work on humans because their life cycle is far longer. A new technique, developed in 1967, changed this. Somatic cell hybridisation enabled work to be done on mapping human genes. Somatic cell hybridisation mixes chromosomes from human cells and mice cells, creating single cells containing both sets of chromosomes. These cells are not very stable and as they divide human chromosomes are lost. When only one human chromosome is left in the cell, any human proteins produced by the cell must be the expression of genes on that chromosome.

Genetic sequencing determines the sequence of nucleotides (the individual nucleic acids adenine, thymine, guanine and cytosine) present in a gene. Sequencing of genes did not become possible until the structure and role of DNA were understood. The development of the codon dictionary was particularly important to this.

Frederick Sanger began work on DNA sequencing in 1977, building on his previous work on establishing the sequence of amino acids in proteins. He completed the first genome sequence (of a bacteriophage named phiX174) in 1978. Another method of sequencing was developed at the same time which used chemicals instead of dideoxynucleotides to split up the DNA. 'Since then, the two methods have been standardized, speeded up and in a large part automated' (Kevles and Hood, 1992, p. 66).

The development of the polymerase chain reaction (PCR) in 1980 by the Cetus Corporation helped to speed up the process of sequencing. PCR is a method of replicating fragments of DNA many times over, rapidly providing large amounts for analysis and sequencing. Computers helped both to automate the process and to store the vast data produced.

These developments made conceivable the sequencing of larger genomes, such as the human genome, the idea of which began to be discussed in the mid-1980s. The Human Genome Project, a massive, international, public project to sequence and map the human genome, was approved by the US Congress in 1988 and work began in 1990. The human genome is far larger than any genome previously sequenced (to compare phiX174 has 5,375 nucleotide bases, the human genome has approximately 3,000,000,000). An ambitious target for completion of the sequence in 15 years was set. The work on sequencing the human genome (only one part of the overall project) progressed slowly until a privately funded initiative was set up in competition, in May 1998. This made use of a different sequencing method and promised far quicker results for less money. This move was and still is hugely controversial, but did spur on efforts within the public project. Both projects published rough drafts of the human genome in February 2001, and the public project released a full draft in April 2003.

The human genome sequence will provide the basis for detailed mapping of genes and their functions. One of the most direct benefits to come from sequencing of the human genome will be enhanced understanding and therefore improved treatment of many human diseases, but the information resulting from the HGP will have many other applications as well.

It is not only the human genome that has been sequenced, but also key reference genomes such as the fruit fly, nematode worm and common house mouse; over 1,200 other genomes have been completely sequenced (Genomes Online Database, 2009), most of them microbial. The fruit fly was sequenced by the private team prior to their work on the human genome, to show that their sequencing method worked, and the nematode worm was sequenced by the public project to serve as a reference genome.

The mouse genome will also serve as an important reference for the HGP as it 'will allow researchers to gain insights into the function of many human genes because the mouse carries virtually the same set of genes as the human but can be used in laboratory research' (National Institutes of Health, 6 May 2002).

Sequencing of the genomes of other organisms has established that sequencing tools and techniques work, and has provided important reference information, as well as giving an understanding of the particular organism involved. An offshoot of the HGP is a Microbial Genome Program, which will increase understanding of various microorganisms in order that they might be better utilised by humans in waste treatment and environmental management and so that disease-causing microbes can be more effectively targeted by drugs. Information on many other genome sequencing projects can be found through websites such as the Genomes Online Database (http://www.genomesonline.org).

The sequencing and mapping of genomes have contributed to increased knowledge of the biological processes of various organisms and to understanding of genetic functions. They provide vast amounts of data to which the tools of genetic engineering can be applied, in turn increasing the scope of biotechnology applications.

Biotechnology Applications

Humans have been making use of living organisms and biological processes for thousands of years; the earliest applications were probably in the production of food and drink products such as beer, bread and cheese. Early applications made use of entirely natural processes and did not require any understanding of what these processes were. Some applications of modern biotechnology still use naturally occurring processes, which are now far better understood. Genetic engineering has been used to improve understanding of biological processes and to improve them, and it has also been used to create new sources of particular products and completely novel products that have never before occurred in nature. Biotechnology is now applied across a huge range of industries and there has been great expansion in the scope of its applications since the development of rDNA techniques.

The present range of industrial sectors using biotechnology includes health care, food, mining, plastics, chemical, textiles and waste treatment. It is also widely used in agriculture and animal husbandry. There are far too many applications for them all to be discussed here, but some of their uses within these sectors are briefly outlined.

Health Care

The earliest applications of rDNA were to address problems of human health, and the pharmaceutical industry is the area where modern biotechnology has had its biggest impacts so far. The first applications of rDNA were to

produce bacteria to 'manufacture' human proteins. An early example of this was the adaptation of *E. coli* bacteria to produce human insulin. Insulin for the treatment of diabetes had previously been sourced from animals. The human version is better suited to fulfil this function and the huge quantities necessary to treat the 220 million people worldwide that have the disease (WHO, November 2009) and can be produced more reliably. The license to market human insulin produced in bacteria was granted in 1982 (Biotechnology Industry Organisation, 2002).

There are currently products approved for the treatment of many diseases and disorders including haemophilia, hepatitis, certain cancers, heart disease, anaemia, cystic fibrosis and epilepsy. Recombinant vaccines and new diagnostic tests have also been developed.

Agriculture

Biotechnology has been applied to agriculture in a number of ways, to both plants and animals. In food crops genetic engineering has been used to transfer or create a number of desirable traits. These include increased yields, reduced need for inputs like pesticides and herbicides and the production of plants with improved nutritional value for both human consumption and use in animal feed. Currently there are genetically modified crops being developed to produce other useful products such as pharmaceutical drugs, vaccines, blood-clotting factors and chemicals for use in industrial processes (Union of Concerned Scientists, 15 December 2004).

Animals have also been genetically engineered to enhance desirable traits and to act as 'factories' for producing other useful products. For example cows have been genetically engineered to produce some human proteins in their milk. Similar developments have occurred in aquaculture or fish farming, particularly with the aim of speeding up growth rates.

Food and Beverage Industry

This is the area with the longest history of applications of biotechnology. Natural biological processes have traditionally been exploited in processes such as the fermentation of alcohol, bread-making and cheese-making. Modern biotechnology is being used to increase understanding of and improve these processes. Rennet, for example, used to be sourced from calves' stomachs, but can now be produced in genetically engineered bacteria, which produces a cheese suitable for consumption by vegetarians. New uses and processes have also been developed, particularly as the properties of more yeasts and fungi have been discovered and exploited. Further examples of uses are in preservatives and flavourings.

Mining

Modern biotechnology has enabled the replacement of chemical methods for extracting some mineral ores by biological ones, which are often more

effective and create fewer unwanted by-products. Sometimes the bacteria used are entirely natural, although genetic analysis may have been used to work out the most suitable bacteria and the optimum conditions for them to work under. Other bacteria may be specifically designed to do this work.

Environmental Management

Biotechnology is extremely useful in the treatment of waste products since biological processes are involved in the degrading of all wastes. Biological processes are used by many industries to treat their waste products in order to reduce the amount of pollution they create. Biotechnology is also used in the general treatment of public waste water and sewage. Scientists have also begun work on optimising the action of bacteria in landfill sites to speed up processes of degradation. Bacteria can also be used as a method of cleaning up oil spills. Similar to the use of bacteria in mineral extraction, many of the current applications make use of naturally occurring processes which are now better understood and can therefore be more effectively applied. There can also be genetic modification of the bacteria involved, for example to enable them to work under specific conditions and cloning can be used to create large amounts of either naturally occurring bacteria with specific traits or the custom-made versions.

Biotechnology has a major role not only in the treatment of wastes and spillages, but also in preventing environmental damage in the first place by creating more environmentally friendly production processes: 'biotechnology offers us many options for minimizing the environmental impact of manufacturing processes by decreasing energy use and replacing harsh chemicals with biodegradable molecules produced by living things' (Biotechnology Industry Organisation, 2002). Biological processes are already replacing the use of some chemicals in industries such as the paper pulp and textiles industries.

The Industry

Modern biotechnology has been applied across a wide variety of long established industries, and it has also led to the formation of its own industry. The biotechnology industry has developed rapidly since its origins in the mid-1970s. As the applications of modern biotechnology continue to increase based on new scientific developments, so the industry is also likely to continue its expansion.

Over the past thirty years strong links have been developed between academia and industry in the biotechnology area, with commercial applications often coming directly from work in academic laboratories. From the mid-1970s onwards many small biotechnology start-up companies were created, often concentrating on the development of products, which would subsequently be manufactured and marketed by larger, established

companies. The first such company, Genentech, was created in 1976. Genentech's first commercially available product was cloned human insulin (Olson, 1986, p. 85). Over the next few years several other start-up companies were set up by scientists. Genentech did not take its product to market itself but instead licensed production to the pharmaceutical giant Eli Lilly. This made sense because Genentech did not have the capacity to manufacture or resources to market the product, which Eli Lilly as an established pharmaceutical company had.

Following the success of the small companies, the established pharmaceutical companies moved into the area in the early 1980s taking over small biotechnology companies or setting up their own biotechnology sectors. An example of such a company is GlaxoSmithKline, one of the world's largest pharmaceutical companies, which currently has several biotech products approved and on the market. Its first biotech product – a recombinant hepatitis B vaccine – received approval in 1989 (Biotechnology Industry Organisation, 2002). More recently GlaxoSmithKline has moved into genomics to enhance its research and development processes (GlaxoSmithKline, no date).

In the mid- to late 1980s other companies from the chemical and seed industries began to enter the biotechnology area, often consolidating into huge life-science companies. A well-known example of such a company is Monsanto. Monsanto was formed as a chemical company in 1901 and soon expanded its range of products and bought out many other companies. Monsanto has had an agricultural division since 1960 and moved into biotechnology in 1989 (Monsanto, 2002a). Its first biotech product POSILAC bovine somatotropin, designed to improve milk production in dairy herds, was approved in 1993 (Monsanto, 2002b). Since then Monsanto has had over twenty genetically modified crops approved (AGBIOS, 9 March 2010). From 1997 Monsanto became involved through collaborations in genomics research and merged with a large pharmaceutical company in 2000 to form the Pharmacia Corporation. (A new Monsanto company was established as a subsidiary of Pharmacia in 2000 and became a separate company in 2002, which focuses on agricultural biotechnology and genomics.) The industry is predominantly based in major industrialised countries and centres in Europe, Japan and the United States.

Conclusion

Biotechnology, being the use of biological processes to create useful products, has a long history. Rapid scientific developments in the past few decades have produced a knowledge base and set of tools and techniques that enable biological processes to be understood and controlled to an extent never before possible. This has created the biotechnology revolution. During the first half of the twentieth century knowledge from the scientific fields of chemistry and genetics combined to provide the basis for a revolution in the life sciences. Advances in genetic engineering since 1953, which have allowed

the manipulation of life processes at a genetic level, have given modern biotechnology its central tools and techniques. The unprecedented nature of these advances – in particular the ability to transfer genetic material from one organism to another (including across species boundaries) – has given the new biotechnology its revolutionary effects. Modern biotechnology has incorporated genetic engineering to create transgenic plants and animals, novel pharmaceutical products, improved methods of waste treatment and far more.

There has clearly been a revolution in the life sciences based on a new understanding and knowledge of genetics and new tools and techniques to apply this knowledge. The next chapter will examine what the current status of the biotechnology revolution is and how this science-based revolution has extended its impacts into the social and economic spheres.

3. The Uncertain Consequences of the Biotechnology Revolution

The biotechnology revolution has involved major technological change – the move to the new ability to understand and manipulate life forms at the genetic level. All major technological change has social and economic consequences and because of the breadth of applications of modern biotechnology, the socio-economic consequences will be many and diverse. It promises a new level of control over ourselves and our environment. There are many positive consequences to this. Human health can be improved through better understanding, treatment and prevention of disease. New solutions can be found to some of our environmental problems with alternative sources of energy, cleaner manufacturing processes and new means of reducing pollution. Novel agricultural technologies can provide crops with enhanced or novel traits: reducing inputs; improving nutritional value; or expanding land available for agricultural use – all of which can contribute to improved food security. Plants can be used for growing drugs and vaccines. Modern biotechnology has potential to contribute to poverty alleviation through improvements in health and food security, boosting economic development prospects. In the security realm, biodefence (i.e. defence against biological attack) capabilities can be improved through use of genetic engineering technologies.

However, it is extremely unlikely that the revolution will have only positive consequences – historically this has not been the case with any major new technology. This is pointed out by Jeremy Rifkin in *The Biotech Century* (1998, pp. 35–6):

> If history has taught us anything, it is that every new technological revolution brings with it both benefits and costs. The more powerful the technology is at expropriating and controlling the forces of nature, the more exacting the price we will be forced to pay in terms of disruption and destruction wreaked on the ecosystems and social systems that sustain life.

The negative consequences of the biotechnology revolution may well be severe due to an unprecedented level of directed interference with natural processes. While modern biotechnology can give us new tools to manage environmental problems it also presents new dangers, particularly in its threat to biodiversity. It may also present new threats to human health. It certainly challenges many human values and beliefs. Development may be hampered by changes in ownership patterns in relation to novel crops and seeds and related shifts to monocultural agriculture practices. And the same

tools that can improve biodefence can also be used to create more effective biological warfare agents, increasing the threat of their use.

As well as these more specific consequences, the biotechnology revolution will have more general consequences. Changes in the geography of agricultural production are likely to occur, and changes in global trade relations may create new winners and losers or act to reinforce current inequalities. There will be changes in labour relations and in manufacturing processes. Many ethical dilemmas are raised by the new technologies and the possibilities they bring. People will face new choices about health care and reproduction. Social values and beliefs may have to adjust to incorporate new knowledge. Far more knowledge will be available about people's genetic endowments and what the implications of these are; which also opens the possibility of new forms of discrimination. There are implications for changes in power relations. There will be a need for political direction to deal with many of these challenges at the same time as state control is diminishing in areas such as health care.

Significantly the consequences of the biotechnology revolution are unlikely to be evenly spread among nations and those that are positive for one group may have negative implications for another. Research and development in biotechnology (as in all scientific fields) is overwhelmingly concentrated in rich, developed nations, particularly in the United States, Europe and Japan. It tends, therefore, to be directed towards meeting the interests of populations in the developed nations rather than the needs of the majority of the global population. Current trade and intellectual property laws also favour the interests of the developed states. Because of this context modern biotechnology may, instead of fulfilling its potential to promote development, exacerbate the gaps between rich and poor, in turn causing increased tensions between the developed and the developing worlds. Current global conditions appear to work against the widespread diffusion of innovative technologies and related products to developing countries, preventing the much-needed improvements in health and food security from reaching their populations.

There is a great deal of controversy and debate about exactly what the consequences of modern biotechnology will be. It is impossible to precisely predict the final outcomes of a technological and socio-economic revolution that is only in its infancy. But there is no doubt that its impacts will be significant and an examination of debates in the literature gives an indication of their likely scope.

This uncertainty exists largely because there are many factors (beyond the issue of what is technically achievable) that affect the speed and direction of scientific and technological advances in biotechnology and therefore the nature of its applications and their consequences. These include the prevailing political, economic, social and environmental conditions. Some conditions will drive technological change forward, others will hold it back, and there will be changes in these conditions across time and space, creating a complex interplay that frustrates exact foresight.

Because there are so many potential benefits of these new biotechnologies it is desirable to move forward with the biotechnology revolution. It will at the same time be desirable to avoid the negative consequences of these new technologies. And, because the tensions caused by increased inequalities between rich and poor could impede the development of the biotechnology revolution, and because these gaps hinder full realisation of its benefits, it is also desirable to try to spread the benefits as evenly as possible.

Specific Consequences of Biotechnology Applications

As discussed in the previous chapter, biotechnology has a huge range of applications. So far most developments have been concentrated in the pharmaceutical and agricultural industries. Many claims are made about the positive and negative consequences of applications of modern biotechnology and the literature in this area is mostly polarised between that which emphasises costs and that which emphasises benefits. The products of genetic engineering began to emerge onto markets only in the early 1980s. This means that the long-term consequences of even the earliest commercial applications of modern biotechnology are yet to be fully assessed.

In an attempt to give a more balanced view of potential consequences of some specific biotechnology applications, this chapter starts by providing examples of both positive and negative consequences in the areas of environment, health, development[1] and (protection against) misuse, as illustrations of debates in the literature.

There is also discussion, towards the end of this section, of the uneven spread of consequences of the biotechnology revolution. The current global context means that the benefits (positive consequences) are likely to be concentrated in the developed world. If this occurs it is likely to influence the direction and speed of the revolution and it will also create difficulties for the full realisation of the revolution's benefits, many of which are claimed on behalf of the poor, but may not reach them. Developing countries are also less likely to have the capacity to deal with any negative consequences.

Positive Consequences

Environmental

A major aim in the genetic modification of agricultural crops[2] has been to reduce the use of environmentally harmful inputs, creating crops which are cheaper to grow and more environmentally friendly. Use of agricultural chemicals/biologics (such as pesticides and herbicides) poses a threat to the environment and often to human health as well and so a reduction in the use of these products will be beneficial. Some of the negative environmental effects of pesticides are listed by Dinham (1993, p. 64) as: 'water pollution, soil degradation, insect resistance and resurgence, the destruction of native flora and fauna, and some, as ozone depleters, contribute to the greenhouse effect'.

Two examples of plant genetic engineering for this purpose are the creation of crops that tolerate the application of glyphosate herbicides such as Roundup Ready™ soybeans, and crops with a 'Bt' gene inserted. Bt stands for *Bacillus thuringiensis*, spores of which, when ingested by certain insects, produce a toxin that kills the insect. The gene transferred to Bt crops is that which codes for production of this toxin. When crops have the Bt gene inserted they gain enhanced resistance to attack by certain pests and the need for applications of insecticide is significantly reduced.

Worldwide in 2009 almost 16.1 million hectares of GM cotton and 69.2 million hectares of GM soybeans were grown (ISAAA, 2009). Data from the United States Department of Agriculture's National Agricultural Statistics Service (NASS) indicate a reduction in the use of Bt on cotton and a switch to glyphosate herbicides (from more toxic alternatives) for soybeans since these new crops were introduced. The percentage of cotton acreage treated with Bt in the United States fell from 15 per cent in 1995 to 3 per cent in 2000 (no statistics are provided after 2000), and the percentage of soybean acreage treated with glyphosate rose from 20 per cent in 1995 to 91 per cent in 2006, while at the same time three more toxic alternatives fell in usage from 20 per cent to 2 per cent, from 26 per cent to 3 per cent and from 44 per cent to 3 per cent (respectively for trifluralin, pendimethalin and imazethapyr) (NASS, no date). However, the Union of Concerned Scientists (UCS) has reported that, after the first few years of planting in the United States, glyphosate-tolerant crops have required increasing amounts of herbicide in comparison to conventional crops as weed resistance has become a significant problem (UCS, October 2004, pp. 35–6).

Genetic engineering of crops appears to have been successful in reducing the use of harmful agricultural pesticides, which should have environmental benefits, but it is unclear whether these benefits will persist in the long term.

Health

Advances in genomics (deciphering the genetic codes of living organisms) are providing greater understanding of diseases, which should lead to the development of better treatments and preventative measures. It is the opinion of the World Health Organisation (2002) that, 'Given the huge burden of infectious diseases in developing countries, this research has the potential to change the lives of millions of people'. Understanding of individual differences in susceptibility to diseases and in responses to treatments should allow tailoring of drugs to meet individual needs, providing more effective treatment and reducing undesirable side effects.

One disease to which modern biotechnology is being applied is malaria. The genome sequences of the mosquito *Anopheles gambiae* and of the most deadly malarial parasite *Plasmodium falciparum* were both published in October 2002. This information should enable more effective targeting of drugs and increase understanding of resistance mechanisms so drugs can

be produced to work around them. Projects building on this information[3] include attempts to eradicate the malarial parasite, to make mosquitoes resistant to the parasite and to make the mosquitoes infertile, as well as creating 'new drugs, mosquito-repellents, insecticides and vaccines' (Young, 2 October 2002).

According to recent figures published by the World Health Organisation, malaria caused approximately 247 million cases of acute illness and over 880,000 deaths in 2006 (WHO, 2008a, 2009) and is estimated to account for up to 40 per cent of public health expenditure in the worst affected countries (CSD, 2006). Clearly finding a means of preventing transmission of this disease will be hugely beneficial. And this is only one of the diseases that modern biotechnology has the potential to help prevent, treat, eradicate or cure. Additionally, gene therapies (therapies that aim to correct expression of faulty genes) may help combat or prevent genetic diseases such as Huntington's disease, thalassaemia and sickle cell anaemia. Modern biotechnology has the potential to bring huge benefits to human health.

Development

Another motivation behind the genetic engineering of crops is to increase yields and improve nutritional value, both of which could make significant contributions to food security. The Food and Agriculture Organisation states that: 'Food security exists when all people, at all times, have physical and economic access to sufficient, safe and nutritious food to meet their dietary needs and food preferences for an active and healthy life' (FAO, no date a). The number of undernourished people worldwide passed 1 billion for the first time in 2008 (FAO, June 2009). Populations in the developed countries account for less than 2 per cent of this figure.

The above-mentioned engineering of crops for herbicide and pesticide resistance, as well as having positive environmental impacts, should result in a reduction of crop losses and thus increase yield. Nutritional value of crops can be enhanced by inserting genes novel to the plant so that useful additional proteins are produced. A variety of rice known as 'Golden Rice' has been created that contains betacarotene (a precursor to vitamin A). Research on enhanced nutritional value is also underway on rice, sorghum, cassava and banana under the Grand Challenges in Global Health Programme (no date). Micronutrient deficiencies are estimated to account for 1.62 billion cases of anaemia, almost 2 billion cases of iodine deficiency (741 million at clinical levels) and 250 million cases of childhood vitamin A deficiency each year (FAO, 2003; WHO, 2008b, no date a). The nutritional value of crops used for animal feed can also be enhanced removing the need for and expense of additives. Food security is not only based on the availability of food, but modern biotechnology has great potential to improve that aspect of food security.

Protection against Misuse

In recent years the threat of attacks using biological weapons has been perceived to increase. Terrorist attacks aimed at causing mass casualties have raised awareness of the possibility of attacks with weapons of mass destruction (biological, chemical and radiological). Letters containing anthrax sent in late September and October 2001 in the United States demonstrated the widespread fear and disruption that even a low level, limited casualty, biological attack can have. All of this has led some states, particularly the United States, to increase their research and development into defence against such attacks. Governmental funding for biodefence in the United States has risen from $568 million in 2001 to over $6 billion budgeted for 2010, with a high of over $8 billion in 2005 (Franco, September 2009).

Genetic and genomic technologies can be extremely useful in such work against biological attack, assisting in creation of detection devices, vaccines, treatments and countermeasures. The National Institute of Allergy and Infectious Disease (NIAID) *Biodefense Research Agenda* released in 2002 'focuses on the need for basic research on the biology of the microbe, the host response and basic and applied research aimed at the development of diagnostics, therapeutics and vaccines against these agents' (NIAID, 2002). The agenda particularly recognises the significance of genomics in aiding understanding of human immune responses and susceptibilities to biological agents. Protection against misuse extends beyond biodefence research, including for example health monitoring systems in which genomics can assist in the identification and tracing of disease outbreaks.

Summary

There is clear potential for many, often very important, positive consequences to emerge from the biotechnology revolution. These include improvements to human, animal and plant health, less environmentally damaging forms of agricultural production, enhanced food security and new means of defence against biological attacks. This is not the whole story, however, and there are potentially many negative consequences that should not be ignored when considering governance of the revolution.

Negative Consequences

Environmental

While the use of GE crops may bring environmental benefits through reduced use of agricultural chemicals, there is concern that they also threaten environmental stability. A prominent concern is that cultivation of GE crops will lead to reductions in biodiversity. Biodiversity is essential for environmental stability, and is recognised to form an essential resource base, valuable for food security and sustainable development. Indeed, as Madeley (1996, p. 6) explains, 'This diverse variety is an essential link in the food

chain – it is the base for increased productivity and it gives humankind the capacity to adapt and develop crops for the future'.

The Convention on Biodiversity Secretariat defines biodiversity as 'the variety of life on Earth, from the simplest bacterial gene to the vast, complex rainforests of the Amazon' (14 May 2009). GE crops could threaten biodiversity in several ways.

Current commercial cultivation of GE crops appears to encourage the spread of monocultural farming practices, which reduce the diversity of crops grown. Rather than cultivating a number of different varieties of a particular crop, farmers are encouraged to plant only the specific GE variety. Monocultures are more vulnerable to disease and pests because what affects one plant will affect the entire crop, instead of there being varied resistance (Madeley, 1996, p. 9). Zilberman, Ameden and Qaim (January 2007, p. 73) point out that this is likely to be a particular problem for low income countries that have 'limited capacity to genetically modify local varieties' and so may rely solely on a limited range of GE varieties.

GE crops may also threaten biodiversity through effects on other plants both within and across species. GE crops may be advantaged against other wild relatives pushing them out of ecosystems. There is also the risk of horizontal gene transfer (transfer of the novel genetic trait to other plants), which could result in weeds developing insect resistance or herbicide tolerance. Or the genes may transfer to insects or bacteria causing them to take up resistance too. The increased use of glyphosate herbicides on tolerant GE crops has also promoted resistance in weeds (UCS, October 2004).

There is additional concern about the direct and indirect effects of GE crops on insects and other wildlife. They may affect and kill untargeted insects directly or have indirect effects on other wildlife because if insects are eradicated, this has knock-on effects for the rest of the food chain (Rissler and Mellon, 1996, p. 42). Even though certain insects may be viewed as pests by farmers, they also form part of larger ecosystems, and the effects of their removal from these systems may be extremely damaging (Pilnick, 2002, p. 129). There is also the potential for toxic proteins to pass up the food chain.

Some examples of contamination via horizontal gene transfer have been found, including a study conducted in October and November of 2000 in which genetic contamination of non-GE varieties of maize was found in Mexico, which is a natural centre of maize biodiversity (Quist and Chapela, 29 November 2001), and reports of contamination of non-GE oilseed rape in Australia and Japan in August 2005 (ABC, 26 August 2005). Insect resistance to the Bt toxin has also been documented in field and laboratory studies but does not appear to be a significant problem for farmers yet (Griffits, Whitacre, Stevens and Araion, August 2001; UCS, October 2004); in fact some studies have shown an increase in insect populations where Bt cotton is grown due to the reduction in use of insecticides (Marvier, McCreedy, Regetz and Kareiva, June 2007; Pray and Naseem, January 2007).

A complicating factor is that many of the environmental consequences of the introduction of GE crops are likely to be seen only over the longer term. The Organisation for Economic Cooperation and Development (OECD) recognised this problem in its book on *21st Century Technologies* (1998, p. 94): 'Transgenic plants have been on the market only a few years and the effects of cultivation and consumption over a long period are not yet known. It is possible that ecological damage will only occur after ten, twenty or thirty years.' The insects that affect cotton, for example, have historically taken ten to fifteen years to build resistance to new herbicides (UCS, October 2004).

Health

While biotechnology has the potential to achieve vast improvements in human health, current side effects to gene therapies have brought its use into question. This may just be a temporary obstacle until further advances are made, but it is a reminder that there is still a lot that is not known about the working of genes, exactly how a living organism reacts to genetic interventions and that 'trying to alter genes without fully understanding their functions could have disastrous consequences' (Pilnick, 2002, p. 108).

An example of problematic side effects can be seen in the case of gene therapy given to several boys suffering from severe combined immunodeficiency disorder (SCID): 'Gene therapy in this case involved providing a normal copy of the defective gene which causes SCID, so enabling the normal growth and development of the immune system' (Pilnick, 2002, p. 109). While the therapy seemed successful in treating the condition, it is also believed to have been responsible for causing leukaemia in two of the patients. The reason for the children developing cancer is suggested to be 'because the gene inserted next to an oncogene, called Lmo2, in a single white blood cell. This could have triggered the cell to proliferate uncontrollably, causing the disease' (McDowell, 15 January 2003).

As well as problems in controlling the targeting of inserted genetic material, concerns have also been raised about the type of vectors used to carry the material into cells. These are generally modified viruses. The Human Genome Project (HGP) in its information on gene therapy (DOE, 2009) states that the use of viral vectors 'present[s] a variety of potential problems to the patient – toxicity, immune and inflammatory response, and gene control and targeting issues. In addition there is always the fear that the viral vector, once inside the patient, may recover its ability to cause disease'. Current gene therapies have not involved interventions that can be inherited; concerns are even higher about the effects of gene therapies where the genetic manipulation can be passed on from generation to generation.

Concerns about the health effects of consumption of GM foods have also been voiced. These include concern that allergens might be transferred along with intended traits or that new allergens could be created, and that antibiotic resistant, or other, genes may transfer to human gut bacteria, resulting in

harmful combinations. These concerns are reflected in paragraphs 47 and 51 of the Codex Alimentarius Commission's (CAC) Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms (2003a): 'Genes derived from known allergenic sources should be assumed to encode an allergen and be avoided unless scientific evidence demonstrates otherwise'; 'strains in which antibiotic resistance is encoded by transmissible genetic elements should not be used where such strains or these genetic elements are present in the final food'.

Very few long-term assessments of the effects of GM foods on human (or animal) health have been conducted, but in many cases there are unlikely to be additional negative impacts to those of the 'conventional counterpart'[4].

Development

While biotechnologies may provide benefits in the area of food security, there may also be negative effects stemming from the way in which they are applied. These could, for example, result from reductions in biodiversity (mentioned above) and also through changes in the patterns of ownership of seeds. Reductions in biodiversity undermine long-term food security because they reduce the available alternatives to currently cultivated crops. The vast majority of GM plants and seeds are developed by private companies in the United States and Europe. Because of the costs of research and development these companies feel that it is necessary and justified to protect their inventions through patents and other forms of intellectual property rights. It is the view of the International Chamber of Commerce (2002) that: 'As with any emerging industry, the protection of intellectual property rights and progressive trade policies are essential to ensure continued innovation and to stimulate investment in biotechnology.'

Farmers wishing to use particular GE seeds will, therefore, generally have to buy them from private producers and in many cases will be prohibited from saving seed from one year to the next and from exchanging seeds with other farmers. Saving of seed is a widespread and long-standing practice in many developing countries and helps to keep the costs of farming down. Some GE seeds were developed with so-called 'terminator technology' which created sterile seeds that could be used for only one season. Due to resistance this technology has not yet been commercially applied.

If farmers are left with little choice but to use corporately owned seeds and plant varieties, at higher cost than traditional sources (such as exchange), this is likely to increase poverty, while pushing out indigenous varieties, leaving little to fall back on. The additional costs of GM seeds may thus be prohibitive, particularly to small-scale farmers in the developing world, meaning that they are unable to use the technology or gain any benefit from it. Indeed, a UCS report points to greater yield increases being achievable by, for example, a switch to organic methods in developing countries than through the use of GE crops (UCS,

April 2009, p. 5). It is also the case that 'the traits that have been introduced in GM crops to date tend to largely favour the existing farming practices of industrial agriculture, rather than meet the needs of the poor' (Pray and Naseem, January 2007, p. 193).

Misuse

Greater understanding of diseases and their interactions with humans can result in better treatments, but the same knowledge can be misused and many of the same technologies and techniques of modern biotechnology that can be applied to enhance defensive capabilities can also be put to hostile use. Several authors (for example Dando, 1999; ICRC, 2002; Meselson, 2000; Rifkin, 1998) point to the continuing historical trend for scientific developments to be used for hostile purposes.

The characteristics of specificity, environmental persistence, infectiousness and lethality are generally sought in the development of a biological weapon. Genetic engineering technologies have the potential to improve on these aspects, increasing the overall effectiveness of biological weapons, which can only serve to make them more attractive to states and terrorist groups. The International Committee of the Red Cross (ICRC) in its initiative on *Biotechnology, Weapons and Humanity* (launched in 2002) identifies eight main concerns regarding the use of biotechnology in the production of biowarfare agents. These are:

1. Manipulation of known biological warfare agents
2. Harmless microbes being made dangerous
3. Development of hostile vaccinations
4. Research that may lead to unintended but dangerous outcomes
5. Artificial creation of extremely dangerous viruses
6. Undetected attacks that can alter bodily functions
7. 'Genetic weapons'
8. Effects on agriculture and infrastructure (ICRC, 2002).

Point 7 of this list relates to the fear that future genetic engineering technology may be able to create biological agents that can target specific groups of people. This possibility increases as genomic knowledge of humans and of disease-causing microorganisms expands. Much of this knowledge is being placed in the public domain. The genomes of several disease-causing microbes – including, controversially, the 1918 influenza virus – have already been sequenced and published and research is underway on establishing the genetic differences between groups that account for different susceptibilities to disease. This work is being carried out *inter alia* in the Haplotype Map Project of the US National Genome Research Institute. Its website states that 'The haplotype map, or "HapMap" is a tool that allows researchers to find genes and genetic variations that affect health and disease' (NHGRI, 10 September 2009).

The Uneven Spread of Consequences

The biotechnology revolution brings negative consequences alongside positive ones. Equally problematic is the fact that these consequences will not be evenly distributed among states. If the biotechnology revolution serves to widen the gap between rich and poor this will be a significant negative consequence in itself. This effect of the biotechnology revolution is a result of the global context in which the revolution is occurring rather than being inherent to the technology.

The biotechnology revolution is taking place in an increasingly globalised world and it is a global phenomenon in terms of its effects. This globalised world is one of great inequalities, dominated by the economic power of a few developed states. This context is an important factor that influences how the impacts of modern biotechnology will be spread. Particularly, current trends mean that developed countries will benefit more than developing countries, due to their much larger capacities for research and development, their dominance of international markets and more advanced regulatory systems. Developed countries are also likely to have greater capacities to cope with socio-economic change and to deal with the negative effects of the new technologies.

Research and development in the health care sector is disproportionately concentrated in the developed world, with an estimated 90 per cent of research and development taking place there (where approximately 20 per cent of the world's population live). Pharmaceutical research and development is a very costly and time-consuming process, and so companies seek to recoup their money by protecting their inventions and selling their drugs generally at higher rates than the cost price. Few people or governments in the developing world can afford these prices. This means that pharmaceutical companies have little incentive to produce drugs and vaccines to meet the developing world's needs (such as combating tropical diseases) and so most research and development is done to meet the needs of people in the developed world. As Goonatilake (1999, p. 120) points out, the same is true for biotechnology-based pharmaceuticals: 'Market forces thus determine what is considered a commercially desirable biotechnology product. Operating globally these forces preselect particular biological products for research, development and production.'

Ill health contributes to poverty and constrains development. Gaps in health are therefore closely related to the gap between rich and poor and contribute to it. Clearly, as Qaim (2000, p. 8) argues, 'if biotechnology R&D would only benefit the richer population segments while neglecting the needs of the poor, the innovation could engender an aggravation of existing income disparities'. Differences in regulatory capacity in the health area are also of concern to the WHO, which pointed out in its 2002 report on *Genomics and World Health* that 'A general feature of many developing countries is a

lack of well-developed regulatory apparatus to deal with either the scientific issues in genetic research and technology, or with the ethical, legal and social issues'. Countries may also lack necessary experience and expertise for timely and effective policy-making in these areas.

This concentration of benefits in the developed world may well exacerbate gaps between rich and poor; it may also cause tensions between countries and contribute to resistance to the new technologies. Examples of this have already been seen in campaigns by developing countries against patents on drugs and resistance to food aid that contains GM products. These issues have caused tensions in international forums, and particularly in the World Trade Organisation (WTO), because of its agreement which requires harmonisation of national patent rules (the Agreement on Trade Related Aspects of Intellectual Property Rights or TRIPS).

At a meeting of the WTO in Doha in 2001, developing countries challenged the patent rights held by and licensing practices of multinational pharmaceutical companies and the resulting costs of essential medicines. This campaign was partially successful and is ongoing. The November 2001 *Doha Declaration* of the WTO states in paragraph 17: 'We stress the importance we attach to implementation and interpretation of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) in a manner supportive of public health, by promoting both access to essential medicines and research and development into new medicines and, in this connection, are adopting a separate declaration.' (WTO, 20 November 2001). The separate declaration was the *Declaration on the TRIPS Agreement and Public Health*, under which developing countries would be allowed to 'seek a waiver on public health grounds from strict WTO rules which guarantee drug patents for 20 years' (Denny, 2001). However, some countries, particularly the United States, refused to support the Declaration and so it has had little practical effect (BBC News Online, 21 December 2002).

Some developing countries seem particularly wary of, and have opposed, having products of agricultural biotechnology forced upon them, before concerns about their safety for health and the environment have been answered, particularly when the products have not been designed with their needs in mind, and when they are unsure what it will mean in terms of export markets. In Autumn 2002 while parts of its population faced starvation, Zambia refused to accept food aid that contained GM products. Other African countries (Malawi, Mozambique, Lesotho and Zimbabwe) insisted that such food aid be milled before distribution so that the seed could not be used by farmers (Knight, 30 October 2002). Again, due to market forces, research and development in this area is concentrated on the needs of farmers in the developed world. Most developments have been for crops grown in the United States (predominantly soybeans, maize, canola and cotton) and

suited to defeating the pests and diseases prevalent there, and to growth in particular environmental conditions. Pray and Naseem (January 2007, pp. 193–4) outline some of the main forces at work here:

> Multinational firms are unwilling to make the necessary investments in biotechnology research relevant to developing country agriculture due to limited market potential, fear of piracy of their intellectual property and the high cost of meeting regulatory requirements. Taken together, this has meant that research on crops important to poor farmers yields low private returns and hence provide limited incentives for private firms to invest.

Development of new crops aimed at meeting the needs of farmers in the developing world has been largely left to small, public research centres. Developing countries generally lack the capacity to undertake much basic research – although there are some exceptions to this such as India and China – these countries may also lack 'the scientific capacity to know which technologies would be most useful, or how to use them even if they were to get access' (Pray and Naseem, January 2007, p. 208). Additionally many developing countries lack regulatory and risk assessment capacities supportive of safe development and application of these technologies (Thies and Devare, January 2007).

The environmental risks from GE crops will be highest in areas that are centres of biodiversity, which are concentrated in the developing world, because gene transfers are more likely to occur where the engineered crop is in close proximity to wild relatives. Also the costs of containment and clean up of environmental damage may well be unaffordable to many developing nations. This means that the countries that are most likely to be negatively affected by the biotechnology revolution will probably be those that are also least able to cope with these effects.

Summary

Due to the international context, while the impacts of the biotechnology revolution are and will continue to be globally felt they are not evenly distributed. Research and development for many applications of biotechnology is dominated by private companies based in the developed world and the products of biotechnology are focused on the needs of their populations. Such uneven distribution of the consequences of modern biotechnology seems likely to further widen existing gaps between rich and poor within and between the developing and developed worlds. In turn this will cause tensions that could impede the progress of the biotechnology revolution. Most importantly it is likely to prevent the much-needed advances in food security and health becoming a reality for the world's poor.

Specific Consequences – Conclusion

When looking at the consequences of specific applications of biotechnology, although precise outcomes may be unclear, there are still some obvious trends that can be identified. There will be both positive and negative impacts arising from the biotechnology revolution. Evidence of impacts is limited so far as the revolution remains in its infancy and many effects are likely to appear only over the long term. It is the view of the OECD that: 'Since modern biotechnology goes back only a few decades, its possibilities are by no means exhausted, although it is difficult to assess their range and impact. Modern biotechnology is therefore a scientific and technological development trend which is at the beginning of its life cycle.' (1998, p. 77).

Modern biotechnology has the potential to greatly improve human health, but also presents it with new hazards. It has the potential to reduce and counter humanity's negative impacts on the environment, but also to cause devastating loss of biodiversity. It has the potential to help feed the world, but it may also result in greater food insecurity. It can create better defence against biological attack, but also encourage and enable development of improved biological weapons. Finally, the consequences will be different for different countries. The claimed benefits biotechnology will bring to the poor may not reach them. The benefits could well remain concentrated in the developed world.

General Consequences of the Biotechnology Revolution

Alongside the specific consequences associated with particular applications of modern biotechnology, there will be many, more general socio-economic consequences. Again, most of these consequences will be felt globally and their impacts will vary between nations. Something that is (perceived as) positive for one country or group may be (perceived as) negative for another. These more general consequences are not yet widely seen and indeed many may be hard to quantify; however, their effects are likely to be substantial.

Prentis, in *Biotechnology: A New Industrial Revolution*, explains that all major technological change has socio-economic consequences and that the biotechnology revolution will be no exception: 'Any major new technology has profound social, economic and political effects. Biotechnology is no exception, and the potential consequences of the growth of biotechnological industries on the health of workers and on the public, on national and international trade, on economic power and on the position of science in society need to be examined' (1984, p. 171).

Because the changes involved deeply impact life processes themselves, societies will face challenges to values and beliefs about life. Genetic interventions raise many ethical dilemmas which societies and governments must struggle with. Genomics will produce new forms of knowledge which

will present novel choices in health and reproduction, but could also provide the basis of additional forms of discrimination. The OECD (1998, p. 41) argues that: 'No aspect of the human being, whether physical, mental, intellectual, social, psychological or physiological, will be beyond practical manipulation and change, all of which will be made possible and practical through technology.'

In the economic realm there are likely to be changes in patterns of international trade, and changes in the geography of (agricultural) production, new economic winners and losers, new labour relations and changes in production processes. These socio-economic effects may also bring about political changes. Particularly there may be a need to enable democratic debates to take place to resolve ethical dilemmas and to facilitate choice-making. New forms of state control may be demanded (e.g. to prevent genetic discrimination or limit genetic interventions) while at the same time some areas that are now dominated by the state may move to more individual control (e.g. health care options). It is Yoxen's (1986, p. 212) view of the biotechnology revolution that: 'It is a major economic phenomenon that will have social and political repercussions. It will affect the patterns of trade ... it will force some industries to the wall, it will have profound effects on the global structures of power.'

Of course there are many factors that will influence exactly what happens, and capacities to deal with such changes vary, but it is clear that modern biotechnology will result in significant and widespread socio-economic change.

Economic Changes

The new biotechnologies have rapidly found commercial application. The raw materials used in research and development and the resulting products are traded on international markets. Often they present an alternative or substitute for current products and as such can result in major shifts in demand. This could cause significant changes in trade relations, but it may also strengthen current trends in the dominance of international trade by a few rich nations and multinational companies.

Changes in the geography of agricultural production could occur if countries decide to adapt a crop (like coffee) that they currently import to grow successfully in their local climate. This is a possibility because, as Bijman, van den Doel and Junne (1987, p. 3) explain, 'biotechnology has meant that plants which could only be grown in a certain area for climatic reasons can now be grown elsewhere, thus representing new competition for the traditional producers'.

The biotechnology revolution will also bring changes to production in other industries particularly those based on petrochemicals and those involved in the processing of food. Goonatilake (1999, p. 134) explains what changes in trade could mean for developing countries – 'The change will signify a lesser use of earlier raw materials and so a weakening of the trade links established

in the 19th century. The effect on commodity exports from the developing world because of biotechnology would therefore be dramatic.'

Technological revolutions also cause changes in labour relations. Biotechnology will probably reinforce trends towards knowledge-based economies in the developed world since many of its applications emerge directly from basic research. In the developing world labour changes are more likely to result from changes in agricultural production as many GE crops suit large-scale, industrialised farming methods.

Social Implications of Human Genetics

All major technological change has social impacts. Those associated with modern biotechnology are potentially huge because of the unprecedented level of control over and ability to intervene in basic life processes involved. The social impacts will be many, varied and complex. The exact impacts will, of course, vary between societies, but, because of the global nature of the biotechnology revolution, it is likely to impact in some way on the vast majority of societies. Many of the most direct social impacts are emerging from advances in human genetics. A few of the major concerns about the social impacts of modern biotechnology will be outlined here – including possible eugenic outcomes, discrimination and new social divisions – but first a brief overview of advances in human genetics is provided.

Developments in Human Genetics

Advances in human genetics have centred on two main areas: genomics which has provided and continues to provide new knowledge and understanding of the human genome, of the functions of certain genes, and their interaction with diseases and environmental influences; and genetic engineering which provides the tools to apply this knowledge, most successfully at present through genetic testing and screening, but also in the form of gene therapy.

Genomics is the study of genomes, i.e. the complete genetic sequences of organisms. Significant advances in the study of the human genome have taken place in the international, publicly funded, HGP and its private rival Celera, which both published draft sequences of the human genome in February 2001. The final draft of the human genome was announced in April 2003. The HGP is now concentrating on discovering and mapping the functions of genes and on understanding how they interact with each other and with external factors. A particular purpose of human genomics is to facilitate understanding of disease mechanisms and genetic disorders, and to identify the particular genes involved so that they can be targeted for treatment. Pharmacogenomics, a sub-discipline of genomics, is the study of how genes interact with certain pharmaceutical drugs. This work is done to improve the effectiveness of drugs, to avoid adverse reactions and to minimise side effects. This has the potential to lead to 'tailor-made' drug treatments designed to be safe and optimally effective for a particular individual's physiological responses.

New knowledge of human genes and their role in disease is already being applied through genetic screening, testing and gene therapy. The terms genetic screening and genetic testing are often used interchangeably, although they can be differentiated with genetic screening applying to whole population groups and genetic testing applying to individuals. Genetic testing is carried out to find out whether 'abnormal' genes or harmful genetic mutations are present and is done to test the individual for a particular disease/disorder, for the risk of developing a particular disease or for carrying a gene for a hereditary disorder. Genetic testing can be carried out on foetuses in the first few months of pregnancy, giving the option of termination if the foetus is shown to be carrying the mutation. More recently there has emerged the possibility of testing embryos *in vitro* and selecting only the 'healthy' embryos to be implanted. This technique is known as pre-implantation genetic diagnosis (PGD).

Once a gene has been identified as having a fault that makes it responsible for causing a disease or disorder and it has been located on the genome, then there is the possibility (at least for single-gene genetic disorders) of intervention to correct that fault. This can be done through the provision of 'correct' copies of the gene transmitted, usually through a viral vector, into the cells of the patient. This is known as gene therapy. While gene therapy has had little success so far and has run into some problems, there is still a lot of research being conducted in this area, and it will probably have more widespread application in the future. Gene therapy is, so far, being limited to interventions in somatic cells (e.g. cells that are not involved in reproduction) so that the genetic changes cannot be inherited.

Concerns about Possible Eugenic Outcomes

One concern that is frequently raised is that new genetic knowledge and technologies will be used for eugenic purposes. The literal meaning of eugenic is good gene. The idea behind eugenics is the improvement of the human gene pool by promoting the inheritance of 'good' genes (known as positive eugenics) and removing 'bad' genes from the gene pool (known as negative eugenics). Eugenic practices have a long but generally troubled history having been used to justify genocide and human rights abuses. The ability of new genetic technologies to be put to eugenic uses has raised alarm over a potential return to past abuses. Appleyard (1999, p. 47) outlines the reasons for such concern:

> Precisely because a belief in fundamental biological differences has led to such horrors in the past, and precisely because it is obvious that such knowledge was deliberately rigged to provide a spurious basis for bigotry, we should be very, very, cautious about using biological differences to explain behaviour, personality or even disease. The history of biological justifications is a bloody one, far too bloody for us ever to contemplate taking such risks again.

This is an extremely complicated issue; there are different types of eugenics and not all are perceived (by everyone) as bad. Societies face the problem of deciding where and how to draw the line when it comes to selecting 'good' genes over 'bad' genes. That sort of selection is already implicit in genetic testing, screening and therapy, where there is always some notion of a 'faulty' or 'abnormal' gene involved. Indeed Rifkin (1998, p. 128) raises the point that all genetic engineering decisions are inherently eugenic choices involving the selection of one gene over another – 'Everytime a genetic change of this kind is made, the scientist, corporation or state is implicitly, if not explicitly, making a decision about which are the good genes that should be inserted and preserved and which are the bad genes that should be altered or deleted.'

Current proponents of eugenics differentiate between past compulsory and enforced state-run eugenics programmes and the current opportunity to have voluntary eugenics based on individual choice. However, the idea of voluntary eugenics is also problematic if you recognise that society can exert a great deal of influence over individual choices and that lack of or mis-information about the meaning of test results and the quality of life of individuals suffering from certain diseases may also skew decisions. Several authors (for example Appleyard, 1999; Hindmarsh, Lawrence and Norton, 1998; Pilnick, 2002) raise the point that many individual choices may have the cumulative effect of a national eugenics practice. In the words of Hindmarsh, Lawrence and Norton (1998, p. 102): 'one person's personal preference – when part of a broader trend involving many people – creates the injustice of discrimination against a whole class or category of other people'.

It is also necessary to look at the implications that determining certain traits (disease-causing or otherwise) as undesirable may have for people already living with those traits. What happens to their right to life? Will they feel fully valued by society? And will the state provide the social services necessary for them to take part in society? The WHO in its 2002 report *Genomics and World Health* explains why many disabled people object to prenatal genetic testing – 'Disabled people see society's message in supporting genetic testing for the conditions they have as being that it would have been better if they had never been born, a message that they and others quite understandably reject.'

If we accept that genetic selection may be permissible under certain circumstances and for certain purposes (e.g. the provision of a stem-cell donor match for a seriously ill sibling) difficulties still arise over what should count as a genetic 'fault' that may be corrected, who gets to decide this and what the implications of this decision will be. While current uses of PGD and prenatal genetic screening have so far mainly been limited to avoiding serious genetic diseases or helping to save the life of an existing child, exactly the same techniques could be used to select embryos on the basis of a whole

range of other traits, some of which have nothing to do with disease or impairment, such as sex or eye colour. Appleyard (1999, p. 18) argues that this technology could in the future be used to create 'designer' babies:

> More rapid DNA sequencing techniques and greater knowledge about the effects of specific genes would mean that a much larger range of conditions could be sought in the embryonic cell. These conditions need not be what we now classify as serious diseases. In time they could, for example, forecast anything from the eye colour, to the likely intelligence or sexual orientation of the child. Preimplantation genetic diagnosis could offer, to those who could afford it, a choice of what kind of child they would like.

If further research identifies such genes (and it seems likely that it will), selection could take place on the basis of intelligence or behavioural traits. There is even disagreement over what should count as a serious disease. The British Human Genetics Commission (HGC) in its first annual report *Debating the Ethical Future of Human Genetics* advised that: 'PGD should be limited to specific and serious conditions', while at the same time stating that 'it has proved impossible to define what "serious" should mean in this context' (HGC, 2001, pp. 45–6).

Since eugenics labels (implicitly or explicitly) particular traits as normal/abnormal, good/bad, desirable/undesirable it carries with it an implied relationship of superiority and inferiority between people which may well undermine the fundamental concept of humans being equal and worthy of equal respect, treatment and rights. Appleyard (1999, p. 49) draws attention to the dangers of this:

> The point is that once people decide you are a lesser creature, for whatever reason, either superstitious or scientific, there appears to be no limit to what cruelty they may inflict on you. And they are likely to inflict that cruelty feeling justified, because it is but a small step from believing another human being is inferior to believing that he is bad, dangerous or threatening to 'superior' beings.

Concerns about Discrimination

New genetic knowledge will provide opportunities for new forms of discrimination. If it is discovered that a particular gene makes someone susceptible to a particular disease, and that gene can be tested for, then insurers and employers (among others) may wish to discriminate on the basis of the presence of the gene in an individual's genome, whether or not the disease actually develops. Insurance premiums may be set higher or cover refused for individuals carrying certain genes. An example of this is a British woman who found herself unable to get insurance due

to carrying the BRCA2 gene which has been implicated in some cancers (Boseley, 24 June 2003). However, for the moment, most insurers have placed a moratorium on use of genetic test results. Employers may wish to avoid later litigation if a potential employee is found to have a gene that interacts with the particular working environment to cause a disease.

If genes are found that affect intelligence this may exclude certain people from mainstream schooling. A gene for a behavioural trait like aggression may lead to the refusal to employ someone, as could a gene for mental illness or a propensity to alcoholism. This is despite the fact that such traits are largely socially defined/constructed. Hindmarsh, Lawrence and Norton (1998, p. 101) state that: 'A real danger therefore exists that a focus upon genetic factors will result in some people being classified in a manner which excludes them from employment, from education, from access to credit and other financial services, and even from being able to marry and form a family.' They also point out that, 'significantly, a person who is denied access may often not become ill or incapacitated and might never be so' (1998, p. 101).

This same genetic knowledge may well be, in medical terms, extremely beneficial to the individual, allowing early diagnosis, prevention or treatment of disease. For medical purposes some governments are encouraging the collection of individual genetic information. For example the British Department of Health stated in its *Genetics White Paper* (2003) that it would consider whether to collect genetic blueprints from all babies at birth. However, societies need to decide who should have access to the information, and what it should be used for. There is also a need to consider that an individual may not want to have this information (and may not want their doctor to have it either) – will they be given a choice? This is a real possibility. At present some people who may have Huntington's disease choose not to be tested for it because they do not want to know if they have it, since it cannot be treated. Also what would happen if an individual refuses to act on the genetic information by for example refusing to follow dietary and lifestyle advice despite being shown to have an increased risk of heart disease – would they be refused state funded health care/private health insurance?

New genetic knowledge is expected to revolutionise health care and may be very beneficial to society, but it carries many pitfalls and raises new and difficult dilemmas. It is also open to abuse and challenges ideas of privacy, confidentiality and informed consent.

Changes to Values and Concepts

The sanctity of life, particularly human life, is a powerful, fundamental and widely held concept and not only for religious reasons. It is a central concept of many, if not all, societies and the 'right to life' is seen as a basic and core human right (Article 3, *Universal Declaration of Human Rights*, 1948). Modern genetics and genomic technologies challenge some widely

held ideas about life as they allow basic life processes to be manipulated and exploited in a deliberate manner. The right to patent genes (including human genes) is seen by many as an unwanted and unwarranted commodification of life. Genomics can reduce 'life' to a code, a form of information, open to intervention and 'improvement' by human hands. Appleyard (1999, p. 134) explains what effect this might have: 'There is no sanctity attached to the individual; rather he or she becomes a collection of characteristics, each of which can be judged on some scale of relative significance. At this point it becomes difficult to distinguish human beings from consumer goods.' Many people thus view genetic technologies and particularly human genetics as fundamentally wrong.

There are also right to life issues raised by the use of prenatal genetic testing and PGD where the former often has abortion as the only alternative and the latter often entails the disposal of several embryos. Similarly there have been objections raised to the use of embryonic stem cells in research, where they have a huge potential to assist in therapies. Research using embryonic stem cells is banned in many countries at present due to moral and ethical objections, PGD is, however, allowed under certain circumstances, and prenatal genetic testing is now routine in many countries.

There are further problems raised by modern biotechnology for concepts of human rights and human responsibilities. What does the concept of a right to health now entail – does it include the right to have genetic faults corrected? The right to a dignified life is also challenged: what does it mean for someone's dignity if they were selected to be born on the basis that they would save the life of another? Further problems arise if genes are found that influence human behaviour – what does this mean for human autonomy and the concept of responsibility for one's own behaviour? If it is someone's genes that make them aggressive and violent, is it their fault if they murder someone? Are they less culpable? Could they have avoided the particular route they have taken? Should a different term of punishment be applied to such individuals? The example of a gene for aggression is used by Pilnick (2002, p. 41): 'Raising the question of what societies might practically do with this knowledge poses some uncomfortable answers. If aggression is linked to genetics alone, aggressive behaviour may be condoned or seen as inevitable. The principle of the individual's responsibility for their own behaviour is undermined.'

New genetic technologies are also redefining the social meaning of concepts such as health and sickness, disease and abnormality. The concept of health is widened beyond being free of symptoms, to being free of genetic defects, and perhaps even not having the propensity to suffer from certain diseases. Since every individual will have some 'faults' in their genome, does this then mean that everyone is ill? Some believe that such changes may reduce discrimination, since if everyone carries abnormalities, then this will be perceived as 'normal' – 'Molecular biologists argue that, because the genetic tests they are developing will show that all of us are flawed in one way or

another, these tests will bring an end to genetic discrimination' (Hubbard and Wald, 1993, p. 36).

But what will it mean for people to view themselves as unhealthy when there is nothing that can be done? Or to be prescribed life-long treatment for a disease that may never afflict them? This is likely to affect the provision of social services (particularly health care). There is also a fear that this focus on genetics as a cause of disease will lead to environmental factors being ignored and yet, basic sanitation, clean water and improved nutrition could save millions of lives each year (UNICEF, no date) and can be achieved at relatively low cost via application of existing technologies.

Concerns about Power and Control

Many of the concerns about the social implications of modern biotechnology stem from issues of power and control. Who will make the decisions? Who will have access to the information? And how will they be able/permitted to use it?

Social divisions may widen if access to the benefits of the new technologies is uneven. Kitcher (1996, p. 198) raises the prospect of a future where the rich can afford to pay to have genetically guaranteed healthy and intelligent children, while the poor cannot and find that resources have been diverted from social services and national health care to genetic technologies that benefit the few. New social divisions that occur along genetic lines are feared, particularly if some form of eugenics goes ahead. Hubbard and Wald (1993, p. 36) also point out that discrimination is more likely to affect the already disadvantaged: 'Like other forms of discrimination, genetic discrimination will be felt most by people who are already stigmatised in other ways. People with access to power and resources are more likely to be shielded.'

Summary

Advances in modern biotechnology have many social implications, although it is difficult to be certain of what the precise effects might be. The new technologies make possible a new form of eugenics, they may encourage genetic discrimination, and they challenge core concepts such as the meaning of life, health and normality. They may create new social divisions and/or exacerbate existing ones, and create tensions and clashes of values. And these advances could undermine the ideals of basic human rights, shared by all. Appleyard (1999, p. 3) provides a good summary point: 'Genetics is … a historically unique combination of philosophy, science and technology that confronts humanity with the most fundamental questions, our answers to which will determine the human future.'

Like the other impacts of modern biotechnology, the social impacts will be global, but not evenly spread, and some societies are likely to have greater capacities to cope with social change and to diffuse any resulting tensions. While states may choose to prohibit certain uses of the new technologies to

protect their social values, the global nature of the biotechnology revolution presents problems for this – research and application of the new technologies can simply move elsewhere. This means that a global response is required.

Political Impacts

The political impacts of the biotechnology revolution are closely connected to the nature of its economic and social impacts. Governments are likely to find themselves called upon to take a lead on certain issues, while at the same time finding that their control over certain policy areas is diminishing (with, for example, the individualisation and privatisation of health care). There is also likely to be demand for greater democratic involvement in policy-making on genetics issues, and a demand for accountability and transparency in decision-making. As the Centre for Genetics Education (2002) states: 'Society and its governments will need to consider the boundaries that have to be put in place to monitor developments and ensure ethical applications of this new and advancing technology.' Governments will need to formulate policies nationally to deal with the socio-economic effects of biotechnology and also make an effort to harmonise such policies internationally, to gain effective control.

General Consequences – Conclusion

The biotechnology revolution will result in significant socio-economic changes. These general consequences of the biotechnology revolution will involve changes in production and employment and in international trade. Many ethical dilemmas have already been raised by the new power over life that genetic technologies bring. Changes in values are likely to occur as the meaning and sanctity of life are challenged. Societies will be presented with new choices and may demand a chance to participate in decisions about the control of these new technologies. New types of discrimination may arise. The overall consequences of these changes may be positive or negative, either way they will result in disruption.

Because the biotechnology revolution is a global phenomenon these socio-economic changes will occur globally, but the precise nature of their impacts will vary, and negative consequences are more likely to be felt by countries and societies that lack the capacity to deal with such changes. Just as with the specific consequences there is uncertainty about what the general consequences of modern biotechnology will be. This is because there are a number of complicating factors that will affect what the exact outcomes of the revolution will be.

Factors Affecting the Speed and Direction of Technological Change and Its Socio-economic Consequences

It is impossible to predict the precise outcomes of the biotechnology revolution. Certainty is made impossible because of the many complicating

factors that can influence the speed and direction of technological change. These include regulatory frameworks, economic conditions, government policies, public perceptions, the cost of alternatives and environmental necessity. Some of these factors will drive technological change, others will constrain it. Their influence will vary across space and time. In their report on the *Global Technology Revolution*, Anton, Silberglitt and Schneider (2001) explain that 'The actual realization of these possibilities will depend on a number of factors, including local acceptance of technological change, levels of technology and infrastructure investment, market drivers and limitations, and technology breakthroughs and advancements. Since these factors will vary across the globe, the implementation effects of technology will also vary, especially in developing countries'.

The Effects of Regulation

Regulation can both drive and impede technological change; it can also influence its course. This is true of national, regional and international regulation. Because biotechnology has so many different applications a wide range of laws are applicable to it. This means that the revolution is influenced by a variety of standards, guidelines, laws and conventions, which work in different ways to shape its pace and direction. The various regulations frequently overlap, interact and compete with each other. Their influence will vary for different applications of biotechnology, between states and regions and across time.

Economic Conditions

The pace and course of the biotechnology revolution will also be influenced by a variety of economic conditions at various levels – national, regional and international. The OECD in its 1998 assessment (*21st Century Technologies: Promises and Perils of a Dynamic Future*) considered economic policies that provide a stable economic environment to encourage innovation. It also stated that: 'More flexible labour markets, transparent and open capital markets, and competitive goods and services markets are all essential to the fluid resource reallocation and experimentation that is likely to be typical of robust socio-technical dynamism' (p. 31). Conversely, economic recession is likely to slow technological change by discouraging risk-taking. International economic conditions and policies such as free trade may encourage innovation by ensuring open markets for end products. Encouragement of competition at any level is also thought to drive technological change by providing an incentive to stay ahead of competitors. The influences created by economic conditions will again vary over time and between states.

Government Policies

In connection with the above sections, government regulatory and economic policies will have an influence on the pace and direction of the

biotechnology revolution. For example if a government decides to raise environmental standards this could encourage a move towards alternative energy sources (from fossil fuels to biomass for example) and to less polluting means of production, which could drive technological change as new alternatives are sought.

An example of government policy that might impede technological change is the decision of some governments to restrict commercial growing of GE crops, which clearly removes a major incentive to develop and market such products. Government policies obviously vary among states, although there may be some regional harmonisation and the policies of international organisations may also have a harmonising influence; policies also vary over time. Therefore, the influence of policies on the speed and direction of the biotechnology revolution will vary over time and between states. There are also numerous factors that contribute to the creation and choice of particular policies.

Public Views

Where the public resists new technology, at any level from local to global, this can impede technological change or change its course. Public resistance also varies within and between states and over time. An example of this is public resistance to consumption of GM foods. This resistance has been far more prevalent in Europe than in the United States; these differences are reflected in official policies.

Public resistance often occurs when values are challenged; this can be seen in the area of human cloning, where public responses also vary. While some people reject all human cloning as an affront to human dignity, others view cloning limited to production of embryonic stem cells for therapeutic uses to be justified under the human right to health. Technological development in the area of therapeutic human cloning has been impeded by government prohibitions in many countries driven by public resistance.

Resistance may change over time as further knowledge of the health and safety implications is gained and as new technological breakthroughs are made improving the safety of certain procedures or products. Public resistance varies with different applications of biotechnology and sometimes within applications too.

Costs of Alternatives

The potential for new biotechnology products and processes to replace existing ones based on, for example, petrochemicals means that the relative costs of the two alternatives will be a factor affecting the speed of technological change. While petrochemicals remain cheaper than the biotechnology-based alternative, even if there are environmental benefits to be gained by switching products, this is unlikely to happen. For example, while fuel alcohol can be produced from biomass and is considered (at least by some)

to be a less polluting alternative, most vehicles still use petrol because fuel alcohol is relatively expensive. This factor also varies across place and time. Brazil makes widespread use of biomass-derived fuel alcohol, because in its particular national context it is a cost-effective alternative. So the progress of the biotechnology revolution will also be influenced by the costs of alternative products, processes and technologies.

Environmental Necessity

Environmental necessity may also influence the speed and direction of the biotechnology revolution. Because biotechnology can provide less environmentally damaging alternatives to current energy sources and manufacturing processes, the biotechnology revolution may be driven forward by the necessity to implement such alternatives to reduce pollution. Awareness of the damage humanity is causing to our environment and of our dependence on the planet's life systems is growing and the necessity to act is gaining recognition. This can be seen in the growth of international environmental agreements, such as the Kyoto Protocol, in which governments promised to meet targets in the reduction of greenhouse gas emissions. Modern biotechnology can provide tools and products to help meet such targets.

Summary

One of the reasons for there being such uncertainty about the consequences of the biotechnology revolution is that there are a number of complicating factors that will influence its speed and direction, some of which were discussed above. They include regulatory, economic and political conditions, public opinion and environmental necessity. These influences will vary across space and time and can both drive and impede technological change. The nature of these influences and their complex interactions with other factors make them impossible to predict, which means that we cannot be sure of the speed and direction of the biotechnology revolution and uncertainty about its consequences therefore results.

Conclusion

Considerable uncertainty remains about precisely what the outcomes of the biotechnology revolution will be. This is partly because the revolution is still in its infancy with many scientific and technological advances still to come and because of a lack of information about the long-term effects of even its current applications. The uncertainty is also caused by the unprecedented level of interference in and control over nature that this revolution involves, allowing rapid and direct intervention in the basic processes of life itself. Further significant causes of uncertainty are the complex and unpredictable effects of a wide range of factors that will influence the speed and direction of change.

Despite this uncertainty, some broad points are clear. The biotechnology revolution will bring many positive consequences (or benefits) for human, animal and plant health, for the environment, for food security and other aspects of development and for security. The revolution will also have negative consequences in the same areas, threatening health, environmental stability, development and security. It will also result in general socio-economic changes and some significant political effects. These broader changes will also have positive and negative aspects.

The biotechnology revolution is occurring within a global context that already includes great disparities in wealth within and between countries, and international relations of dominance and dependence socially, economically and politically. This context means that the consequences of the biotechnology revolution will not be evenly spread. It is likely that the positive consequences will be concentrated in the developed world, which also has a better capacity for dealing with many of the negative consequences. This disparity may well be problematic and not only on humanitarian grounds, particularly if it exacerbates the gap between rich and poor, which is a likely consequence. This may lead to increased tensions between developed and developing countries, and may negatively affect the progress of the revolution by creating resistance to its products.

So while we cannot be certain of the exact outcomes of this revolution, the consequences are potentially huge (both positive and negative). There is a need to decide what is desirable (what applications and what outcomes) and to open up debates on this. There is a need to find mechanisms for coping with the socio-economic impacts so that change is as smooth and beneficial as possible. The benefits of biotechnology need to be promoted, but at the same time the negative consequences and disruptions need to be minimised. There need to be reductions in the inequalities of benefit distribution and misuse must be prevented.

An important way of dealing with these issues will be through regulation of biotechnology at all levels from local to international. It is likely to be easier to regulate specific and known consequences than to regulate the potential or more general impacts. The next chapter specifically looks at what is required of biotechnology regulation in general and international biotechnology regulation in particular.

4. Regulatory Needs

Regulation of the applications and impacts of modern biotechnology at the international level is a vital addition to regulation at other levels. Four key roles for biotechnology regulation are identified here and the global context of the revolution is explored – it is this context which necessitates international governance efforts. International regulation serves the key role of coordinating state action in areas of high international interdependence, where separate action by individual states will often be insufficient to address common concerns. Following a brief outline of the development and use of international regulation by states, seven issue areas are identified in which there is a recognised need for coordinated state action and in which the biotechnology revolution has significant applications and impacts – these are the areas in which international regulation of biotechnology is required. The chapter ends with an outline of the functions of international regulation. Sets of international regulation that relate to a particular matter (in this case governance of biotechnology) require coherence in order to effectively fulfil these functions.

Necessary Roles for Biotechnology Regulation

The previous chapter drew conclusions about the potential consequences of the biotechnology revolution, which are helpful in identifying what needs to be achieved by regulation. Across the range of sectors affected by the revolution, the consequences will be both positive and negative and the impacts will be unevenly distributed. In some areas there are also risks of deliberate misuse associated with the new knowledge and technologies. The negative consequences may be severe and it will be desirable to minimise or avoid them. The positive consequences (benefits), on the other hand, should be encouraged and maximised. Moves towards a more equitable distribution of consequences are also desirable, particularly in terms of enhancing countries' capacities to deal with risks and negative impacts.

In consideration of the above, there are four main roles that the regulation of biotechnology needs to play:

- Promotion of benefits
- Identification, assessment and management of risks
- Prevention or minimisation of negative impacts
- Promotion of capacity-building

The following illustration provides an example of how these four roles apply to the regulation of one particular biotechnology application. In relation to a genetically modified food, regulation should:

- Promote the benefit of enhanced nutritional value.
- Identify and assess any risks to human health resulting from the changes made to the food and manage these risks, for example by setting a recommended daily intake.
- Prevent types of changes that produce too high a risk to human health, for example by banning insertion of genetic material from known allergenic sources.
- Promote capacity-building in the conduct of effective risk assessment.

The need for regulation to fulfil these roles extends across the full range of areas that the biotechnology revolution impacts upon.

Another important point drawn out in the previous chapter was that uncertainty exists about what the precise outcomes of the biotechnology revolution will be, particularly in the long term. This uncertainty should not be viewed as an obstacle to regulation. Once decisions are made on which outcomes are desirable or acceptable and which are not, regulatory action can be taken – it does not matter whether or not a particular outcome will occur. If, for example, it is decided that it would be undesirable for a genetically enhanced biological warfare agent to be produced, then measures can be taken to prevent this occurring, without evidence being needed that such an agent will actually be developed. In fact, a lot of regulation deals with uncertainty in this way – rather than prescribing action once outcomes have occurred, it focuses on the optimum way of achieving desired outcomes and avoiding undesirable ones.

The Context in which the Revolution is Occurring

Regulation of the biotechnology revolution is important as a mechanism through which to ensure that its outcomes are effectively managed. There are a number of levels at which such regulation can be set – local, national, regional and international. Regulation at each of these levels is valuable, but because of the global nature of the revolution, and the particular global context in which it is occurring, international regulation is an essential supplement to regulation at these other levels.

Joyner (2005, p. 292) gives a general explanation about why current globalisation trends increase the need for international regulation, particularly in regard to new technologies:

> With certain technologies, globalization creates an apparent need for a high degree of international cooperation. More so than ever, technologies and information can easily move across borders. Thus if the regulatory goals are to contain or ensure the safe applications of a given technology, some level of agreement between governments will be needed to control the development and flow of such technologies. In fact, globalization increases the need for an international approach to policymaking.

The broad reason that international level regulation is essential for effective control of the biotechnology revolution is the nature of the global context in which the revolution is taking place. This context is a highly interdependent international system that has massive and persistent inequalities both between and within states. In this interdependent world neither the applications nor the impacts of modern biotechnology can be limited by national boundaries. People, knowledge, technology and material resources are highly mobile and can disseminate rapidly around the globe. The independent actions of individual states will often be insufficient in terms of control. If, for example, a particular application is stringently controlled in one state or region it can simply be moved to an area with less stringent regulation, a point which has been emphasised by The Royal Society (the UK's national science academy): 'Global cooperation on measures to prevent the misuse of scientific research is needed to ensure that misguided scientists cannot simply move to another country to carry out unsafe work' (6 September 2005).

Murphy (Winter 2001, p. 60) uses a specific example – xenotransplantation – to illustrate the dangers of inconsistent national regulation: 'national regulations may be developed in some states to prevent animal viruses from spreading to humans. However, if comparable regulations do not exist in other states, leading to the risk of such viruses originating elsewhere and then travelling to the highly regulated states, then the national regulations will be undermined'.

Because of the inequalities in the global context the impacts of the revolution will not be evenly distributed, and without intervention to achieve a more equitable distribution of benefits and burdens, the revolution may in fact exacerbate existing inequalities and create new ones. International regulation has greater potential than regulation at other levels to contribute to a more even distribution of benefits and to establish measures to ameliorate negative impacts. It can play a role in introducing accountability and responsibility for management of transnational risks; help to balance the varying needs and interests of different countries; and promote transfer of technology, financial assistance, information and skills for capacity-building.

International Regulation/International Law

The term international regulation is used in this book to mean regulation (i.e. official rules) agreed by and made for states to govern their relations and actions and which is open to all states to subscribe to, with no geographical limitations. The term covers a range of rules from voluntary standards, guidelines and codes to legally binding treaties. International regulation is closely related to international law. A distinction between the two terms is made here, however, because some theorists would dispute the inclusion of the voluntary standards, guidelines and codes in a definition of international law because they are not legally binding or of customary[1] force, as the following definitions show: 'A rule is part of International Law if: (1) It is based upon

custom, i.e. is observed by states generally; or (2) It is embodied in a Law-making treaty' (Winfield, 1941, p. 21); 'international law consists of rules that are generally recognized as binding the members of the international community in their relations with one another' (Joyner, 2005, p. 4).

Other theorists refer to these non-binding rules as 'soft law' – and there are debates about whether such rules are as effective as 'hard law' (treaties and customary rules). Non-binding rules, it is stated, 'while not resting on very secure foundations, are nevertheless important considerations in many decision-making situations' and 'Despite their informalities, they may have as much importance in policy-making as more formal instruments and, in some cases, even more. The important point is that they do guide behaviour, and for much the same reason as treaties: The costs of breaking or repudiating agreements are often very high' (Holsti, 1994, p. 300). Since both legally binding treaties and non-binding agreements are used by states to govern their relations, both are covered in this book.

Legally binding treaties are established following negotiation (usually over several years) between states and their subsequent signature and ratification (or other instrument of acceptance such as accession) of the agreed text. Negotiations may occur within an established international organisation, or a forum specifically set up for that purpose. Soft law instruments are usually developed and drafted by an international organisation itself, although they may still require formal approval by member states of the organisation to be officially adopted.

When a treaty is not developed within an international organisation, it usually establishes one to oversee its administration and future development. Other bodies are frequently established or an existing body nominated to take responsibility for a particular role by the treaty too. These include a governing body – responsible for such matters as decision-making, review, amendment and negotiation of additional rules – that is made up of the states parties to the treaty; and a secretariat responsible for the day-to-day administration of the treaty. Additional bodies may be set up by the treaty for technical support, advice and for negotiation of further rules on either a permanent or *ad hoc* basis.

Negotiations to develop, for example, the Convention on Biodiversity (CBD) – one of the regulations covered within this book – took place under the auspices of the United Nations (UN) Environment Programme. The Convention text established the CBD Secretariat to administer the Convention (Article 24); the Conference of the Parties as its governing body (Article 23); a Subsidiary Body on Scientific, Technical and Technological Advice to assist effective implementation (Article 25); and enabled its Conference of the Parties to establish subsidiary bodies as required (Article 23).

While a variety of other actors – for example multinational corporations, international organisations and non-governmental organisations – are

playing increasingly significant roles in international relations, states remain the most significant actors and the main focus of international law/regulation. States are not only the main subjects of international law, but also its creators. There is no authority above the state in the international system, and this is a major reason why international law is different from national legal systems. There is no legislative body to create laws, and no executive body to enforce them. There is an international judicial body – the International Court of Justice – but its role is very limited: it can only rule on legal cases that are voluntarily submitted to it by the states involved or give advisory opinions on legal questions referred by the UN Security Council, General Assembly or other UN organs/specialised agencies (see Articles 36 and 65, *Statute of the International Court of Justice*, 1945, and Article 96 of the *Charter of the United Nations*, 1945).

There has been some criticism that these factors render international law weak, ineffective and unlikely to be obeyed. This is not the case. While international law suffers from some major flaws (e.g. its bias towards the interests of powerful states), it serves a variety of functions that make it extremely useful to states, who will obey it in the majority of cases. Sometimes states do choose not to obey international law, but despite the fact that there is no supranational enforcement body, there are still consequences to such action. A reputation for law-breaking dents prestige and damages relations with other states, who may be reluctant to enter into further agreements with the transgressing state. Disobedience may also provoke reprisals. Also, there are many advantages to states of obeying international law. It serves a number of important functions in international relations from which all states benefit (discussed later in this chapter).

Development of and Approaches to International Law

The development of international legal rules has been based on the need to facilitate international transactions – as the volume of transactions has expanded, so too has the need for international rules to govern them. States have long found it useful to have rules governing relations between them, but it was not until a sense of the existence of an international system or community of states began to emerge that these rules became 'international'.

The development of the concept of the nation state as a sovereign independent unit in the seventeenth century motivated the development of generally acceptable rules to govern transactions between these units (Shaw, 1997, p. 18). The origins of international law are generally dated to the mid-seventeenth century alongside the origins of the European nation state in the 1648 Treaty of Westphalia, but some of the principles on which it is based have a much longer history.

There are two main theories that have dominated thinking on international law. These theories are mainly concerned with the sources of or basis for

international law (and also, therefore, what counts as international law). The earlier of the two theories, which can be traced back to Greek and Roman thinking, is the theory of natural law. This holds that laws can be rationally deduced from a pre-existing universal basis – be it a divine or human-reasoned 'natural' order (Peters, 2001, p. 27). The concept of universality is intrinsic to modern international law. In natural law theory, the law has a moral basis and provides a guide to what ought to be – in international law, what states ought to do. The other major theory – legal positivism – instead claims that law is based on what actually is, that is that law is determined by (law-making) practice, and international law by the practices of states, and particularly what they have expressly agreed to in treaties (Peters, 2001, p. 27; Shaw, 1997, p. 22).

Both the natural law and legal positivist approaches can be seen to be reflected in current international law: there are rules based on the actions of states and what they have agreed to (custom and treaties); and there is also a well-established, and widely accepted, concept of universal principles, rights and obligations (e.g. in the area of human rights).

In addition to these two dominant approaches, there are other theories of international law which provide further useful insights – three of which will be discussed briefly here. First is 'policy-oriented jurisprudence' or legal realism. This was developed in the United States in the early stages of the Cold War. It places law firmly within its political context. In this theory law-making is a form of policy, and it reflects the political concerns of the powerful. This is viewed as a legitimate bias. International law is indeed not separate from international politics – it is created by and for states and can be used (not always successfully) as a policy tool. As Joyner (2005, p. 9) explains: 'Implementing political solutions for international problems can become transformed into legal rules through treaties, customs, practices, and principles. Put tersely, making international legal rules is an inherently political process.'

Second is the 'international law and economics' approach. This views international law as a method for states to realise their goals with limited resources – a form of 'market participation' (Peters, 2001, p. 32). It emphasises the bargaining process in the creation of international law. This approach also provides useful insights. In many areas of international law states seek to achieve certain (common) goals by pooling their resources – one of the key functions of international law (discussed later in this chapter) is to reduce the costs of individual state action and increase efficiency. The bargaining process is also important. The creation of new laws and the amendment of existing laws generally take many years of negotiation.

The third approach, or set of approaches, is referred to as the 'new' or 'critical' approach to international law. Like legal realism these theories

emphasise the political context of international law – particularly in terms of international power relations. Unlike legal realism they critique the existing power relations and international law as being based on maintaining those relations (generally in a disguised form). As Peters (2001, p. 33) states, in this perspective 'the law is merely an ideology for the purpose of gaining, cementing and justifying the exercise of power'.

Again useful insights are provided by these approaches. Power is important in international politics and international law. Powerful states can, based on their superior resources, dominate the processes of international law-making. They have the resources to be able to enforce the laws that they support and to bear the costs of attempted enforcement actions by others. This said, even powerful states cannot ignore international law entirely, and can attract strong criticism for breaking it – for example, there was widespread international condemnation of the United States for its treatment of prisoners in Guantanamo Bay, and its policy of 'extraordinary renditions' (e.g. in the UN Economic and Social Council's 2006 report *Situation of Detainees at Guantanamo Bay*; and the Council of Europe's 2006 report on secret detentions).

International law expanded greatly in scope in the twentieth century driven by the increasing volume of international interactions and also the experience of two devastating World Wars. International law was initially predominantly directed towards establishing a more peaceful world order, with particular progress being made after the Second World War with the establishment of limited circumstances in which the use of force in international relations is considered to be legitimate (in the United Nations Charter, 1945) and attempts to limit the effects of any conflicts which did occur (in international humanitarian law).

Technological developments, particularly in travel, trade and communications, rapidly increased international transactions across a wide range of areas throughout the twentieth century, and so international rules were developed in these areas as well (e.g. in trade, health and environmental protection). The need for international law remains based on the need for states to facilitate transactions or coordinate action in areas in which there is a high degree of international interdependence, and where individual state action will be insufficient to address matters of common concern.

Areas Requiring International Control of the Biotechnology Revolution

Many of the applications and impacts of biotechnology affect issue areas[2] in which high interdependence between states exists, and for which individual state action is insufficient for effective control. Particularly, it can be seen that applications and impacts of biotechnology require international regulation in the following issue areas:

1. *Arms control*

In the area of arms control most action needs to be coordinated at the international level because for states to feel secure in limiting their own capabilities they need to be reassured that other states are taking the same action. Relevant to biotechnology is arms control in the area of biological and toxin weapons (the latter also being covered by rules on chemical weapons). International regulation needs to prevent misuse of biotechnology and reassure states that it is being prevented, while allowing beneficial research, for example in the medical field, to continue.

2. *Health and disease control*

Certain aspects of health, particularly the prevention of disease and limitation of its spread, need to be regulated internationally – this applies equally to human, animal and plant health. Measures taken to prevent disease spread can severely disrupt travel and trade and cause major economic damage, but are necessary to prevent the spread of serious diseases, which can move rapidly around the globe through transport connections. Other health-related areas subject to international control are the transport, handling and use of infectious substances – again as a measure to prevent disease spread – and also food safety, as food is traded internationally. There are many benefits to be promoted in the area of health, but also areas of risk, and harms that need to be avoided and it is an area of great global disparity.

3. *Environmental protection*

Since the early twentieth century there has been increasing recognition of the interconnectedness of the environment at the global level and the need for action at the international level towards the solution of many environmental problems. Among the areas in which international action is deemed necessary are three outlined in the CBD: 'the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources'. Biotechnology has the potential both to protect and to damage biodiversity.

4. *Trade*

Trade is obviously an international issue and there are a variety of trade-related regulations that operate at the international level. The main motivation for trade regulation following the Second World War has been to bring an end to protectionist trade policies that can prove economically disastrous through reductions in tariffs and other barriers to trade. Rules on reducing barriers to trade, on intellectual property rights and on access to genetic resources are relevant to the end products of biotechnology, to the basic resources used in research and development and to innovative processes.

5. *Drugs control*

There is a massive international trade in illicit drugs and attempts have been made to control it internationally since the early twentieth century. There is also a large market for the use of performance-enhancing substances in sport that requires international control. Biotechnology can be misused in the production of illicit drugs and drugs designed to be undetectable in doping tests. The knowledge and techniques used in this way may also be used for licit purposes, for example the adaptation of medical drugs to avoid adverse reactions. Again there are harms to be avoided and benefits to be promoted and the supply of drugs for legitimate medical and scientific uses needs to be improved and maintained.

6. *Development*

The interconnectedness of the global economy and trading systems means that many development issues cannot be dealt with solely at the national or regional level. While biotechnology has the potential to make significant contributions to development, this will require supportive actions such as technology transfer, technical and financial assistance, information exchange and capacity-building efforts, which can be encouraged by international regulation.

7. *Social and ethical impacts*

Some of the potential social and ethical impacts of modern biotechnology can be regulated at a lower level, but there is an additional need for international coordination and direction, as these impacts affect all societies. Some of the biggest challenges are arising in the area of human genetics, although they are not exclusive to this area. The new knowledge about human genetics and its applications could have huge benefits, but again there are many risks, and decisions need to be made about how the knowledge should be controlled and who should have access to it, and whether certain applications, for example reproductive human cloning, pose too great a risk and should be prohibited.

Functions of International Regulation

International regulation has specific roles to fulfil in control of the applications and impacts of biotechnology (outlined at the beginning of this chapter). It also needs to fulfil general functions of international regulation for this area. Within the broad purpose of coordinating state action, a wide range of important functions can be identified from the literature on international law. The following list identifies key functions that it serves:[3]

- Defining the rights and obligations of states
- Regulating conduct
- Providing predictability and reducing uncertainty
- Reducing costs of individual action and increasing efficiency

- Authorising or prohibiting certain actions
- Facilitating cooperation
- Imposing constraints
- Realising values
- Establishing and shaping expectations
- Channelling conflict and providing mechanisms for its resolution
- Simplifying and facilitating transactions
- Assisting policy-making
- Dealing with common threats/problems
- Promoting peace

This list of functions gives an indication of what international regulation should generally be achieving. Where a set of regulations exists with applicability to a particular matter, coherence[4] among the regulations will be important for the fulfilment of these functions. Uncertainty will not be reduced if states are unclear which rules to apply in particular cases. Improving predictability and creating expectations will be problematic too – some states may be unaware of the full range of rules that operate in a particular area and it will, therefore, be difficult for one state to know which rules others will choose to apply.

A lack of coherence can also present problems for the resolution of conflicts where more than one method/mechanism of dispute settlement is available, because states may be tempted to move around the different mechanisms to find the one that suits their case best. It is likely to be unclear exactly what the rights and obligations of states are, particularly if the regulations contain provisions that contradict (or can be interpreted as contradicting) each other. Where states are uncertain about which rules to apply and what their rights and obligations are, they are unlikely to act in a coordinated manner.

Where regulations lack coherence their provisions may overlap and duplication of certain actions could result, which will not increase efficiency. Fragmented regulation will allow states to compete over values by what is known as 'forum-shifting'[5] and if the principles that underlie the regulations are put in contention, uncertainty and incoherence will increase. Activities may not be effectively constrained if one regulation can be interpreted as allowing an action that is prohibited by another.

Fragmented, contradictory and overlapping regulation will not assist in simplifying transactions. States will face uncertainties in policy-making too if they are unclear which rules to apply. For all these reasons sets of regulation that do not display coherence are unlikely to adequately coordinate state action to effectively govern challenges.

Conclusion

It is clear that a number of applications and impacts of biotechnology need to be regulated at the international level, because they involve issues where

there is high international interdependence and coordinated state action is needed for effective control. The important functions of international regulations are unlikely to be adequately fulfilled by a set of regulations that lack coherence. The question, therefore, that the rest of this book seeks to answer is whether the international regulations applicable to the control of biotechnology are coherent. The following chapter establishes criteria for identifying coherent sets of international regulation. Later, the various international regulations that are applicable to the control of the biotechnology revolution are outlined and subsequent chapters will examine the degree to which the identified regulations match the criteria for coherent regulatory sets, before discussing the implications of this for the effective governance of modern biotechnology.

5. A Model of Coherent International Regulation

In order to assess the coherence of the international regulatory response to the applications and impacts of modern biotechnology, a model of coherent international regulation is needed. The model presented here consists of sixteen key characteristics indicative of coherence. For illustrative purposes it is applied to the Geneva Conventions and Protocols, which provide a clear example of a coherent regulatory set. (The model is more widely applicable and this is demonstrated in Table 5.2 at the end of the chapter.) This chapter is the first of two that lay the basis for the technical analysis in the third section of the book.

The Geneva Conventions and Protocols

The Geneva Conventions and Protocols are a key part of international humanitarian law (IHL), that is the law that applies to armed conflict. They are designed to protect those who do not participate in the fighting and those who are no longer able to fight. They consist of seven separate texts:

- Convention (I) for the Amelioration of the Condition of the Wounded and Sick in Armed Forces in the Field
- Convention (II) for the Amelioration of the Condition of Wounded, Sick and Shipwrecked Members of Armed Forces at Sea
- Convention (III) Relative to the Treatment of Prisoners of War
- Convention (IV) Relative to the Protection of Civilian Persons in Time of War
- Additional Protocol I Relating to the Protection of Victims of International Armed Conflicts
- Additional Protocol II Relating to the Protection of Victims of Non-international Armed Conflicts
- Additional Protocol III Relating to the Adoption of an Additional Distinctive Emblem

Additional Protocol I provides additional details for the areas covered by the Conventions and follows a similar structure. Additional Protocol II only provides additional details on Article 3 of the Conventions, and has less in common in terms of content and structure. Additional Protocol III is even more specific, adding a red diamond to the traditionally recognised emblems of the red cross and red crescent. Because it is so specific it receives limited attention in the following analysis.

Characteristics of Coherent Regulatory Sets

The model presented in this chapter suggests that coherent sets of international regulation are expected to display sixteen key characteristics. The key characteristics of coherent international regulation are:

- Common (primary) purpose
- Common principles
- Common historical development
- Common identity (external awareness of connections)
- Self-referencing (internal awareness of connections)
- Shared definitions
- Unifying provisions
- Complementary provisions
- Common structure
- Common administration and review procedures
- Common enforcement and dispute settlement mechanisms
- Same strength of force
- Single international organisation with responsibility for oversight, coordination, implementation, monitoring and development
- Self-contained
- Clear issue focus
- Comprehensive coverage of issue

Common (primary) purpose:
Coherent sets of regulation will have a shared purpose. While the detailed objectives of the regulations may vary, their main objective will be common.

Common principles:
Coherent sets of regulation should be based on a core set of common principles. The provisions contained within regulations are unlikely to be complementary if they are based on divergent principles.

Common historical development:
Coherent sets of regulation will have a shared history. This does not require that all the regulations were adopted at the same time, but that their principles and provisions have a common developmental history.

Common identity (external awareness of connections):
Coherent sets of regulation will have a common identity. They will often be referred to as a complete regulatory set. This identity may be established in the regulations themselves or by the international organisation that oversees them. It will be evidenced in how the regulations are referred to by the public, the media, governments and other groups and organisations.

Self-referencing (internal awareness of connections):
Coherent sets of regulation will self-reference. That is, one regulation will refer to others where this is necessary, for example to avoid duplication or

to make it clear to the reader that a particular issue is covered elsewhere in the regulatory set.

Shared definitions:
It is expected that coherent sets of regulation will have shared definitions, particularly for key terms. Definitions used should not be contradictory.

Unifying provisions:
Since they share a common purpose, coherent sets of regulation will have some provisions that are the same in each text, which reinforce their common identity.

Complementary provisions:
Coherent sets of regulation will also contain complementary provisions. Of course, not all of the provisions of the regulations will be the same, otherwise it would not be necessary to have separate texts. However, it is expected that the provisions will be complementary in the sense that they work towards the same overall objectives and there should not be any contradictory provisions within a coherent set of regulation.

Common structure:
Coherent sets of regulation should have a common structure. This may be to the extent that related provisions are contained in the same articles in the different regulatory texts or just that related provisions appear in a similar order in each text.

Common administration and review procedures:
Coherent sets of regulation should have common administration and review procedures. This may include matters such as how often the regulations are to be reviewed, how they are monitored, procedures for withdrawal, etc.

Common enforcement and dispute settlement mechanisms:
Coherent sets of regulation will have common enforcement and dispute settlement mechanisms. This includes, for example, the implementing measures required by states and any enforcement roles assigned to the international organisation associated with the regulations.

Same strength of force:
This term has various elements including, for example, the number of states parties to the regulations. It is expected that in a coherent regulatory set, each regulation will have roughly the same number of states parties. (This will only apply to treaties which require states to ratify or accede to them and not to regulations based on voluntary

arrangements.) Another element relates to enforcement procedures. As stated above, it is expected that coherent regulatory sets will have the same enforcement procedures.

Single international organisation with responsibility for oversight, coordination, implementation, monitoring and development:
The particular roles and functions assigned to an international organisation will vary depending on what is required by the regulations. It is expected that coherent sets of regulation will have only a single international organisation, which will generally perform the same functions for each of the regulations.

Self-contained:
This term means that the regulations will be able to cover the particular matter with which they are concerned without requiring reference to regulations external to their set. All international regulation is based on certain basic rules and norms of international law, for example state sovereignty, and therefore reference to these is excluded from the analysis relating to this characteristic.

Clear issue focus:
This links quite closely to common purpose. It should be clear from the text of each regulation that they focus on the particular issue that forms their common objective. This issue should be their primary focus.

Comprehensive coverage of issue:
A coherent set of regulation should provide comprehensive coverage of the issue on which it focuses. This does not mean that the coverage of the regulations will be perfect; there are always likely to be flaws and areas which require updating. However, there should be no major gaps in the coverage or imbalances that leave one area poorly covered.

Application of the Model to the Geneva Conventions and Protocols

Common (Primary) Purpose

The Geneva Conventions and Protocols all share the common primary purpose of protecting the victims of armed conflict. The following is a statement from the website of the International Committee of the Red Cross (ICRC): 'The Geneva Conventions and their Additional Protocols are international treaties that contain the most important rules limiting the barbarity of war. They protect people who do not take part in the fighting (civilians, medics, aid workers) and those who can no longer fight (wounded, sick and shipwrecked troops, prisoners of war)' (ICRC, 3 June 2004).

Common Principles

The Geneva Conventions and Protocols are based on humanitarian principles to be applied during armed conflict. The key principle is to protect those who do not take part in the fighting and those who are no longer able to fight. The people protected must be treated humanely without any adverse distinction. The use of non-discriminatory means and methods of warfare is forbidden. These principles are applied across the regulations, for example the following is found in Article 12 of Convention I:

> Members of the armed forces and other persons mentioned in the following Article, who are wounded or sick, shall be respected and protected in all circumstances. They shall be treated humanely and cared for by the Party to the conflict in whose power they may be, without any adverse distinction founded on sex, race, nationality, religion, political opinions, or any other similar criteria.

And similar provisions are located in Article 12 of Convention II, Articles 13 and 14 of Convention III, Article 27 of Convention IV, Article 10 of Protocol I and Articles 4, 5 and 7 of Protocol II.

Common Historical Development

Regulation of warfare has a long history. The first moves towards modern international regulation came in the nineteenth century. The ICRC was established in 1863 and the first Geneva Convention – for the Amelioration of the Condition of the Wounded in Armies in the Field – was adopted by sixteen states in 1864 at a conference convened by the ICRC. Several international treaties that aimed to regulate armed conflict were agreed prior to the Second World War. These were further developed after the War. Laws regulating armed conflict are referred to as international humanitarian law (IHL) or the laws of war. They apply during armed conflict, rather than in times of peace. The four Geneva Conventions, adopted in 1949, form a core part of IHL, protecting the victims of armed conflict. Two Additional Protocols were adopted in 1977 in response to the need to update and strengthen the Conventions and a third Additional Protocol was adopted in 2005 to add an additional protected emblem – the red diamond – that avoids the religious connotations that some groups associate with the red cross and the red crescent.

Common Identity (External Awareness of Connections)

The Geneva Conventions and Protocols, while consisting of seven separate documents with different titles, have the common identity of 'the Geneva Conventions' or the 'Geneva Conventions and Protocols'. This can be seen in the way they are referred to by the ICRC, in news stories and other publications and in policy debates. For example a search on 'Geneva Conventions' on the BBC News website on 23 March 2010 brought up over

400 stories; a search on 'Convention for the Amelioration of the Condition of the Wounded and Sick in Armed Forces in the Field' brought up two results (BBC News Online Search Facility).

Self-referencing (Internal Awareness of Connections)

References are made between the Conventions and Protocols where necessary to clarify coverage of certain issues. Table 5.1 lists where some of these references are located.

Table 5.1 References between the Conventions and Protocols

Convention/Protocol	Refers to	In article
Convention I	Convention III	16
Convention I	Convention II	20
Convention I	Convention III	28
Convention I	Convention III	30
Convention I	Convention III	49
Convention II	Convention I	4
Convention II	Convention I	23
Convention II	Convention III	50
Convention III	Convention I	33
Convention IV	Conventions I, II and III	4
Convention IV	Convention I	18
Convention IV	Convention I	20, 21, 22
Protocol I	Conventions I, II, III and IV	1, 2, 3
Protocol I	Convention I	9
Protocol I	Convention I	12
Protocol I	Convention I	18
Protocol I	Convention II	22, 23
Protocol I	Convention III	41, 42, 44, 45
Protocol I	Conventions I and II	44
Protocol I	Convention IV	45
Protocol I	Convention IV	49
Protocol I	Convention IV	58
Protocol I	Convention IV	68, 69, 70
Protocol I	Convention IV	72, 73
Protocol II	Conventions I, II, III and IV and Protocol I	1

Shared Definitions

Certain key terms are given the same basic definition in the Conventions. The most prominent example of this is the definition of the term 'grave breach'. In all the Conventions this includes 'wilful killing, torture, or inhuman treatment, including biological experiments, wilfully causing great suffering or serious injury to body or health' (Article 50 of Convention I, Article 51 of Convention II, Article 130 of Convention III and Article 147 of Convention IV). And Protocol I states that 'Acts described as grave breaches in the Conventions are grave breaches of this Protocol' (Article 85).

Unifying Provisions

The Conventions and Protocols have some common provisions that connect them further. The most prominent example is 'Common Article 3' on non-international armed conflict, which is exactly the same in all four Conventions. Other examples include a statement on the use of emblem: 'with the exception of the cases mentioned in the following paragraphs of the present Article, the emblem of the red cross on a white ground and the words "Red Cross" or "Geneva Cross" may not be employed, whether in time of peace of time of war' (Article 44 of Convention I, with similar wording in Article 44 of Convention II, Article 18 of Protocol I and Article 12 of Protocol II); and a statement on humanitarian organisations: 'The provisions of the present Convention constitute no obstacle to the humanitarian activities which the International Committee of the Red Cross or any other impartial humanitarian organisation may … undertake for the protection of the wounded and sick, medical personnel and chaplains, and for their relief' (Article 9 of Convention I, with similar wording in Article 9 of Conventions II and III and Article 10 of Convention IV).

Complementary Provisions

The Conventions and Protocols form complements to one another, each extending protection to different subject matter for the same aims: armed forces on land; armed forces at sea; prisoners of war; citizens of occupied territories; and victims of non-international armed conflict. This can be seen in the sections on repression of grave breaches, which, after stating the common definition, have specific provisions for the particular area covered. For example:

- Article 130 of Convention III adds 'compelling a prisoner of war to serve in the forces of the hostile Power, or wilfully depriving a prisoner of war of the rights of fair and regular trial'; and
- Article 147 of Convention IV adds 'unlawful deportation or transfer or unlawful confinement of a protected person, compelling a protected person to serve in the forces of a hostile Power, or wilfully depriving a protected person of the rights of fair and regular trial … taking of hostages, and extensive destruction and appropriation of property not justified by military necessity and carried out unlawfully and wantonly'.

Common Structure

The articles in the Conventions and Protocols flow in a similar way from general points, through specific provisions, to administrative detail. Such a structure is common to many treaties but is present at a more detailed level in the Conventions and Protocols, where similar provisions can be found in similar positions in the documents. For example, the provision that people protected by the Conventions cannot renounce their rights under the Conventions is found in Article 7 of Conventions I, II and III and Article 8 of Convention IV. The provisions which outline which violations constitute 'grave breaches' are found towards the end of the Conventions and Protocol I, before the final provisions.

Common Administration and Review Procedures

The Conventions do not specify any particular review or amendment procedures. There are very similar provisions in the Conventions and Protocols for some administrative matters such as authentic texts, ratification, accession and denunciation procedures. The ICRC, as guardian and promoter of IHL, is responsible for its development.

Common Enforcement and Dispute Settlement Mechanisms

The Conventions and Protocols all use the same methods of enforcement and implementation, primarily through action by contracting states, such as education and the implementation of legislation to prevent and punish grave breaches and to protect the emblems of the red cross, red crescent and red diamond. For example: 'The high contracting Parties undertake, in time of peace as in time of war, to disseminate the text of the Convention as widely as possible' (Article 47 of Convention I, Article 48 of Convention II, Article 127 of Convention III and Article 144 of Convention IV, with similar wording in Article 83 of Protocol I).

Dispute settlement provisions can be found in Article 11 of Conventions I, II and III and Article 12 of Convention IV. The Articles begin: 'In cases where they deem it advisable in the interest of protected persons, particularly in cases of disagreement between the Parties to the conflict as to the application or interpretation of the provisions of the present Convention, the Protecting Powers shall lend their good offices with a view to settling the disagreement.'

There is also a provision for enquiry into alleged violations: 'At the request of a Party to the conflict, an enquiry shall be instituted, in a manner to be decided between the interested Parties, concerning any alleged violation of the Convention.' This provision can be found in Article 52 of Convention I, Article 53 of Convention II, Article 132 of Convention III and Article 149 of Convention IV. There is a similar provision in Articles 8 and 9 of Protocol I.

Same Strength of Force

The Conventions and Protocols are all legally binding treaties and compliance is mandatory for all contracting parties. Some provisions are also part of customary international law. There is some variation in the number of states parties. There are 194 states parties to the four Conventions, 169 to Protocol I, 165 to Protocol II and 52 to Protocol III (ICRC, 16 March 2010).

Single International Organisation

From the outset of their development the Geneva Conventions and Protocols have been overseen by the ICRC. It is responsible for their development and promotion and for many aspects of their monitoring and implementation. It provides a large, easily accessible information source on its website, which is open to the public, and provides technical guidance to states on implementation through an Advisory Service: 'As the promoter and guardian of international humanitarian law, the ICRC must encourage respect for the law. It does so by spreading knowledge of the humanitarian rules and by reminding parties to conflicts of their obligations' (ICRC Advisory Service, July 2004).

Self-contained

While resting, as all international regulations do, on basic customs, principles and rules of international law – for example that states have the right to make treaties – the Geneva Conventions and Protocols cover the area of protection of people during armed conflict without relying on other regulations to complete this coverage. They also form part of a wider set of international rules (IHL), but can function independently of it.

Clear Issue Focus

The Conventions and Protocols all clearly and primarily focus on the issue of regulating armed conflict to protect those who are not fighting or are no longer able to fight.

Comprehensive Coverage of Issue

While requirements for coverage will vary over time, the Conventions and Protocols do give reasonably comprehensive coverage to the protection of the victims of armed conflict. There have been recent criticisms of the scope of the Conventions and Protocols, as they do not cover the issue of the legality of humanitarian interventions, and their applicability to conflicts that form part of the 'War on Terror' has been challenged. The ICRC feels that the issue of humanitarian intervention should not be dealt with under IHL, but instead under international law on the use of force. In regard to the War on Terror, the Conventions and Protocols do apply to those parts

that constitute international or non-international armed conflicts. The ICRC does not support the concept of there being a category of individuals – 'illegal combatants' – the treatment of whom IHL does not apply to (ICRC, 21 July 2005).

Conclusion

The model of coherent regulatory sets provided in this chapter enables the assessment of coherence of the international regulations relevant to the applications and impacts of biotechnology which follows. The Geneva Conventions and Protocols clearly form a coherent set of international regulation, displaying all of the expected characteristics of the model. Table 5.2 shows that this is not a unique case – other sets of international regulations also match the model closely.

Table 5.2 Applying the Model to Other Sets of Regulation

Characteristic	Regulatory set		
	Geneva Conventions and Protocols[a]	Dangerous Goods Regulations[b]	UN Drugs Conventions[c]
Common (primary) purpose	Yes	Yes	Yes
Common principles	Yes	Yes	Yes
Common historical development	Yes	Yes	Yes
Common identity	Yes	Yes	Yes
Self-referencing	Yes	Yes	Yes[d]
Shared definitions	Yes	Yes	Yes
Unifying provisions	Yes	Yes	Yes
Complementary provisions	Yes	Yes	Yes
Common structure	Yes	Yes	Yes
Common administration and review procedures	Yes	Yes	Yes
Common enforcement and dispute settlement mechanisms	Yes	There are none in the regulations	Yes
Same strength of force	Yes	Yes	Yes[e]

(*Continued*)

Table 5.2 (*Continued*)

Characteristic	Regulatory set		
	Geneva Conventions and Protocols[a]	Dangerous Goods Regulations[b]	UN Drugs Conventions[c]
Single international organisation	Yes	Yes[f]	Yes[g]
Self-contained	Yes	Yes	Yes
Clear issue focus	Yes	Yes	Yes
Comprehensive coverage of issue	Yes	Yes	Yes

[a] Convention (I) for the Amelioration of the Condition of the Wounded and Sick in Armed Forces in the Field (ICRC, 1949a); Convention (II) for the Amelioration of the Condition of Wounded, Sick and Shipwrecked Members of Armed Forces at Sea (ICRC, 1949b); Convention (III) Relative to the Treatment of Prisoners of War (ICRC, 1949c); Convention (IV) Relative to the Protection of Civilian Persons in Time of War (ICRC, 1949d); Additional Protocol I Relating to the Protection of Victims of International Armed Conflicts (ICRC, 1977a); Additional Protocol II Relating to the Protection of Victims of Non-international Armed Conflicts (ICRC, 1977b); and Additional Protocol III Relating to the Adoption of an Additional Distinctive Emblem (2005).

[b] The International Maritime Dangerous Goods Code; the Technical Instructions for the Safe Transport of Dangerous Goods by Air; the European Agreement Concerning the International Carriage of Dangerous Goods by Road; and the Regulations Concerning the International Carriage of Dangerous Goods by Rail. All are based on the UN Model Regulations for the Transport of Dangerous Goods.

[c] The Single Convention on Narcotic Drugs; the Convention on Psychotropic Substances; and the Convention against Illicit Trade in Narcotic Drugs and Psychotropic Substances.

[d] Due to the gaps of several years between each Convention's negotiation and adoption, the Single Convention on Narcotic Drugs does not refer to either of the later Conventions, and the Convention on Psychotropic Substances does not refer to the Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances. The Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances refers to both earlier Conventions.

[e] There is a slight variation in the number of states parties (184 to the Single Convention on Narcotic Drugs and the Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, and 183 to the Convention on Psychotropic Substances). The Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances strengthened the enforcement mechanisms available for use under the earlier Conventions.

[f] The United Nations Committee of Experts on the Transport of Dangerous Goods provides model regulations on the transport of dangerous goods which are monitored and updated regularly. Once issued other international organisations (the International Maritime Organisation, the International Civil Aviation Organisation, the United Nations Economic Commission for Europe and the Intergovernmental Organisation for International Carriage by Rail) amend their regulations in line with the model. There is a single international organisation responsible for monitoring and review, but there are also intermediary organisations responsible for particular transport areas.

[g] The International Narcotics Control Board is the main international organisation responsible for the monitoring and review of the UN Drugs Conventions, but the Commission on Narcotic Drugs has a role in policy-making and the UN Office on Drugs and Crime provides advice to states on compliance with the Conventions.

6. The Regulations

Chapter 4 identified seven issue areas in which there are both a high degree of international interdependence, where separate action by individual states will be insufficient to address matters of common concern, and significant applications and impacts of biotechnology. These are: arms control; health and disease control; environmental protection; trade; drugs control; development; and social and ethical impacts. Rather than there being separate regulations in the development area, several of the other regulations have development-related provisions, such as clauses on technology transfer, financial and technical assistance, and knowledge exchange. In total thirty-seven regulations from the other issue areas are covered in this book.

Arms Control

Most of the knowledge, tools and techniques of biotechnology are dual-use in nature and in addition to their beneficial uses, are open to deliberate misuse to cause harm. There is a risk of new biological and biochemical warfare agents being created to target humans, animals and plants. A vast amount of dual-use knowledge and materials are now openly available and as the technologies become cheaper, faster and easier to use, the threat of their hostile application increases. This may take the form of bioterrorism, which the anthrax mail attack of September and October 2001 highlighted, but the continued threat of state-run biowarfare programmes should not be ignored.

There are four international agreements of relevance to preventing the misuse of biotechnology. They are the:

- 1925 Geneva Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases and of Bacteriological Methods of Warfare
- Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction
- Convention on the Prohibition of Military or Any Other Hostile Use of Environmental Modification Techniques (EnMod)
- Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on Their Destruction

The 1925 Geneva Protocol

Restrictions on the use of certain weapons deemed to be abhorrent, indiscriminate and/or to cause unnecessary suffering have been integral to the development of principles and rules of international humanitarian law (also known as the laws of war). The 1907 Hague Regulations Concerning the Laws and Customs of War on Land (ICRC, 1907), for example, declared

that: 'The right of belligerents to adopt means of injuring the enemy is not unlimited' (Article 22); and 'it is especially forbidden (a) To employ poison or poison weapons' (Article 23).

Despite such early attempts to regulate the conduct of war, chemical weapons were used extensively during the First World War. Their horrific effects motivated international attempts to remove the possibility of such weapons being used again. This was reflected in the peace agreements signed immediately after the War and in the negotiation of the 1925 Geneva Protocol.

The Protocol is very short in comparison to the later agreements. Its preamble condemns the use of 'asphyxiating, poisonous or other gases, and of all analogous liquids, materials or devices' and declares that a prohibition on them is already contained within international treaties. The Parties to the Protocol then agree 'to extend this prohibition to the use of bacteriological methods of warfare'.

A large number of states attached reservations to the Protocol that would allow them to retaliate in kind if attacked with such weapons – this essentially rendered it a 'no-first-use' treaty (SIPRI CBW Project, 22 March 2001). The Protocol only banned use of such weapons and many states retained or built up stockpiles. This was a significant flaw since non-possession is an important means of ensuring that a banned weapon will not be used, and it is one of the reasons that the negotiation of additional treaties was necessary.

The Protocol remains significant as the only treaty that bans the use of biological weapons. The Biological Weapons Convention (BWC) does not, instead noting that it does not change states' obligations to abide by the Geneva Protocol (Article VIII, BWC). Most of the reservations to the Protocol have now been withdrawn and it is widely accepted to be part of customary international law.

The Biological Weapons Convention

After the Second World War it was recognised that the Geneva Protocol was insufficient to prevent the use of chemical and biological weapons, but it was more than twenty-five years before substantial progress was made towards the negotiation of additional treaties. By this stage, proliferation was becoming a serious concern as chemical and biological weapons provided a comparatively cheap alternative to developing nuclear weapons.

The BWC was adopted in 1972, entering into force in 1975. Its later articles (XI–XV) deal with administrative matters such as amendment, entry into force, review (through conferences of the states parties), ratification and withdrawal. The scope of the Convention is outlined in Article I:

> 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 or in quantities that have no justification for prophylactic, protective or other peaceful purposes;
(2) Weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.

It is clear from this article that the Convention aims to address proliferation because acquisition is included within the prohibition. Proliferation is also dealt with in Article III which commits states not to transfer any of the agents, materials or equipment listed in Article I. States are instructed not to impose unjustified export controls under the guise of supporting the Convention's aims, so that they do not unnecessarily hamper 'the economic or technological development of States Parties' (Article X). They are also expected to take necessary national implementing measures (Article IV).

Suspected breaches of the Convention can be referred to the UN Security Council (Article VI) and states are expected to cooperate to assist any party affected by a breach (Article VII) and in the 'fullest possible exchange of equipment, materials and scientific and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes' (Article X).

The BWC's provisions apply to biological agents and toxins produced by or consisting of genetically engineered organisms. Reviews of the Convention are to 'take into account any new scientific and technological developments relevant to the Convention' (Article XII) and review conferences have repeatedly affirmed that the Convention's prohibitions are comprehensive enough to cover all scientific and technological developments including those in the fields of biotechnology, genetic engineering and genome studies.

Despite lengthy investigation, development and negotiation efforts during the 1990s, the BWC still has no verification mechanisms. This is a significant weakness given that permitted peaceful uses of biological agents and toxins may be difficult to distinguish from hostile uses, and that confidence that states are adhering to their treaty obligations is extremely important to the success of arms control agreements, because otherwise states may be motivated to breach a convention because of suspicions that their rivals are doing the same.

The EnMod Convention

Widespread use of herbicides in the Vietnam War and growing international awareness of the detrimental effects of man-made activities on the environment led to negotiation in the 1970s of a convention to limit the use of environmental modification techniques as a method of warfare. The EnMod Convention was adopted in 1976. It prohibits: 'military or any other hostile use of environmental modification techniques having widespread, long-lasting or severe effects as the means of destruction, damage or injury to any other State Party' (Article I).

The term environmental modification technique is defined in Article II as: 'any technique for changing – through the deliberate manipulation of natural processes – the dynamic composition or structure of the Earth, including its biota, lithosphere, hydrosphere and atmosphere or of outerspace'. A separate Document of Understandings produced by the Committee of the Conference on Disarmament defined the other key terms as: '(a) "widespread": encompassing an area on the scale of several hundred square kilometres; (b) "long-lasting": lasting for a period of months or approximately a season; (c) "severe": involving serious or significant disruption or harm to human life, natural and economic resources or other assets' (Federation of American Scientists, September 1976).

Thus the Convention does not contain a general prohibition on environmental modification techniques, but is limited in scope by these definitions; it is also limited to the use of such weapons. These limitations appear to have affected support for the Convention, which has less than half the membership of the BWC and Chemical Weapons Convention (CWC). It also lacks a verification mechanism, review conferences have only been held twice, and breaches would be difficult to prove, given the requirement of intent to cause 'destruction, damage or injury' (Article 1).

The Chemical Weapons Convention

Article IX of the BWC contracted its Parties to reach early agreement on a prohibition on development, production and stockpiling of chemical weapons, but this took another two decades. Negotiations were spurred when the risks of proliferation were highlighted by the use of such weapons by Iraq in the 1980s. The CWC was adopted in 1993 and entered into force in 1997.

The CWC contains highly detailed and robust provisions on verification of compliance, which are considered to be a significant achievement. It contains twenty-four articles and well over 100 pages of annexes. Article I details the main obligations of states parties, who undertake:

> Never under any circumstances:
> (a) To develop, produce, otherwise acquire, stockpile or retain chemical weapons, or transfer, directly or undirectly, chemical weapons to anyone;
> (b) To use chemical weapons;
> (c) To engage in any military preparations to use chemical weapons;
> (d) To assist, encourage or induce, in any way, anyone to engage in any activity prohibited to a State Party under this Convention.

States also committed to destroying all of their chemical weapons and related production facilities, with detailed provisions in Articles IV, V and an Annex on Verification.

Article II provides a detailed definition of chemical weapons. Similar to the BWC, the CWC has a general purpose criterion, which means that it allows development and production of toxic chemicals and their precursors for any purposes not prohibited by the Convention. It lists these as including:

(a) Industrial, agricultural, research, medical, pharmaceutical or other peaceful purposes;
(b) Protective purposes, namely those purposes directly related to protection against toxic chemicals and to protection against chemical weapons;
(c) Military purposes not connected with the use of chemical weapons and not dependent on the use of toxic properties of chemicals as a method of warfare;
(d) Law enforcement including domestic riot control purposes.

The CWC makes use of schedules of chemicals, which are listed in its Annex on Chemicals. These list certain toxic chemicals and precursors in three schedules. The listed chemicals, their precursors and facilities related to them must be open to verification because of their dual-use nature. Declarations on these chemicals, precursors and facilities are required (Article VI) and states must submit declarations to the Organisation for the Prohibition of Chemical Weapons (OPCW) on stockpiles, production facilities and destruction schedules, which can then be checked in routine inspections (Article II). Information held by OPCW on the basis of declarations and inspections is classified according to sensitivity and details on this are provided in another annex – the Confidentiality Annex. The OPCW was established by the Convention to promote and support its operation and implementation and particularly to take on responsibility for verification activities.

Compliance is covered in Articles IX and XII. There are procedures for raising and discussing concerns about non-compliance and for challenge inspections to take place for the investigation of suspected breaches. States are committed to assisting other Parties who have been or are under threat of attack with chemical weapons. The Convention's provisions are not to be implemented in a way that would hinder economic and technological development of states or that would restrict cooperation, research, development, production, trade in or use of chemicals for purposes not prohibited by the Convention (Articles VI and XI).

Summary

While the four arms control treaties were not specifically designed to prevent misuse of biotechnology – the Geneva Protocol was adopted long before the biotechnology revolution and the BWC and EnMod Convention in its early stages – due to the scope of their provisions, they do apply to hostile application of modern scientific advances. These advances make the prohibitions even more important, as such applications become easier and cheaper.

Health and Disease Control

Biotechnology can be used in the identification, diagnosis and treatment of disease, to track disease spread and identify changes in bacteria and viruses that may influence their virulence, and to provide more effective drugs and vaccines. Knowledge and techniques developed in this area can also be misused or inadvertently have damaging health effects and while the prohibition on deliberate use of disease is contained within arms control agreements, the application of disease control and biosafety and biosecurity rules could assist in identifying and containing such outbreaks.

The intensification of globalisation processes over the last century has increased the need for international cooperation on health. Of particular significance has been the emergence and re-emergence of various infectious diseases. Early detection and rapid response are extremely important for the control of disease spread. This necessitates effective surveillance and regular, reliable and rapid reporting of information, with an international body to process and disseminate this information and coordinate subsequent responses.

There are several relevant international regulations focusing on the protection of human, animal and plant health. These are overseen by the World Health Organisation (WHO), Office International des Epizooties (OIE – also known as the World Animal Health Organisation) and the Food and Agriculture Organisation (FAO). All three have guidance on disease control, with a focus on preventing the spread of disease through international travel and trade. In addition, WHO and OIE publish guidance for those working with pathogenic agents within laboratories or during transport, which includes specific provisions on genetically modified organisms (GMOs). This guidance aims to protect workers' health and safety and prevent disease spread. WHO and FAO jointly oversee the Codex Alimentarius Commission (CAC), an international organisation responsible for food safety standards, which has adopted principles and guidelines related to foods derived from modern biotechnology.

Disease Control

Early efforts to cooperate internationally for control of transmissible diseases emerged in the mid-nineteenth century. From the outset these efforts have been closely connected to the issue of facilitating international travel and trade, and the balancing of health protection with trade considerations is incorporated in the four agreements covered here. For example, the International Health Regulations (IHR) use the following wording: 'The purpose of the International Health Regulations is to ensure the maximum security against the international spread of diseases with minimum interference with world traffic' (WHO, no date b).

International Health Regulations

The IHR relate to the control and prevention of the spread of human diseases. The most recent version was adopted in 2005 and has been in force since 2007. They require reporting of all 'public health emergencies of international concern' which are defined in Article 1 of the Regulations as 'an extraordinary event which is determined, as provided in these Regulations: (i) to constitute a public health risk to other states through the international spread of disease and (ii) to potentially require a coordinated international response'. The previous version of the IHR focused only on cholera, plague and yellow fever.

States' responsibilities under the IHR include the establishment of 'core capacities' in surveillance, detection, verification, notification, determination of control measures (Annex I) and of national focal points for communication with the WHO on a twenty-four hour basis. Designated points of entry (e.g. ports and airports) should also establish capacities for dealing with travellers who are either infected or suspected of being infected.

The IHR make use of a decision instrument to help states decide whether a particular disease event should be notified to the WHO, which is contained in Annex 2 to the Regulations. Subsequent to a notification of a potential public health emergency, the WHO (through its Director-General and an Emergency Committee) is responsible for determining whether an emergency is occurring, issuing temporary recommendations of measures to be adopted by states, terminating any measures and determining when an emergency has ended (Article 12). Recommendations ought to be based on scientific evidence and information and will involve the least restrictive and intrusive measures necessary (Article 17). Measures that may be recommended include: medical examination; vaccination; quarantine; treatment; refusal of entry; inspection of conveyances; and seizure or destruction of materials (Article 18). WHO has a Roster of Experts for the IHR. Relevant experts from this list are appointed to any Emergency Committee established to assess a disease event.

The IHR are to be reviewed periodically by the World Health Assembly (WHO's governing body) with the first review due by 2012. Any disputes under IHR are to be settled by negotiation, mediation, conciliation or, if necessary, referral to the Director-General.

Terrestrial and Aquatic Animal Health Codes

The OIE publishes two reference documents relevant to disease control for terrestrial and aquatic animals. These are not legally binding agreements; however, standards and guidelines developed by the OIE are referred to as a legitimate basis for trade restrictions in the World Trade Organisation's (WTO) Sanitary and Phytosanitary (SPS) Agreement (covered later in this chapter), which is legally binding. The Terrestrial Animal Health Code and Aquatic Animal Health Code (TAHC and AAHC) have been developed

to assist the control of animal disease internationally and detail 'health measures to be used by the veterinary authorities of importing and exporting countries to avoid the transfer of agents pathogenic to animals or humans, while avoiding unjustified sanitary barriers' (TAHC, Foreword). The Codes are regularly updated on the basis of recommendations made by OIE expert Commissions – the Terrestrial Animal Health Standards Commission and the Aquatic Animals Health Standards Commission – and are currently in their eighteenth and twelfth editions respectively.

The TAHC is divided into two volumes. The first provides general guidance on disease control measures and responsibilities, and the second has guidance specific to certain diseases. The Code makes use of a system of international veterinary certificates which should accompany exports of animals and animal products. The certificate describes 'the animal health and/or public health requirements which are fulfilled by the exported commodities' (TAHC, Glossary). Certification procedures are detailed in Chapters 5.1 and 5.2, with an example provided in Chapter 5.10.

The TAHC also incorporates a disease notification system so that all member states can be aware of significant disease events relating to 'listed' diseases (diseases that the OIE determines to be of particular risk of international spread and/or to have a severe effect on animals or humans). The notification system includes requirements for both initial and follow-up reporting of disease events. It is the responsibility of national veterinary authorities to provide all relevant information to the OIE's Central Bureau. Member states can attain the status of freedom from particular listed diseases, either through self-declaration or – for bovine spongiform encephalopathy, foot and mouth disease, rinderpest and contagious bovine pleuropneumonia – through application to the OIE for recognition (Article 1.6.1).

In order to provide accurate and timely disease reports, countries are expected to undertake animal health surveillance activities, which can take various forms outlined in Chapter 1.4 of the Code. Selection of measures should relate to intended outcome and should be appropriate to particular diseases in design and frequency of use. The following chapter (1.5) gives additional advice relating to surveillance of arthropod vectors of animal disease.

States should undertake import risk analysis to determine the 'disease risks associated with the importation of animals, animal products, animal genetic material, feedstuffs, biological products and pathological material' (Article 2.1.1). This analysis should form the basis of any import requirements imposed on animals and animal products. Chapter 2.1 provides advice on risk analysis, recommending the steps of hazard identification, risk assessment, risk estimation, risk management and risk communication.

Exporting states should ensure the quality of their veterinary services so that other states can have confidence in their international veterinary certificates. Recommendations on quality are provided in Chapter 3.1. and Chapter 3.2 provides recommendations on evaluation of veterinary services,

which can be done with or without assistance from OIE. The TAHC also recommends the use of animal identification and traceability systems by veterinary authorities to assist disease control and treatment, food safety, surveillance, notification and import/export procedures (Chapter 4.1).

There is a full chapter (5.3) detailing the OIE procedures that are relevant to the SPS Agreement of the WTO, with a particular focus on judging equivalency of sanitary measures. This chapter also notes that OIE will continue its own voluntary dispute settlement process (Article 5.3.8).

Chapter 5.8 covers international transfer and laboratory containment of animal pathogens. This is supplemented by advice in the Terrestrial Manual (covered below). It recognises 'the risk that disease may occur as a result of the accidental release of animal pathogens from laboratories that are using them for various purposes such as research, diagnosis or the manufacture of vaccines' (Article 5.8.2) and the need to prevent this from occurring. In a similar way to the WHO's Laboratory Biosafety Manual (LBM) (also outlined below) pathogens are classified into four risk groups. Any importation of animal pathogens or infected material/organisms should be done under licence and with appropriate packaging and must be sent only to laboratories of the appropriate biosafety level (BSL). A laboratory 'should be allowed to possess and handle animal pathogens in group 3 or 4 only if … it can provide containment facilities appropriate to the group' (Article 5.8.5). This should be determined by the relevant authority, which should inspect and license facilities.

The AAHC has very similar aims to the Terrestrial Code but applies to aquatic animals and their products. The Aquatic Code has eleven sections; the first seven contain general recommendations, and the remainder are disease specific. It also makes use of notification, listed diseases, surveillance, import risk analysis and certification.

International Plant Protection Convention

The International Plant Protection Convention's (IPPC) main purpose, stated in Article I, is 'securing common and effective action to prevent the spread and introduction of pests of plants and plant products and to promote appropriate measures for their control'. The original IPPC was adopted by FAO in 1951. The current version was adopted in 1997 and entered into force in 2005.

Article II effectively determines the scope of the Convention through its definition of key terms. 'Plants' includes seeds and germplasm ('The genetic material that carries the inherited characteristics of an organism' – Department of the Environment, Sport and Territories, 1996). 'Pest' is 'any species, strain or biotype of plant, animal or pathogenic agent injurious to plants and plant products'; 'Quarantine pest' is one 'of potential economic importance to the area endangered thereby and not yet present, or present but not widely distributed and being officially controlled'. It is these pests that are the main focus of the Convention.

The IPPC is to be implemented through designated National Plant Protection Organisations, which are responsible for: issuing phytosanitary certificates; surveillance and inspection of plant products; reporting outbreaks; imposing control measures; and conducting pest risk analyses. Phytosanitary certificates accompany exports of plants/plant products and incorporate identifying information, details of exporter and consignee and a statement that the exported plant/plant product has been inspected/tested and is free of any pests specified by the importing state (Annex I – Model Phytosanitary Certificate). Regional Plant Protection Organisations (RPPOs) may be used to coordinate implementation of some aspects of the Convention and have an important role in collection and dissemination of information (Article IX).

Any phytosanitary measures required on imports must be 'no more stringent' than those applied domestically, 'limited to what is necessary to protect plant health' and 'technically justified'[1] (Article VI). Measures can include: inspections; prohibitions; restrictions on movement; treatment; or destruction (Article VII.I). They should be published and implemented in such a way as 'to minimize interference with international trade' (Article VII.2).

Compared to the previous (1979) version, the current IPPC makes increased reference to its relationship with international trade agreements. IPPC is used by the WTO as a basis for acceptable international standards under its SPS Agreement. In connection with this role, the IPPC established a Commission on Phytosanitary Measures (CPM) with responsibility for standard-setting (Article XI). States parties are expected to participate in these activities. This, more recent, version of the IPPC also introduced the practice of pest risk analysis, which enhances transparency and provides a scientific basis for decision-making on phytosanitary measures. Article XX on technical assistance is also new to the 1997 IPPC. It has the particular motivation of assisting developing countries to meet their obligations under the Convention.

Dispute settlement can take place through a committee whose recommendations are non-binding (Article XIII.2). Parties can also refer disputes to the WTO (Article XIII.3); those procedures are binding. The IPPC Secretariat has pointed out that this means that WTO settlement decisions 'can have serious economic and political consequences' and therefore encourages states 'to begin with technical consultation with the aim of dispute avoidance' (IPPC Secretariat, 21 April 2006).

Biosafety and Biosecurity

Laboratory Biosafety Manual

The LBM is a guidance document developed as part of the WHO's Biosafety Programme and is designed to prevent accidental release of pathogenic agents from laboratories. The most recent (third) edition of the Manual briefly covers measures that can be taken to prevent deliberate releases.

This has since been expanded in the WHO's Laboratory Biosecurity Guidance.

Different agents pose different risks and the Manual makes use of four categories related to risks to individual workers and to the wider community:

Risk Group 1 – low or no risk to individuals or the community
Risk Group 2 – moderate risk to individuals, low risk to the community
Risk Group 3 – high risk to individuals, low risk to the community
Risk Group 4 – high risk to individuals and to the community

Guidance is given on classifying agents into the risk groups, which may vary due to local conditions, for example immunity levels in the local population, and should, therefore, be drawn up on a national or regional basis. Risk assessments should include, *inter alia*, consideration of: pathogenicity; infectious dose; outcome of exposure; routes of infection; environmental stability; local availability of treatments; and 'any genetic manipulation of the organism that may alter the host range of the agent or alter the agent's sensitivity to known, effective treatment regimes' (p. 7).

Related to risk group, there are four Biosafety Levels to be applied in the design, operation and use of laboratories. Requirements for these are outlined in Chapters 3–5 of the Manual. BSL 1 is used where there is no or very low risk and BSL 4 where there is very high risk. BSL requirements are cumulative. Basic requirements, to be applied at all levels, include: provision of a manual identifying hazards and practices and procedures to avoid them; restricted access; use of protective clothing; reporting of accidents; and regular safety training.

BSL 3 laboratories have more stringent access conditions, require additional protective clothing, entrance through interlocking doors, controlled ventilation, and must be sealable for decontamination. BSL 4 laboratories require dedicated filtered air supply and exhaust systems, personnel showers, airlock entry for personnel, equipment and materials, and maintenance of differentiated air pressure with full redundant capacity, and primary containment must use either Class III biosafety cabinets or positive-pressure air suits (Chapter 5).

Chapter 9 introduces the concept of laboratory biosecurity, which is distinguished from biosafety as follows: '"laboratory biosafety" is the term used to describe the containment principles, technologies and practices that are implemented to prevent unintentional exposure to pathogens and toxins or their accidental release. "Laboratory biosecurity" refers to institutional and personal security measures designed to prevent the loss, theft, misuse, diversion or intentional release of pathogens and toxins' (p. 47). The Manual recognises that good biosafety and biosecurity can be mutually supportive. Biosecurity is covered in more detail in the Laboratory Biosecurity Guidance.

Chapter 16 of the Manual provides an introduction to recombinant-DNA (deoxyribonucleic acid) technology and includes recommendations on risk

assessment of the donor organism, recipient organism and any viral vectors used in work with GMOs and transgenic animals and plants. Particular consideration should be given to the possibility that donated genetic material could code for products that increase the risk to humans and to whether the recipient or host organism's pathogenicity, host range or immune status could be altered (pp. 103–4).

The risk assessment and BSL guidelines form Part I of the Manual and discussion of biosecurity Part II. Part III – Laboratory Equipment – details the purpose and use of equipment that can minimise laboratory hazards, and Part IV covers 'good microbiological technique' (i.e. safe handling, storage and transport of hazardous agents). Transport of infectious substances is given further coverage in the WHO's Guidance on Regulations for the Transport of Infectious Substances. Chapter 16 on Biosafety and Recombinant-DNA Technology is Part V of the Manual. Part VI outlines hazards that can arise in laboratories due to the use of chemicals, from fire, electricity and radiation, and Part VII covers safety organisation and training. Primary responsibility for biosafety rests with the head of the laboratory facility, though some duties can be delegated to a biosafety officer and/or a biosafety committee. The final part of the Manual (Part VIII) provides a checklist to aid assessment of laboratory biosafety and biosecurity. Five annexes to the Manual cover first aid, immunisation, WHO Biosafety Collaborating Centres (which provide advice and training), equipment safety, and chemical hazards and precautions.

Biorisk Management: Laboratory Biosecurity Guidance

The Laboratory Biosecurity Guidance published by the WHO in September 2006 provides detailed, though non-prescriptive, guidance on appropriate procedures for achieving laboratory biosecurity. It is a response to growing international concern about the possibility of individuals or groups managing to get hold of dual-use biomaterials for hostile use through a lack of security at laboratory facilities. It aims to prevent the 'unauthorized access, loss, theft, misuse, diversion or intentional release' of what it refers to as valuable biological materials (VBM)' (p. iv). VBM are 'biological 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' (p. v). Thus the Guidance covers not only pathogens, toxins and other biological materials that may be put to hostile use, but also biological materials that have value for other reasons, for example important reference strains or culture collections.

In creating the Guidance, WHO was careful to provide recommendations with a high degree of flexibility in the methods through which they can be applied within particular settings. It is also hoped that by involving those who work in the laboratories in decisions on how to most appropriately

achieve biosecurity, they are more likely to respect and comply with any resulting rules and procedures. They are also likely to have the knowledge and experience to know what is most appropriate for their facility. Therefore:

> A specific laboratory biosecurity programme, managing identified biorisks, should be prepared and designed for each facility according to its specific requirements, to the type of laboratory work conducted and to local and geographical conditions. Laboratory biosecurity activities should be representative of the institution's various needs and should include input from scientific directors, principal investigators, biosafety officers, laboratory scientific staff, maintenance staff, administrators, information technology staff, law-enforcement agencies and security staff, if appropriate.
>
> (Laboratory Biosecurity Guidance, p. 7)

Biosecurity requirements will also vary over time, as the materials worked on in the laboratory change and biosecurity risks and measures should be regularly re-evaluated. The Manual makes recommendations in the areas of: biosafety; risk assessment and management; accountability; recruitment and training of personnel; transport; and emergency events. Good biosafety practices are an essential part of achieving biosecurity; however, if due care is not taken, conflicts may arise in implementation of biosafety and biosecurity (covered in Section 2.1 of the Guidance) and the Guidance suggests that existing biosafety committees within laboratories should take on responsibility for reviewing laboratory biosecurity.

For the purposes of the Guidance, WHO has created the concepts of biorisk assessment and biorisk management. This involves identification of risks relating to particular agents and the consequences of any adverse events, and devising systems and controls to reduce the chances of adverse events occurring. The consequences to be assessed include health impacts, economic impacts, impacts on the laboratory concerned and the security of its other assets, and impacts on public behaviour (p. 13). Biorisk management includes: avoiding accidental exposure or release and 'unauthorised access, loss, theft, misuse, diversion or intentional release of VBM', 'providing assurance … that suitable measures have been adopted', training and awareness raising, a working culture in which breaches resulting in infection are considered unacceptable, and appropriate storage, use, transfer and destruction of VBM, along with documentation of these activities (pp. 11–12).

The dual-use nature of pathogens and toxins is noted and laboratories are expected to protect them, particularly where they have been associated with biological warfare programmes. The Guidance raises particular concerns about 'genetically engineered pathogens that express enhanced or unique virulence properties' because 'there may be no known effective treatment for exposed and infected persons or animals', about bioregulators and the ability

to reconstitute replicating viruses using genetic elements and published files (pp. 16–18).

The Guidance notes that GMOs are covered by provisions of the Convention on Biodiversity (CBD), Cartagena Protocol on Biosafety and the BWC (p. 17). It also suggests that laboratory facilities have a voluntary code of conduct to promote legitimate and ethical research that 'should involve evaluation of the purpose of the work, consideration for its impact … and enumerate considerations and conditions for or against the publication of results that may have dual-use implications' (p. 21).

The Guidance deals briefly with biosecurity during transport, referring readers to other documents such as the UN Model Regulations on the Transport of Dangerous Goods and national import/export rules. Biosecurity during transport requires appropriate accountability and control procedures be put in place (p. 22).

Guidance on Regulations for the Transport of Infectious Substances

There is a risk of disease spread from infectious substances in transport if they are not packaged and handled appropriately. The Guidance is designed to 'provide information for classifying infectious substances for transportation and ensuring their safe packaging' (p. 2), with an emphasis on the relationship between sender, carrier and receiver. It is based on recommendations of the UN Committee of Experts on the Transport of Dangerous Goods, in particular the UN Model Regulations on the Transport of Dangerous Goods as they apply to infectious substances. The Guidance also refers to other 'international modal agreements'[2] on the transport of dangerous goods, which are also based on the UN Model Regulations. The modal regulations are not covered here because the Guidance's focus on infectious substances provides comprehensive coverage of the sections of the dangerous goods regulations most relevant to biotechnology for all modes of transport.

The Guidance focuses on 'substances which are known or are reasonably expected to contain pathogens' (p. 4) and aims to ensure that they are correctly identified, packaged and labelled. They are categorised as either Category A – 'an infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals' (p. 4) – or Category B for those which do not fit that definition.

A basic triple-packaging system is recommended for both Categories. This consists of: a watertight and leakproof primary receptacle, which should contain sufficient 'absorbent material to absorb all fluid in case of breakage' (p. 7); secondary packaging that encloses the primary receptacle and is also watertight and leakproof; and outer-packaging that protects the secondary packaging from physical damage. More than one primary receptacle may be placed in the secondary packaging.

Packages should be marked to give information on the shipper, UN number and shipping name, temperature storage requirements and details of any refrigerant used, and labelled with hazard and handling labels as necessary. The responsibilities of shipper, carrier and receiver are outlined in a section titled Transport Planning (pp. 18–19). Good coordination is essential alongside advance arrangements, appropriate documentation and authorisation, and tracking through the various stages.

There are five annexes to the Guidance, covering: links to the modal regulations and model regulations; examples of Category A substances; packing instruction P620 (required for Category A); packing instruction P650 (required for Category B); and classification of infectious substances and patient specimens.

Manual of Diagnostic Tests and Vaccines for Terrestrial Animals and Manual of Diagnostic Tests for Aquatic Animals

These Manuals, developed by the OIE, are designed to operate alongside the animal health codes and have the same overall aim, but are directed primarily towards 'laboratories carrying out veterinary diagnostic tests and surveillance, plus vaccine manufacturers and regulatory authorities' (Terrestrial Manual). The Manuals include specific recommended standards for listed diseases. The Terrestrial Manual includes advice on packaging and transport of infectious substances and diagnostic specimens, including on advanced consent from receiving laboratories and consultation of the relevant dangerous goods regulations (Chapter 1.1.1).

Chapter 1.1.2 of the Terrestrial Manual is titled Biosafety and Biosecurity in the Veterinary Microbiology Laboratory and Animal Facilities. The first stage, similar to that in the LBM, is risk assessment and classification of pathogens to risk groups – based on risk to both humans and animals. Four groups are used – from low harm from disease and low likelihood of spread (Group 1) to severe disease and high likelihood of spread and 'usually no effective prophylaxis or treatment' (Group 4) (1.1.2.b). Once the risk level has been assigned then the appropriate containment level can be assigned. As in the LBM, requirements at each containment level are cumulative. All must: be easy to clean; have restricted personnel access; have safe storage; not discard infectious material into drains; and report all accidents. For Group 2 biosafety cabinets should be used where there is a chance of aerosolisation. For Group 3 the laboratory should 'be in an isolated location', there should be emergency procedures in place, staff should be fully trained, the laboratory positively pressurised and sealable, airlock entry used and exhaust air HEPA (high-efficiency particulate air) filtered. For Group 4 there should additionally be HEPA filtering of incoming air and double HEPA filtering of exhaust air, use of Class III biosafety cabinets or Class II plus positive-pressure suits and destruction of any infectious material in waste water. Animal facilities must also apply appropriate standards

of biosafety and containment (Article 1.1.2.g). Transport of infectious substances is covered in 1.1.2.i, and a table is provided that summarises biosafety requirements (1.1.2.k).

Chapter 1.1.7, titled Biotechnology in the Diagnosis of Infectious Diseases and Vaccine Development, provides background information on such methods, noting that they need to achieve the criteria of being 'easy, safe, sensitive, reproducible and eventually automated'. Nanotechnologies are also covered in this chapter.

The Aquatic Manual covers, in its general section, quality management in veterinary testing laboratories, validation of diagnostic assays and methods for disinfection of aquaculture establishments.

Food Safety

The Codex Alimentarius Commission has adopted four relevant documents:

- Principles for the Risk Analysis of Foods Derived from Modern Biotechnology
- Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants
- Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms
- Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals

The Principles were adopted in 2003 and form the basis of the three Guidelines. The Codex Alimentarius already included Working Principles on Risk Analysis; however, these were aimed at analysing individual components that could be present in foods, rather than whole foods, so additional principles were developed for genetically modified foods. The Principles provide 'a framework for undertaking risk analysis on the safety and nutritional aspects of foods derived from modern biotechnology' (point 7).

Risk assessment compares a new food product to its 'conventional counterpart' in order to identify any new or altered hazards to human health, their nature and severity (point 10). Where hazards are identified, risk management measures including labelling and post-market monitoring and tracing may also be required. Risk communication is encouraged and decision-making processes should be transparent and include consultation. The Guidelines all refer to the risk analysis framework provided in the Principles.

Recognition of equivalence of different measures that achieve the same level of protection is encouraged (point 17). Risk analysis procedures should be reviewed in line with new scientific information (point 30). Information exchange between governments and relevant international organisations is encouraged (point 28) and the need for capacity-building, particularly for developing countries, for risk analysis, management and communication (point 27) is recognised.

The Guidelines all adopt a very similar approach to food safety assessment. Generally assessments will make use of comparison with a conventional counterpart that has a history of safe use as a food – only additional or altered hazards need to be assessed (section 3.13) and the result will be a conclusion as to whether the new product is as safe. Assessments ought to:

- provide descriptions of the host and donor plant, microorganism or animal and their historical uses as food;
- describe and characterise the genetic modification(s) sufficient to allow the identification of all transferred material and resulting expressed substances, covering, for example, size, location, function and sequence data;
- identify any toxic or allergenic effects;
- describe the chemical nature and function of any newly expressed substances;
- where the substances are proteins, describe the amino acid sequence;
- assess the consequences of any nutritional modification (deliberate or unintentional);
- consider the possible accumulation of substances harmful to human health as an indirect result of the modification (e.g. from the use of chemicals on herbicide-tolerant plants).

Annexes to the Guidelines provide additional information on assessing allergenic potential. Antibiotic resistance markers should not be present in the final food. For recombinant-DNA microorganisms there is an additional requirement that immunological effects of interaction with gut microorganisms be considered.

Environmental Protection

There are two main environmental agreements of relevance: the CBD and the Cartagena Protocol on Biosafety to the Convention on Biodiversity. These agreements recognise the interaction of controls to protect the environment and international trade rules. Markets are generally unable to put a proper value on ecological products and services and therefore fail to provide incentives for their conservation and sustainable use (Swanson, 1997, p. 76). It is necessary for some environmental agreements to have an impact on trade in order to compensate for this; however, regulation of the two areas is not yet adequately coordinated. There is a particularly strong connection between trade and environment in ongoing negotiations on access to and benefit-sharing of genetic resources. Rules on genetic resources are covered later under the 'trade' sub-heading.

The need to manage the impacts of biotechnology, both to promote its benefits and to avoid negative effects on the environment, is referred to within the Convention (particularly in Articles 8 and 19) and is the main focus of the Cartagena Protocol in relation to transboundary movements of living modified organisms (LMOs).

Convention on Biodiversity

The CBD, adopted in 1992, is a framework convention. These lay down general principles and requirements for action but generally 'require further action by states to prescribe the precise measures to be taken' (Birnie and Boyle, 1992, p. 13). The CBD's three main objectives are: 'the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources' (Article I). Biodiversity is defined in Article 2 as: 'the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are a part; this includes diversity within species, between species and of ecosystems'. Article 2 also recognises states' sovereign rights over their natural resources, alongside their responsibility not to detrimentally affect the environments of other states.

Transfer of resources (financial, scientific, technical and technological) and information from developed to developing countries is recognised as essential for the effective implementation of the Convention. The CBD recognises biotechnology as both a threat to biodiversity and a potentially useful tool in its conservation and sustainable use. For example, in Article 19 it calls for exchange and transfer of biotechnology (19.2) and asks parties to consider the need for additional action to protect biodiversity from biotechnology possibly in the form of a protocol to the Convention (19.3).

The CBD recommends that environmental impact assessments be used for any project that may have adverse effects on biodiversity (Article 14). Article 15 covers access to genetic resources. These are vital to humanity, particularly as a resource base for the agricultural and pharmaceutical industries. Article 15 interprets the principle of sovereign rights as giving states the right to determine access to genetic resources within their territories. Where the end-use is environmentally sound, it recommends access be facilitated. Provisions on genetic resources were further developed by the CBD's Conference of the Parties (COP) in the Bonn Guidelines on Access to Genetic Resources (covered later in the 'trade' section).

Articles 16 to 18 give detailed guidance on the cooperation that should take place between states. This includes: access to and transfer of technology, including how this should be related to intellectual property rights (IPRs) (Article 16), information exchange (Article 17), and scientific and technological cooperation. A voluntary Clearing House Mechanism was established to facilitate information exchange and cooperation.

The CBD's scope covers aspects of trade and economics and it recognises that it operates in the context of other international agreements covering these issues. Article 22 – Relationship with Other International Conventions – states that the CBD will not affect states' obligations under other agreements unless this would pose a serious threat to biodiversity.

The responsibilities of the CBD's COP include reviewing implementation of the Convention and adopting any protocols and annexes. The Convention is administered by the CBD Secretariat. CBD also has a Subsidiary Body on Scientific, Technical and Technological Advice which has the role of providing advice on how to assess the status of biodiversity and to otherwise assist implementation of the Convention (Article 25). Dispute settlement can be undertaken through processes outlined in Annex II of the Convention including arbitration, conciliation, mediation and referral to the International Court of Justice. These procedures automatically apply to any protocols negotiated, unless they are overridden. They were for the Cartagena Protocol which has separate procedures.

Cartagena Protocol on Biosafety

The Cartagena Protocol, which so far is the only protocol to the CBD, incorporates many of the principles and concepts used in the Convention including reference to the precautionary approach, the view of biotechnology as being both beneficial and threatening, and the idea that resources will have to be transferred from developed to developing countries for effective implementation to be achieved. The Protocol concentrates on transboundary movements of LMOs, enabling states to make informed choices about whether allowing imports of particular LMOs would pose too great a risk to biodiversity and/or human health. In some cases socio-economic considerations may also be taken into account (Article 26). The Protocol established procedures by which importing states must explicitly consent to movements of LMOs into their territory. This consent is only required prior to the first transboundary movement of a particular LMO.

LMOs are defined by the Protocol as 'any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology' (Article 3.g). Such organisms are also commonly referred to as genetically modified organisms. The Protocol differentiates between types of LMO. LMOs for pharmaceutical use are excluded from the Protocol's provisions if they are covered by other international agreements (Article 5). There are three additional categories of LMO: (1) for deliberate release into environment; (2) for direct use in food or feed or food processing (LMOFFPs); and (3) for contained use or in transit.

The Protocol's decision-making tool – the advanced informed agreement procedure – does not apply to LMOs for contained use or in transit. A LMO may also be exempted from the procedure if a Meeting of the Parties (MOP) to the Protocol decides that it is unlikely to have adverse effects. Articles 8 to 10 outline the procedure for LMOs for deliberate release. The exporter or exporting state must notify the competent national authority (national body established to administer the Protocol) of the importing state prior to the first transboundary movement of a particular LMO. Annex I to the Protocol

lists the required contents of the notification including: summary of risk assessment; information on the LMO, its parent and recipient organisms and the modification(s) made; dates of the intended movement; and advice on safe handling, transport and use.

It is expected that a decision, which may take the form of approval, refusal, request for additional information or request for extension of the decision-making period, will be sent to the notifier and to the Biosafety Clearing House (BCH) (established by the Protocol for this purpose) within 270 days of the notification being received by the importing state. Risk assessment must be used as the basis for these decisions and the precautionary approach[3] should be applied where necessary. Failure of the importing state to meet its obligations (for example on the time period for a decision) may not be read as implying consent to the transboundary movement.

Risk assessments must be 'scientifically sound' and use recognised techniques (Article 15.1 and Annex III.3). While the importing state must ensure that risk assessments are conducted, it can require the notifier to fund or conduct them (Article 15). Further details on the risk assessment are provided in Annex II to the Protocol. It should result in an estimate of overall risks and provide recommendations on the acceptability of those risks and how they can best be managed (Annex III.8 d–e).

Article 11 sets out decision-making procedures for living modified organisms for food, feed or food processing (LMOFFPs). Parties are to inform the BCH of any approvals for domestic use (Article 11.1) and any relevant national rules (Article 11.5). Decisions on LMOs can be reviewed by importing states. Provided that the BCH is informed in advance, a simplified procedure can be applied in two cases – where an importing state allows movements of certain LMOs at the same time as notification is made, or when an importing state specifies an LMO as exempt.

Regional, multilateral or bilateral agreements on LMO movements are permitted as long as they do not give a lower level of protection (Article 14). National rules may be more stringent than the Protocol as long as they do not contravene existing international agreements (Article 2.4). States should have measures in place to manage any risks identified in assessments, deal with unintentional transboundary movements and prevent and penalise illegal movements. Article 18 requires measures to be implemented by states for the safe handling, transport, packaging and identification of LMOs.

The purpose of the BCH, of which use by states is mandatory, is to facilitate comprehensive information exchange including on: relevant laws; guidelines; regional, bilateral and multilateral agreements; risk assessments; and decisions on import. It is largely internet based with access open to all, although information can only be posted by designated providers. Notifiers may designate certain information in notifications as confidential, but this does not apply to all categories of information with, for example, risk assessments being excluded.

The COP to the CBD serves as the MOP to the Protocol. They also share an administrative body (the CBD Secretariat) and financial mechanism. Parties monitor their own implementation of the Protocol and report on this to the Conference of the Parties serving as the Meeting of the Parties (COP-MOP) (Article 33).

Summary

In suggesting action towards its aims of conservation and sustainable use of biodiversity and fair and equitable benefit-sharing from use of genetic resources, the CBD presents biotechnology both as a tool to assist achievement of these aims and as a threat to biodiversity if not safely applied. The Cartagena Protocol is concerned with enabling states to make informed choices about transboundary movements of LMOs, focusing specifically on the control of a particular application of biotechnology and its associated environmental and health risks. Both agreements build upon a wide range of concepts and principles that have been developed within the area of international environmental law and reflect the trend for agreements in this area to strongly incorporate development considerations.

Trade

There are three main areas of trade regulation relevant to control of biotechnology. The first includes those that aim to reduce technical barriers to trade (for example technical regulations and standards applied to imported products). For biotechnology products these would, for instance, include labelling requirements for foods containing genetically modified ingredients. The second area is rules on the protection of IPRs, particularly those concerning patents. Biotechnology products and processes often involve intensive research, development and innovation, and therefore significant investment. Patents provide a route for innovators to limit exploitation of their products and processes and to recoup money invested. Such protection has proved controversial in some areas, for example where access to essential medicines has been restricted. The third area of regulation is access to plant genetic resources (PGR) and benefit-sharing from their use. PGR form the basis of many biotech products. The countries and communities from which they are sourced hold certain rights over these resources.

Agreements for the Reduction of Barriers to Trade

After the Second World War a series of negotiations were initiated under the General Agreement on Tariffs and Trade which steadily reduced tariffs on goods. Non-tariff barriers were included in negotiations from the 1970s and in the final round of negotiations (1986–94) the areas of services and intellectual property were also included. This round also established a permanent international organisation – the WTO – which administers

a range of agreements on goods, services and intellectual property, and provides a forum for ongoing trade negotiations.

Many of the WTO agreements, including those discussed here, are covered by its Dispute Settlement Understanding (DSU). If attempts at conciliation between states are unsuccessful, disputes can be referred to a Dispute Settlement Body made up of all WTO member states, which will establish a panel to examine the matter. The panel presents its recommendations in the form of a final report which is sent to the Body for adoption as a ruling. If the offending party does not implement the recommendations of the ruling, and fails to provide compensation, the affected state may, after approval by the Dispute Settlement Body, enact measures to remove trade concessions to the offending state sufficient to balance its losses. This provides an effective enforcement mechanism and powerful incentive for states to comply with WTO rules.

Agreement on Technical Barriers to Trade and Agreement on the Application of Sanitary and Phytosanitary Measures

Technical barriers, such as quality standards and technical regulations applied to imports, may be in place for legitimate reasons such as for the protection of health or the prevention of deceptive practices, but they may also be unjustified protectionist measures. Both the Technical Barriers to Trade (TBT) Agreement and SPS Agreement aim to limit the use of technical regulations and standards to those that are necessary and scientifically justified. The TBT Agreement covers technical regulations and standards applied to any products; measures that specifically aim to protect human, animal or plant health are covered by the SPS Agreement.

Annex I of the TBT defines a technical regulation as a 'Document which lays down product characteristics or their related processes and production methods, including applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements' (Annex I.1) and a standard as a 'Document approved by a recognised body, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods with which compliance is not mandatory' (Annex I.2). Sanitary and Phytosanitary measures are defined in Annex A to the SPS Agreement as those which protect human, animal and plant life and health from threats such as the spread of disease and food-based risks.

Under the Agreements, relevant international standards should be used as the basis for national measures wherever they exist and any measures that conform to international standards will be considered compliant with the agreements. The SPS refers to three international bodies whose standards may be particularly applicable: the CAC; OIE; and the Secretariat of the IPPC (Article 3.4 and Annex A.3).

Technical regulations are to be based on scientific risk assessments. Recognition of equivalence of different measures that result in the same level

of protection is encouraged (Article 2.7, TBT; Article 4, SPS). SPS measures should be adopted as appropriate to the areas of origin and destination, particularly in regard to pest and disease prevalence. SPS risk assessments will be either 'evaluation of the likelihood of entry, establishment or spread of a pest or disease … and of the associated potential biological and economic consequences' or 'evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins, or disease causing organisms in food, beverages or feedstuffs' (Annex A.4).

States should publish technical regulations promptly, with an adequate interval before entry into force to give other states opportunity to comment and to take measures to achieve compliance (Article 2.12, TBT; Annex B, SPS). States are also expected to ensure that setting of technical regulations and standards by local- and non-governmental bodies comply with the Agreements. States are to establish enquiry points to provide information on their regulations, standards and assessment procedures.

Developing countries are to be granted 'special and differential treatment' in the implementation of the Agreements (Article 12, TBT; Article 10.1, SPS) and states should provide advice and technical and financial assistance to these countries. It is viewed as particularly important that market access for developing countries is maintained (Article 12.3, TBT; Article 9.2, SPS). There is a significant statement in Article 12 of the TBT Agreement that developing countries are not 'expected to use international standards as a basis for their technical regulations … which are not appropriate to their development, financial and trade needs'.

Both Agreements established committees to serve as consultation forums. The SPS Committee is also mandated to monitor harmonisation of international standards and to coordinate to this end with the CAC, OIE and IPPC Secretariat (Article 12.3). The WTO's DSU applies to both Agreements. Additionally, the SPS Agreement allows states to seek dispute settlement under other relevant international agreements (Article 11.3).

Agreements for the Protection of Intellectual Property Rights

The first international agreement for the protection of intellectual property was the 1883 Paris Convention for the Protection of Industrial Property. The Bureau overseeing this agreement became part of the United International Bureaux for the Protection of Intellectual Property in 1893, which in 1970 became the World Intellectual Property Organisation (WIPO). WIPO now administers more than twenty treaties, including three covered here, and works closely with the WTO.

IPRs give protection to innovators, allowing them to benefit from exploitation of their inventions, by controlling (and often charging for) their reproduction and use. These rights include copyright, trademarks, industrial designs and patents. Patent rights are particularly relevant to biotechnology

innovations as they allow the protection of innovative products and processes. New plant varieties do not have to be patented to receive intellectual property protection, they may instead be subject to agreements on plant variety or breeders' rights.

The Paris Convention (most recently revised in 1979) is still active and overseen by WIPO. Its provisions on patents are now incorporated into the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) and are enforced through it.

Agreement on Trade Related Aspects of Intellectual Property Rights

The Agreement on TRIPS stipulates minimum standards of intellectual property protection; states are free to apply higher levels of protection. States can choose not to apply certain provisions of the Agreement in order to 'protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development' and to 'prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology' (Article 8).

States must have national procedures in place to enforce IPRs, including adequate measures for the prevention and deterrence of abuse. National procedures should be fair, simple, efficient and details on them should be made publicly available (Articles 41 and 63). A Council for TRIPS was established to review implementation of the Agreement, serve as a consultation forum and cooperate with WIPO (Article 68).

Developing countries were granted additional time to implement the Agreement (Article 66) which has been extended to July 2013 (WTO, 29 November 2005). Developed countries are encouraged to promote technology transfer and to provide technical and financial assistance to developing countries on request, particularly for the development of relevant laws, regulations and institutions (Articles 66 and 67).

Patents are dealt with in Section 5 of TRIPS. Generally, they must be granted for 'any inventions, whether products or processes, in all fields of technology' on condition of three criteria being met: (1) novelty; (2) involving an inventive step; and (3) capable of industrial application (Article 27.1). Patent applications must 'disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art' (Article 29.1). Patent protection lasts at least twenty years from the filing of a patent application and the rights granted by a patent mean that third parties must seek consent to make, use or sell the product or use the process, or use or sell 'the product obtained directly by that process' (Article 21.8).

Certain inventions may be excluded from patent protection on the basis of constituting a threat to: public order or morality; human, animal or plant life or health; the environment; or essential security interests (Articles 29.2

and 73). Also excluded are 'diagnostic, therapeutic and surgical methods' and 'plants and animals other than microorganisms, and essentially biological processes for the production of plants and animals other than non-biological and microbiological processes' (Article 27.3).

Patent Cooperation Treaty and Patent Law Treaty

The Paris Convention and TRIPS Agreement provide for certain standards to be applied across national patent systems, creating a degree of harmonisation in approaches, but do not alter the need for inventors to make separate applications to each national patent office of the countries in which they want to receive protection. The Patent Cooperation Treaty (PCT) created an International Patent Cooperation Union among its contracting states and established a unified international application system. The Patent Law Treaty (PLT) provides additional details on and clarification of the application process. Both Treaties consist of the provisions contained within their articles plus an accompanying set of regulations that provide additional administrative details.

The PCT allows patent applications filed in any member state to be filed as international applications for as many designated member states as the applicant chooses (Article 3). Applications must meet various requirements listed in the PCT and its regulations. Applications are filed with the national office of a member state (receiving office) which is responsible for processing them (Article 10, PCT); it has national effect in all designated states from the date of receipt by the receiving office (Article 11). Copies are sent to the Union's International Bureau and to an International Search Authority (ISA). The ISA conducts a documentary search for 'relevant prior art' (ensuring that the invention is novel) and produces a search report (Articles 15, 16 and 18, PCT). The application and search report are sent to the designated offices and the International Bureau produces an 'international publication' of the application eighteen months after the filing date. This has the same effect in designated states as national publication would (Article 29, PCT). The applicant must pay fees to each designated office, which can process the application thirty months after its original filing date.

To assist applicants in deciding whether to submit an international application they can request an 'international preliminary examination' be conducted by an International Preliminary Examining Authority, which will produce a non-binding opinion on whether the invention meets patentability criteria (Article 33, PCT). The International Bureau should provide information to developing countries at or below cost (Article 50, PCT). Governing assemblies (made up of member states) were established by both Treaties to assist their implementation and development. Any disputes under PCT should be settled by negotiation or recourse to the International Court of Justice (Article 59, PCT).

Budapest Treaty on the Deposit of Microorganisms for the Purpose of Patent Procedure

Applications for patents on inventions that involve microorganisms, tissue cultures or plasmids may require that samples be provided in order to fulfil disclosure criteria. Reproduction of the invention may not be possible without having access to the specific sample and a description alone would be insufficient for this purpose. The Budapest Treaty establishes a system of single international deposits, rather than applicants having to make deposits with collections in each state in which they are applying for patent protection.

The Treaty established a Union 'for the recognition of the deposit of microorganisms for the purpose of patent procedure' (Article 1). Deposits made to International Depositary Authorities (IDAs) will be recognised by all member states. IDAs can be governmental or private bodies based in member states. They are expected to: check the viability of deposits; store them; issue receipts of deposits and viability statements; and provide samples as requested (Article 6). Member states or IDAs may apply import or export restrictions to samples where necessary for the protection of health, the environment or national security (Article 5). Microorganisms are stored for a minimum of thirty years. An Assembly of member states meets every two years to oversee development of the Union and implementation of the Treaty.

International Convention for the Protection of New Varieties of Plants

The TRIPS Agreement allows for plant varieties to be protected either through patents or *sui generis* IPRs. The International Convention for the Protection of New Varieties of Plants (UPOV Convention) provides a system of plant variety or breeders' rights. It was first adopted in 1961 and has been revised three times, most recently in 1991.

A new plant variety must meet four criteria in order to be granted protection. It must be: new; distinct; uniform; and stable (Article 5). The terms are defined in Articles 6–9. Those who have bred or developed the new variety, their employers, those who commissioned their work or their successors in title are eligible to apply for plant variety protection (Article 1.iv). Applications are made to a designated authority in whichever contracting party the applicant wishes to use first (Articles 10 and 30). The authority may carry out or cause to be carried out any tests necessary to judge whether the criteria have been met (Article 12). Once a plant breeders' right is awarded the right-holder's authorisation is required if anyone wishes to use the propagating material of the protected variety for: '(i) production or reproduction (multiplication); (ii) conditioning for the purpose of propagation; (iii) offering for sale; (iv) selling or other marketing; (v) exporting; (vi) importing; (vii) stocking for any of the purposes mentioned in (i) to (vi) above' (Article 14).

This does not extend to private, non-commercial or experimental uses, or to the use of the material to breed other new varieties (Article 15.1). States may also choose to restrict breeders' rights in order to allow on-farm use of

saved seed (Article 15.2). The Convention generally sets minimum standards of protection, which states are free to supplement. Plant variety rights last for a minimum of twenty years.

A Union for the Protection of New Varieties of Plants (UPOV) was established to oversee the operation of the Convention (Article 23). The administration of the Union is undertaken by the Office of the Union, which is overseen by a Secretary-General (Article 27). An agreement negotiated with the WIPO has established that organisation's Director-General as the Union's Secretary-General (UPOV, 26 November 1982).

Agreements on Access to Genetic Resources

States, industries, farmers and local communities make frequent and widespread use of PGR and they are regularly traded internationally. In 1983 the FAO adopted an International Undertaking on Plant Genetic Resources and established the Commission on Genetic Resources for Food and Agriculture (CGRFA). In 1993 the FAO began work to revise the Undertaking, to more effectively cover issues of access, benefit-sharing and farmers' rights, particularly in view of the recently negotiated CBD. An early suggestion was that this could take the form of a Protocol to the Convention (FAO/CGRFA, November 1994). Instead its negotiation remained within FAO which adopted the International Treaty on Plant Genetic Resources (ITPGR) for Food and Agriculture in 2001. The CBD's COP developed separate guidance in the 2002 Bonn Guidelines. Work continues under the CBD to negotiate an international regime on access and benefit-sharing.

The agreements on PGR have three main aims. The first is to ensure that access is facilitated in a fair and equitable manner, while maintaining sovereign rights. The second is to ensure that the resources are accessed and used in a manner which contributes to their conservation and sustainable use. The third is to ensure that the benefits arising from use of the resources are shared fairly and equitably – particularly in recognition of the contributions made by farmers and indigenous and local communities in countries of origin.

The FAO's major concern as an organisation is maintaining and improving food security. The CBD Secretariat's focus is on conservation and sustainable use of biodiversity. The two are strongly interconnected and while separate rules have been developed, both explicitly recognise the connections with and significance of the other organisation's work.

International Treaty on Plant Genetic Resources for Food and Agriculture

The ITPGR's objectives are conservation, sustainable use and equitable benefit-sharing for enhanced food security and sustainable agriculture of PGR that may be used in food and feed production (Article 1). The specific definition given for PGR is 'any genetic material of plant origin of actual or potential value for food and agriculture' (Article 2).

States are expected to cooperate in the collection, characterisation and documentation of PGR and to identify and address any threats to them (Article 5). In order to enable developing countries to participate in cooperative arrangements, other states should provide technical assistance for capacity-building (Articles 7, 8 and 18). Farmers' rights are recognised on the basis of their contributions to the diversity and conservation of genetic resources and states have responsibility for promoting these rights through protection of knowledge, benefit-sharing and encouragement of participation in decision-making (Article 9). No limitations are allowed to the rights 'to save, use, exchange and sell farm-saved seed/propagating materials' – however, this is qualified by the clause 'subject to national law' (Article 9.3).

Central to the Treaty is the establishment of a multilateral system of access and benefit-sharing. States agree to exercise sovereign rights over their PGR and grant access to them through this system. It covers PGR selected 'according to the criteria of food security and interdependence' (Article 11.1). The included resources are listed in Annex I to the Treaty and include thirty-seven food crops (including rice, wheat and maize) and twenty-eight forages. Access to the system's resources is to be facilitated provided that it is for research or breeding for food and agriculture and specifically not for 'chemical, pharmaceutical and/or other non-food/feed industrial uses' (Article 12.3).

Any IPR claimed on products derived from the resources must not restrict access to them in their original form (Article 12.3.d). Any benefits from use of the resources should be shared fairly and equitably through such means as information exchange, technology transfer or profit-sharing.

ITPGR's governing body is made up of all states parties and is responsible for cooperation with relevant international institutions and research centres including the CBD's COP and for establishing compliance mechanisms (Article 21). Disputes are to be settled by negotiation, mediation, arbitration, conciliation or recourse to the International Court of Justice (Article 22 and Annex 2).

Bonn Guidelines on Access to and Fair and Equitable Sharing of the Benefits Arising from the Utilisation of Genetic Resources

One of the three core objectives of the CBD is the 'fair and equitable sharing of benefits arising out of the utilization of genetic resources' and this was addressed in several of the Convention's articles including 8(j), 10(c), 15, 16 and 19. In 2000 the CBD's COP established a working group to examine development of guidance related to these provisions and on the basis of its report adopted the Bonn Guidelines in 2002.

The Guidelines are intended to be used by states 'when developing and drafting legislative, administrative or policy measures on access and benefit-sharing' (point I.A.1). The ITPGR and the WIPO are specifically mentioned in point I.D.10. The Guidelines also aim to encourage capacity-building

and technology transfer and to 'contribute to poverty alleviation and be supportive to the realization of human food security, health and cultural integrity' (point I.E.11).

The Guidelines assign specific responsibilities to various users and provider groups – examples of these are given in Table 6.1. A system of specific written prior informed consent is envisaged in the Guidelines, which involves the consent of national authorities and any relevant indigenous or local communities. Benefit-sharing should be on mutually agreed terms, provided in written documents that include provisions on the obligations of both providers and users (point IV.D.1). The types, timing and distribution of benefits should be specified, and they should be shared with 'all those who have been identified as having contributed to the resource's management, scientific and/or commercial process' (point IV.D.3). States are expected to monitor compliance with the Guidelines and promote accountability in access and benefit-sharing agreements.

Table 6.1 Examples of Responsibilities Assigned to Groups in the Bonn Guidelines

Group	Responsibility
Countries of origin	– Report on access applications – Ensure that approved uses do not prevent traditional uses – Encourage participation of indigenous and local communities (II.C.1)
Users	– 'seek informed consent prior to access' – 'respect customs, traditions and values' – maintain documents on access and use (II.C.2)
Contracting states	– prevent use without prior informed consent – encourage disclosure of country of origin in intellectual property protection applications – cooperate with other states on addressing infringements (II.C.4)
Providers	– only supply resources that they are entitled to supply – not impose 'arbitrary restrictions' (II.C.3)

Drugs Control

The development of more effective or specialised drugs for pain relief and the treatment of disease will be largely beneficial, especially if they are made widely available at reasonable cost. However, there is a long history of drugs being diverted from their legitimate medical and scientific purposes for recreational use by individuals. Abuse of and addiction to drugs can have many detrimental impacts for the health and welfare of the individual and for society, particularly due to related criminal activities.

United Nations Drugs Conventions

International controls have been applied to try to prevent the diversion of drugs from their licit uses since the early twentieth century. These

originally focused on opium and then widened to cover other narcotic drugs, psychotropic substances and precursor materials. There now exists an international control regime based on three UN conventions that aim to restrict supply to what is required for licit purposes, to prevent diversion and to treat and rehabilitate abusers. The controls work with a series of lists of controlled substances and materials (referred to as schedules or tables), which can be amended as new drugs become available or new evidence about a drug's abuse potential is found. This is key to the conventions' continued relevancy because new products are developed very rapidly.

There are three international organisations that have a role in developing and implementing the regime: The Commission on Narcotic Drugs (CND) which is responsible for policy-making for the international drugs control system (UNODC, no date a); the International Narcotics Control Board (INCB) which monitors compliance and assists implementation; and the United Nations Office on Drugs and Crime (UNODC) which assists states in fulfilling their obligations under the conventions (UNODC, no date b).

The three conventions are: the 1961 Single Convention on Narcotic Drugs; the 1971 Convention on Psychotropic Substances; and the 1988 Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances. The 1988 Convention extends control measures to precursors, materials and equipment that may be used in the illicit production of drugs and broadened the range of punishable offences. Schedules associated with the 1961 and 1971 conventions list controlled substances (Schedules I, II or IV) and controlled preparations (Schedule III). They are known as the 'yellow list' (1961 Convention) and the 'green list' (1971 Convention). They are regularly updated and form the basis for the control measures that are required. The INCB categorises substances and preparations on the following basis:

> Scheduling of substances ... is guided by the degree of seriousness of the abuse problem and the degree of usefulness of the substance in medical therapy (great, moderate, or little, if any) – in other words the risk–benefit ratio. If the liability to abuse such a substance constitutes an especially serious public health and social problem and if it does not have any usefulness in therapy, the substance is generally recommended to be added to Schedule 1 ... If the liability to abuse the substance constitutes a public health and social problem that is lesser but still substantial or significant, and in light of the degree of usefulness of the substance in therapy, it is generally recommended that the substance be added to Schedule II, III, or IV, as appropriate.
>
> (INCB, 2004, p. 26)

Under the 1961 Convention, states must provide: annual estimates of their licit drug requirements and stocks held; details of establishments producing

synthetic drugs; details of the area and location of opium poppy cultivation; annual statistical returns on quantities of drugs produced, used, seized, disposed of or kept in stocks; and quarterly returns on imports and exports. The 1971 Convention requires annual statistical returns on quantities manufactured, stocked and traded. The reports are important because they highlight where supply may exceed demand (which increases the potential for diversion) and they can help to ensure the availability of sufficient drugs for medical purposes.

The conventions require states to make certain acts – for example production, manufacture, possession, sale, purchase, import and export of illicit drugs – punishable offences. Licences should be required for licit manufacture, trade and distribution of scheduled substances (Articles 29 and 30, 1961 Convention; Article 8, 1971 Convention). Disputes can be resolved 'by negotiation, investigation, mediation, conciliation, arbitration, recourse to regional bodies, judicial process or other peaceful means' or by referral to the International Court of Justice (Article 48, 1961 Convention).

The 1988 Convention strengthens and extends the earlier conventions in two main ways – on matters considered offences and on the materials under control. It uses 'Tables' rather than schedules for listing the controlled materials; these form the 'red list' published by the INCB. Manufacture, transport or distribution of the controlled substances is an offence if they are intended for illicit use. Other offences introduced include: transfer, conversion, possession or use of property derived from commission of offences (Article 3.1.b–c); and the 'possession, purchase or cultivation of narcotic drugs or psychotropic substances for personal consumption' (Article 3.2). States are authorised to confiscate any proceeds, property, substances, equipment and financial records and to trace movements of these items. They should also obtain and/or give effect to confiscation orders on behalf of other states, as part of what is referred to as mutual legal assistance (Article 5).

The INCB produces a combined annual report on the operation of the conventions. The majority of the world's states are parties to the conventions and a majority of parties meet their reporting requirements. However, illicit trafficking and abuse of drugs remain significant global problems and there are many critics of the current control system. Criticisms range from concern about ineffectiveness caused by continued dominance of supply reduction policies to accusations that the prohibitions do more harm than good, and that states are not taking seriously the need to revise current controls (Select Committee on Home Affairs, May 2002; Transnational Institute, March 2003). There have been continual, cyclical problems in international drugs control as agreed restrictions tend to shift the problem to different substances and/or into lucrative illicit channels, while demand is maintained.

Anti-doping

Use of drugs to enhance performance in sporting events (doping) was also recognised as a problem requiring international control in the early

twentieth century but the development of formal international regulation was much slower than for illicit drugs. This may be partly due to difficulties in testing for banned substances and therefore for enforcing any bans. A variety of controls were enacted by national and international sports organisations from the 1960s but it was not until the late 1990s that work to draw these together into a unified international code began. This code – the World Anti-doping Code (WADC) – penalises athletes for use or attempted use of banned substances and other sports personnel for assisting or encouraging such use. It too makes use of an updateable list of banned substances. The WADC specifically recognises the possibility of use of genetic manipulations to enhance athletes' performance, which it refers to as 'gene doping'. The signatories of the Code are sports organisations, not governments; however, an International Convention against Doping in Sport (ICADS) has been adopted by states as a means of providing formalised governmental support for the Code. It encourages states to implement appropriate measures that support the operation of the Code in the form of legislation, regulation, policy or administrative practices (ICADS, Article 5).

The WADC sets out provisions on: doping control measures (Part 1); education, information, dissemination and research (Part 2); roles and responsibilities of organisations, athletes, support personnel and governments (Part 3); and acceptance, compliance and amendment (Part 4). Some provisions are rules that anti-doping organisations must incorporate verbatim into their own rules, others are intended as general principles with which their rules should be consistent.

Part 1 establishes offences, including use, attempted use, possession, administration and unavailability for testing. Prohibited substances and methods are listed in an annually updated document known as the Prohibited List. For substances to be included on the Prohibited List they have to meet two of the following criteria in their use: potential to enhance performance; actual or potential health risk; or violation of the spirit of sport (Article 4.3). Banned substances include: stimulants; narcotics; anabolic agents; peptide hormones; and masking agents. Prohibited methods include: enhancement of oxygen transfer; pharmacological, chemical and physical manipulation; and gene doping. Athletes may be granted Therapeutic Use Exemptions for certain substances required for medical conditions.

The Code details testing regimes and responsibilities, which must conform to international standards developed by the World Anti-doping Association (WADA). WADA accredits laboratories to conduct sample analyses. The Code also establishes procedures and punishments in the event of an adverse finding. More than 640 sports organisations had accepted the Code and ICADS had 132 states parties in February 2010.

Summary

The three UN Drugs Conventions will apply to drugs developed or produced using biotechnology where such substances are included in the lists of controlled substances. The ICADS and WADC will similarly apply to substances and methods using biotechnology that are on the Prohibited List. The list already bans the use of the method of gene doping due to concerns that athletes may find ways to use gene therapies or manipulations to enhance sporting performance.

Social and Ethical Impacts

The texts covered here take the form of declarations rather than prescribed rules and are likely to provide the foundation for future development of guidance, standards or conventions in this area. There are four relevant declarations: the Universal Declaration on the Human Genome and Human Rights (UDHGHR); the International Declaration on Human Genetic Data (IDHGD); the Universal Declaration on Bioethics and Human Rights (UDBEHR); and the United Nations Declaration on Human Cloning (UNDHC). The first three were drafted and adopted by the United Nations Educational, Scientific and Cultural Organisation (UNESCO), the fourth by the UN General Assembly.

UNESCO's role is to promote 'collaboration among the nations through education, science and culture in order to further universal respect for justice, for the rule of law and for the human rights and fundamental freedoms which are affirmed for the peoples of the world' (UNESCO, 16 November 1945, Article 1). One of its five specialised sectors is social and human sciences and within this a bioethics programme was established in 1993. New knowledge and applications of human genetics have many social and ethical implications – UNESCO provides the following outline which summarises its concerns relating to bioethics:

> In addition to issues relating to the beginning and the end of human life, bioethics covers issues raised by the donation of human organs, tissue, cells and gametes; the scientific, epidemiological, diagnostic and therapeutic uses of genetics; embryonic stem cell (ESC) research; pre-implantation genetic diagnosis (PGD); gene therapy; predictive medicine (including, for example, the problems raised by the fact that early diagnosis does not necessarily go hand in hand with availability of necessary therapies); the introduction of transgenic technology and genetically modified organisms (GMOs) into agriculture and stock breeding, etc. All these issues concern ethical choices connected with recent progress in biomedicine and other sciences that were previously inconceivable or thought to be impossible.
>
> Bioethics also deals with the persistent and critical conditions of human beings all over the world and the ethical and legal reflections

> on birth, child exploitation, gender equality, equality between different human populations, access to cures, disease prevention, death, ecology, the protection of the environment and the responsibility towards future generations.
>
> (UNESCO, 13 June 2003, paragraphs 9 and 10.)

Work on the UDHGHR started in 1993 and it was adopted in 1997. It was the first international agreement to focus on human genetics; the three subsequent declarations all built on its foundations. The declarations are also based on principles that have a longer history, giving reference to the protection of human dignity, human rights and fundamental freedoms set out in international human rights law, which has been developed since the adoption of the UN Charter in 1945. Particularly, they refer to the right to health and freedom of scientific research, the protection of human dignity and non-discrimination.

Universal Declaration on the Human Genome and Human Rights

The Declaration contains statements of principles that are intended to form the basis of national, regional and international policy-making and legislative measures. These include that:

- Discrimination on genetic grounds should not be allowed (Article 2.a).
- Prior informed consent must be received for any research on an individual's genome (Article 5).
- Individuals have the right to decide whether to be informed of genetic test results (Article 5.c).
- Genetic data linked to individuals should be kept confidential (Article 7).
- People have a right 'to just reparation for any damage sustained as a direct and determining result of an intervention' affecting their genome (Article 8).
- Research on the human genome must respect human dignity, human rights and fundamental freedoms (Article 11).
- Practices 'contrary to human dignity' should be prohibited (Article 11).
- Benefits from advances concerning the human genome should be available to all (Article 12).
- Applications relating to the human genome should 'seek to offer relief from suffering and improve the health of individuals and humankind as a whole' (Article 12).
- Research on the human genome should be supported alongside consideration of its impacts (Articles 14 and 15).
- Public health should be protected and measures taken 'to ensure that research results are not used for non-peaceful purposes' (Article 15).

There are provisions on development in Articles 18 and 19 of the UDHGHR, which encourage dissemination of scientific knowledge and scientific

cooperation relating to the human genome, particularly between developed and developing countries and cooperation with developing countries to build capacity in risk assessment and management and in research.

International Declaration on Human Genetic Data

The IDHGD covers human proteomic data as well as human genetic data and the biological samples they are derived from. Article 2 defines human genetic data as 'information about heritable characteristics of individuals obtained by analysis of nucleic acids or by other scientific analysis' and human proteomic data as 'information pertaining to an individual's proteins'. The Declaration covers collection, processing, storage and use of such data and samples, except where they are undertaken for 'the investigation, detection and prosecution of criminal offences' or parentage testing as long as the exempted activities are consistent with human rights (Article 1.c). Article 4 outlines why human genetic data are given special status and are entitled to special protection; this includes that they can: predict genetic predispositions; have an impact on the individual's family or wider community groups; and 'contain information the significance of which is not necessarily known at the time of the collection of the biological samples' (Article 4.a.i–iii). The data should only be collected for particular purposes, the first three of which are more specific – diagnosis and health care; medical and scientific research; and forensic medicine, civil, criminal and legal proceedings – the fourth is more general, allowing any purpose 'consistent with the Universal Declaration on the Human Genome and Human rights' (Article 5).

The need for prior informed consent is emphasised in collection, processing, storage and use (Articles 6, 8, 14, 16 and 17). People should have the right 'to decide whether or not to be informed about research results' (Article 10), and genetic counselling should be provided whenever 'genetic testing that may have significant implications for a person's health is being considered' (Article 11).

There are clauses on confidentiality of data, which, in particular, is not to 'be disclosed or made accessible to third parties' – this specifically includes employers and insurance companies (Article 14.b). However, there is a caveat that this is unless consent has been given or there is 'an important public interest reason' (Article 14), a term which is not defined. Data and samples should not be used for a different purpose than that for which they were collected, with the same exceptions as Article 14 (Article 16).

There are some development clauses in Articles 18 and 19. Transnational movements of biological samples or data ought to be regulated to protect individuals and promote international medical and scientific cooperation and fair access (Article 18). Scientific knowledge should be disseminated internationally and scientific and cultural cooperation is particularly encouraged between industrialised and developing states (Article 18). Benefits should be shared with 'society as a whole and the international

community'; these may include, for example, access to medical care, support for health services and capacity-building for research, collection and use of data/samples (Article 19).

Universal Declaration on Bioethics and Human Rights

The UDBEHR aims to provide universal ethical principles to serve as a foundation of societal and governmental responses to developments in the life sciences, particularly as they apply to or affect humans (Article 1). It states that the welfare and interests of individuals 'should have priority over the sole interest of science and society' (Article 3). Benefits from developments in life sciences should be maximised and harms minimised (Article 4). Privacy, confidentiality, equality, justice and equity should be respected (Articles 9 and 10) and there should be no discrimination or stigmatisation on genetic or other biological grounds (Article 11).

Scientific and technological developments should be directed towards measures that promote health, including access to health care, medicine, adequate nutrition and water, improved living conditions, reduced poverty, illiteracy and marginalisation (Article 14). Benefits 'should be shared with society as a whole and within the international community, in particular with developing countries' (Article 15), and the impact of developments on future generations should be considered (Article 16), the environment and biodiversity protected, access to and use of genetic resources facilitated and traditional knowledge respected (Article 17).

Research involving more than one country should be consistent with the Declaration and take into account the importance of 'research contributing to the alleviation of urgent global health problems' (Article 21.3). States are encouraged to take preventative actions against bioterrorism and illicit traffic in biological resources (Article 21.5). Limitations may be placed on the application of the Declaration's principles for reasons of public safety, public health or for criminal investigations (Article 27).

United Nations Declaration on Human Cloning

The UNDHC, while based on principles of the UDHGHR, was developed by the UN General Assembly, rather than UNESCO. It was intended to be a legally binding convention; however, this idea was dropped due to difficulties reaching an agreement on the status of therapeutic cloning. The Declaration states that human cloning is recognised as a particular threat to human dignity, human rights and fundamental freedoms. It calls on states to take necessary measures for the protection of human life 'in applications of the life sciences' (point a), 'prohibit all forms of human cloning' (point b), and prohibit any other applications of genetic engineering that are 'contrary to human dignity' (point c). There is also a clause that asks states 'to take into account the pressing global issues such as HIV/AIDS, tuberculosis and

malaria, which affect in particular the developing countries' in their financing of medical research (point f).

The Declaration is controversial and the support of many states was withheld because it failed to distinguish between reproductive and therapeutic human cloning, the latter of which is considered by many states to be legitimate and ethically justifiable, particularly for medical research (see for example press releases made by states following the General Assembly vote on the Declaration – UNGA, 8 March 2005).

Conclusion

This chapter has identified the thirty-seven international regulations that are currently relevant to governance of biotechnology across the issue areas of arms control, health and disease control, environmental protection, trade, drugs control and social and ethical impacts. No separate regulations were identified in the area of development, but many of the other regulations contain clauses promoting technical and financial assistance, information exchange and technology transfer, which are intended to make contributions to development.

Chapters 5 and 6 have provided the background for the analysis that follows in the third section of the book. This is often quite technical in nature, providing significant additional details that enable assessment of how closely the biotechnology regulations (as outlined in this chapter) match the model (outlined in Chapter 5).

7. Coherence in the Biotechnology Regulations: Purpose, Principles, Development and Identity

The analysis of the degree to which the international biotechnology regulations display the characteristics of coherent regulatory sets begins in this chapter with assessment on the characteristics of having a common primary purpose, sharing common principles and a common historical development, and having a common identity that indicates external awareness of their connectedness. The method of analysis for the characteristic is outlined, before the findings are discussed. Table 7.1, at the end of this chapter, provides a summary list of the regulations, their associated oversight bodies, and dates of adoption and entry into force.

Common Purpose

In order to identify the main purpose of the regulation the texts were searched for explicit statements of purpose, firstly in the main clauses, and if not identified within these, then in the preamble or introductory text. If nothing was stated explicitly in the regulatory text, then the purpose was identified either by deduction and/or from information provided by the appropriate international organisation. The purposes were then compared to see whether any similarities existed. The primary purposes are summarised in Table 7.2 at the end of this chapter. From the analysis that follows it is clear that the biotechnology regulations do not have a common primary purpose; however, there is commonality among some of the regulations within issue areas.

Analysis

Most of the regulations introduced in Chapter 6 were not primarily designed to deal with the applications and impacts of biotechnology. In fact, as noted earlier, some of the regulations were in force prior to the scientific revolution taking place. Their treatment of biotechnology is often as a sub-issue and in some cases incidental to the main purpose of the regulation. The primary purposes of the regulations (as listed in Table 7.2) vary widely and it is clear that there is no common purpose to the regulations in regard to governing biotechnology. Of the thirty-seven regulations, only nine are primarily aimed at controlling its applications and impacts; it is not surprising to find that these have all been adopted within the past thirteen years. They are the:

- Universal Declaration on the Human Genome and Human Rights (1997)
- Cartagena Protocol on Biosafety (2000)
- Codex Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (2003)

- Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (2003)
- Codex Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms (2003)
- International Declaration on Human Genetic Data (2003)
- Universal Declaration on Bioethics and Human Rights (2005)
- United Nations Declaration on Human Cloning (2005)
- Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals (2008)

Common Principles

In order to identify the principles on which the regulations are based, their texts were searched for principles stated explicitly in either the main text or preamble, in the form of normative statements rather than substantive action points (which come under unifying and complementary provisions covered in Chapter 8).

The picture here is a little more complex than for common purpose. As well as some of the regulations within issue areas sharing common principles, there are some common principles shared by regulations in different issue areas. A particular synthesis exists between some of the trade regulations and the health regulations. But there are also significant divergences of principles between and within some of the issue areas and there are no principles common to all of the regulations. Some summary examples of common principles and divergent principles are given below.

Analysis

Common Principles within Issue Areas

For arms control:

- Certain means and methods of warfare should be prohibited due to the grave risks they pose to humankind; and
- Means and methods of warfare must not be indiscriminate or cause unnecessary suffering.

These principles can be found in all four of the arms control agreements that are relevant to biotechnology. For example:

> *Determined*, for the sake of all mankind, to exclude completely the possibility of bacteriological (biological) agents and toxins being used as weapons,
>
> *Convinced* that such use would be repugnant to the conscience of mankind;
>
> (Biological Weapons Convention, Preamble)

> *Desiring* to prohibit effectively military or any other hostile use of environmental modification techniques in order to eliminate the dangers to mankind from such use;
>
> (EnMod Convention, Preamble)

> *Determined* for the sake of all mankind, to exclude completely the possibility of the use of chemical weapons;
>
> (Chemical Weapons Convention, Preamble)

For health, in the area of disease control:

- Reasonable measures should be taken to prevent the spread of disease, but restrictions on travel and trade should be minimised because these can cause severe economic damage.

This principle can be found in the International Health Regulations (IHR), the Terrestrial Animal Health Code and the International Plant Protection Convention:

> The purpose and scope of these Regulations are 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, and which avoid unnecessary interference with international traffic and trade.
>
> (IHR, Article 2)

> International trade in animals and animal products depends on a combination of factors which should be taken into account to ensure unimpeded trade without incurring unacceptable risks to human and animal health.
>
> (TAHC, Article 5.1.1)

> *Recognizing* that phytosanitary measures should be technically justified, transparent and should not be applied in such a way as to constitute either a means of arbitrary or unjustified discrimination or a disguised restriction, particularly on international trade;
>
> (IPPC, Preamble)

For environmental protection:

- Biodiversity should be protected through the identification and management of risks and the promotion of beneficial technologies, including modern biotechnologies; and
- It is also necessary to protect the environment and human health from potential adverse effects of modern biotechnology.

These principles can be identified throughout the Convention on Biodiversity (CBD) and the Cartagena Protocol on Biosafety, for example:

> Each Contracting Party, recognizing that technology includes biotechnology, and that both access to and transfer of technology among Contracting Parties are essential elements for the attainment of the objectives of this Convention, undertakes subject to the provisions of this Article to provide and/or facilitate access for and transfer to other Contracting Parties of technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment.
>
> (CBD, Article 16.1)

> 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 Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question as referred to in paragraph 3 above, in order to avoid or minimize such potential adverse effects.
>
> (Cartagena Protocol, Article 10.6)

For trade, in the area of free trade:

- Barriers to trade which are not scientifically justified unnecessarily restrict trade and should be removed;
- There must be scientific evidence of harm for action taken against that harm to be justified; and
- Trade restrictions on health protection grounds are permissible but must not be more trade restrictive than necessary (i.e. scientifically justified).

These principles can be found in the Sanitary and Phytosanitary (SPS) Agreement and Technical Barriers to Trade Agreement:

> Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence.
>
> (SPS Agreement, Article 2.1)

> Members should, when determining the appropriate level of sanitary and phytosanitary protection, take into account the objective of minimising negative trade effects.
>
> (SPS Agreement, Article 5.4)

> Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create … In assessing such risks, relevant elements of consideration are, *inter alia*: available scientific and technical information, related processing technology or intended end-uses of products.
>
> (TBT Agreement, Article 2)

For trade, in the area of intellectual property protection:

- People should be able to protect their intellectual property and to benefit commercially from its exploitation. This will facilitate technology transfer and promote economic growth.

These principles are incorporated in the Agreement on Trade Related Aspects of Intellectual Property Rights and the Patent Cooperation Treaty:

> A patent shall confer on its owner the following exclusive rights:
> (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product;
> (b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.
>
> (TRIPS Agreement, Article 28.1)

> The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge, and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.
>
> (TRIPS Agreement, Article 7)

> *Desiring* to make a contribution to the progress of science and technology,
> *Desiring* to perfect the legal protection of inventions,
> *Desiring* to simplify and render more economical the obtaining of protection for inventions where protection is sought in several countries,

> *Desiring* to facilitate and accelerate access by the public to the technological information contained in documents describing new inventions,
>
> *Desiring* to foster and accelerate the economic development of developing countries through the adoption of measures designed to increase the efficiency of their legal systems,
>
> (PCT, Preamble)

For trade, in the area of access to genetic resources:

- The conservation and sustainable use of plant genetic resources are vital for food security, and conditions should be placed on access to ensure it meets these aims;
- Farmers, indigenous and local groups who have contributed to the development of plant genetic resources and countries of origin have the right to set conditions on (but not prohibit) access to those resources, and to benefit from any subsequent commercial use.

These principles can be found in the International Treaty on Plant Genetic Resources and in the Bonn Guidelines on Access to Genetic Resources, for example:

> *Acknowledging further* that plant genetic resources for food and agriculture are the raw material indispensable for crop genetic improvement, whether by means of farmers' selection, classical plant breeding or modern biotechnologies, and are essential in adapting to unpredictable environmental changes and future human needs;
>
> *Affirming* that the past, present and future contributions of farmers in all regions of the world, particularly those in centres of origin and diversity, in conserving, improving and making available these resources, is the basis of Farmers' Rights;
>
> (ITPGR, Preamble)

> Providers should:
>
> Only supply genetic resources and/or traditional knowledge when they are entitled to do so;
>
> Strive to avoid imposition of arbitrary restrictions on access to genetic resources.
>
> (Bonn Guidelines, Part II.C)

For drugs control:

- Human health and welfare should be protected from the negative effects of drug abuse and the drugs trade;
- Sufficient availability of drugs should be maintained for legitimate scientific and medical purposes.

These principles are incorporated into the United Nations Drugs Conventions and the International Convention against Doping in Sport. For example:

> *Concerned* with the health and welfare of mankind,
>
> *Recognizing* that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes,
>
> *Recognizing* that addiction to narcotic drugs constitutes a serious evil for the individual and is fraught with social and economic danger to mankind,
>
> (Single Convention on Narcotic Drugs, Preamble)

> No measures taken pursuant to this Convention will impede the availability for legitimate purposes of substances and methods otherwise prohibited or controlled in sport.
>
> (ICADS, Article 8.3)

For social and ethical impacts:

- All research and development in and applications of the life sciences which involve humans should not contravene the rules/principles of human dignity, fundamental freedoms and human rights.

These principles can be found in the Universal Declaration on the Human Genome and Human Rights, the International Declaration on Human Genetic Data, the Universal Declaration on Bioethics and Human Rights and the United Nations Declaration on Human Cloning:

> *Recognizing* that research on the human genome and resulting applications open up vast prospects for progress in improving the health of individuals and of humankind as a whole, but *emphasizing* that such research should fully respect human dignity, freedom and human rights, as well as the prohibition of all forms of discrimination based on genetic characteristics,
>
> (UDHGHR, Preamble)

> *Reaffirming* the principles established in the Universal Declaration on the Human Genome and Human Rights and the principles of equality, justice, solidarity and responsibility as well as respect for human dignity, human rights and fundamental freedoms, particularly freedom of thought and expression, including freedom of research, and privacy and security of the person, which must underlie the collection, processing, use and storage of human genetic data,
>
> (IDHGD, Preamble)

> Human dignity, human rights and fundamental freedoms are to be fully respected.
>
> (UDBEHR, Article 3.1)

> *Emphasizing* that the promotion of scientific and technical progress in life sciences should be sought in a manner that safeguards respect for human rights and the benefit of all.
>
> (UNDHC, Preamble)

Areas of Commonality of Principles across Issue Areas
Arms control and drugs control:
Both of these areas deal with the control of dual-use materials, and they contain some common principles in this regard, for example:

- Dual-use materials should only be developed and used for legitimate purposes;
- Rules on dual-use materials and equipment should not be used as an excuse for unjustified restrictions on trade or development;
- Dual-use materials can have benefits when used for legitimate purposes.

Examples include, from the Biological Weapons Convention (BWC): 'The States Parties to this Convention undertake to facilitate, and have the right to participate in, the fullest possible exchange of equipment, materials and scientific and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes' (Article X.1).

And from the preamble to the Convention on Psychotropic Substances: 'Recognizing that the use of psychotropic substances for medical and scientific purposes is indispensable and that their availability for such purposes should not be unduly restricted.'

Disease control and rules on free trade:
The key agreements on disease control for human, animal and plant health (the International Health Regulations, the Terrestrial and Aquatic Animal Health Codes and the International Plant Protection Convention) all share the principle of not allowing controls to unjustifiably restrict international trade. This is supported by the principle in the Sanitary and Phytosanitary and Technical Barriers to Trade Agreements that while some health protective measures may be justifiable, these should only be used where necessary and should be designed to have minimal impacts on trade.

Examples from the trade agreements include:

> *Recognizing* that no country should be prevented from taking measures necessary to ensure the quality of its exports, or for the protection of human, animal or plant life or health … subject to the requirement that

> they are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between Members where the same conditions prevail or a disguised restriction on international trade.
>
> (TBT Agreement, Preamble)

> *Reaffirming* that no Member should be prevented from adopting or enforcing measures necessary to protect human, animal or plant life or health, subject to the requirement that these measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between Members where the same conditions prevail or a disguised restriction on international trade.
>
> (SPS Agreement, Preamble)

Examples from the disease control agreements include:

> The purpose and scope of these Regulations are 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, and which avoid unnecessary interference with international traffic and trade.
>
> (IHR, Article 2)

> International trade in animals and animal products depends on a combination of factors which should be taken into account to ensure unimpeded trade without incurring unacceptable risks to human and animal health.
>
> (TAHC, Article 5.1.1)

Another common principle is shared by the Sanitary and Phytosanitary Agreement, the Technical Barriers to Trade Agreement and the Terrestrial Animal Health Code – different measures that achieve the same level of protection should be treated as equivalent.

For example:

> Members shall give positive consideration to accepting as equivalent technical regulations of other Members, even if these regulations differ from their own, provided that they are satisfied that these regulations adequately fulfil the objectives of their own regulations.
>
> (TBT Agreement, Article 2.7)

> Members shall accept the sanitary or phytosanitary measures of other Members as equivalent, even if these measures differ from their own or from those used by other Members trading in the same product, if the

> exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary or phytosanitary protection.
>
> (SPS Agreement, Article 4.1)

> It is now recognised that significantly different animal health and production systems can provide equivalent animal and human health protection for the purpose of international trade, with benefit to both the importing country and the exporting country.
>
> (TAHC, Chapter 5.3.2)

Broader Commonalities

- Human health and welfare should be protected.

This principle can be found in the International Health Regulations, Terrestrial Animal Health Code, Codex Alimentarius Principles and Guidelines, Laboratory Biosafety Manual, Laboratory Biosecurity Guidance, Sanitary and Phytosanitary Agreement, UN Drugs Conventions and the World Anti-doping Code. For example:

> In essence the outcome of the safety assessment process is to define the product under consideration in such a way as to enable risk managers to determine whether any measures are needed to protect the health of consumers and if so to make well-informed and appropriate decisions in this regard.
>
> (Codex Guideline Recombinant-DNA Microorganisms, point 25)

> International trade in animals and animal products depends on a combination of factors which should be taken into account to ensure unimpeded trade, without incurring unacceptable risks to human and animal health.
>
> (TAHC, Article 5.1.1)

- Risk analysis, assessment and management are important for effective control.

This principle can be found in the: International Health Regulations; Terrestrial Animal Health Code; International Plant Protection Convention; Codex Alimentarius Principles and Guidelines; Laboratory Biosafety Manual; Laboratory Biosecurity Guidance; Guidance on Regulations for the Safe Transport of Infectious Substances; Manual of Diagnostic Tests and Vaccines for Terrestrial Animals and Cartagena Protocol. For example:

> The backbone of the practice of biosafety is risk assessment.
>
> (Laboratory Biosafety Manual, p. 7)

10. If a new or altered hazard, nutritional or other safety concern is identified by the safety assessment, the risk associated with it should be characterized to determine its relevance to human health.
13. Risk assessment should apply to all relevant aspects of foods derived from modern biotechnology.
16. Risk management measures for foods derived from modern biotechnology should be proportional to the risk.

(Codex Principles)

Divergent Principles

As well as these areas of commonality, areas of tension can be identified among some of the principles embodied in the regulations. This is shown in the following two examples.

Intellectual property rights and access to genetic resources:

While the agreements on access to and benefit-sharing from the use of genetic resources include the right of farmers, local and indigenous groups to benefit from the commercial exploitation of resources that they have helped to develop, or knowledge they have about those resources, these rights are not incorporated into the rules on intellectual property protection. In those rules it is only the person/institution that took the 'innovative step' that is guaranteed reward from an invention's commercial exploitation. Some discoveries/organisms are excluded from patentability, but not all, nor their products. Some controversial cases have already occurred including disputes over the patenting of basmati rice and neem products (BBC News Online, 9 March 2005; Browne, 25 June 2000; Vidal, 8 September 2003).

This is a complex area in terms of which rules should apply or be used internationally. There have been some attempts to address these issues, including within the World Trade Organisation, World Intellectual Property Organisation, Commission on Genetic Resources for Food and Agriculture and the CBD Secretariat. One promising collaboration is that between the CBD conferences of the parties and the World Intellectual Property Organisation, which in the long term may help to resolve some of these issues (see for example CBD, April 2002, 16 January 2006; WIPO, no date; WTO, 8 August 2002). However, the content of the regulations themselves is unlikely to change in the near future.

To illustrate, these provisions from the Agreement on Trade Related Aspects of Intellectual Property Rights:

1. ... Patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.
2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is

necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment …

3. Members may also exclude from patentability: … (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof.

(TRIPS, Article 27)

A patent shall confer on its owner the following exclusive rights:

a. where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling or importing for these purposes that product;
b. where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

(TRIPS, Article 28.1)

can be compared to the following provisions from the International Treaty on Plant Genetic Resources for Food and Agriculture:

1. The Contracting Parties recognize the enormous contribution that the local and indigenous communities and farmers of all regions of the world, particularly those in the centres of origin and crop diversity, have made and will continue to make for the conservation and development of plant genetic resources which constitute the basis of food and agriculture production throughout the world.
2. The Contracting Parties agree that the responsibility for realizing Farmers' Rights as they relate to plant genetic resources for food and agriculture, rests with national governments. In accordance with their needs and priorities, each Contracting Party, should, as appropriate, and subject to its national legislation, take measures to protect and promote Farmers' Rights including:
   (a) protection of traditional knowledge relevant to plant genetic resources for food and agriculture;
   (b) the right to equitably participate in sharing benefits arising from the utilization of plant genetic resources for food and agriculture; and
   (c) the right to participate in making decisions, at the national level, on matters relating to the conservation and sustainable use of plant genetic resources for food and agriculture.

> 3. Nothing in this Article shall be interpreted to limit any rights that farmers have to save, use, exchange and sell farm-saved seed/ propagating material, subject to national law and as appropriate.
>
> (ITPGR, Article 9)

> 3. (b) Access shall be accorded expeditiously, without the need to track individual accessions and free of charge, or, when a fee is charged, it shall not exceed the minimal cost involved …
> (d) Recipients shall not claim any intellectual property or other rights that limit the facilitated access to the plant genetic resources for food and agriculture, or their genetic parts or components, in the form received from the multilateral system …
> (f) Access to plant genetic resources for food and agriculture protected by intellectual and other property rights shall be consistent with relevant international agreements
>
> (ITPGR, Article 12)

Protection of biodiversity and rules on free trade:

A second example of tensions between principles is found between the Cartagena Protocol and the Sanitary and Phytosanitary Agreement and Technical Barriers to Trade Agreement. The Cartagena Protocol incorporates the precautionary principle allowing action to be taken to prevent harm occurring even if, as yet, there is insufficient scientific evidence that the harm may occur. The Protocol applies this principle specifically to decisions on the import of genetically modified organisms (GMOs) and thus it is, under the Protocol, legitimate for a state to implement trade restrictions on a precautionary basis. The Technical Barriers to Trade Agreement, on the other hand, demands evidence of harm for a trade restriction to be justified. Some flexibility is provided in Clause 5.7 of the SPS Agreement (see below) but there is great uncertainty over precisely what the standards are for applying this clause, and for whether it applies to GMO import decisions at all.

The precautionary principle incorporated in the Cartagena Protocol is derived from Principle 15 of the Rio Declaration, which states: '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' (UN General Assembly, 12 August 1992).

If measures to conserve biodiversity are considered to be protecting plant health, then they may come under the SPS Agreement – however, this Agreement does not refer to the CBD or Cartagena Protocol as acceptable sources of international standards. Import restrictions on living modified organisms to conserve biodiversity may therefore come under the Technical Barriers to Trade Agreement.

The relevant provisions of the SPS Agreement are:

1. Members have the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health, provided that such measures are not inconsistent with the provisions of this Agreement.
2. Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence.

(SPS Agreement, Article 2)

2. In the assessment of risks, Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment.
7. In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information … In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.

(SPS Agreement, Article 5)

The relevant provision of the TBT Agreement is:

> Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade restrictive than necessary to fulfil a legitimate objective … Such legitimate objectives are, *inter alia*: national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment. In assessing such risks, relevant elements of consideration are, *inter alia*: available scientific and technical information, related processing technology or intended end uses of products.
>
> (TBT Agreement, Article 2.2)

The Appellate Body of the World Trade Organisation when considering the EC-Hormones case under its Dispute Settlement Understanding looked at the precautionary principle and how it relates to the SPS Agreement (particularly to Article 5.7). Firstly, the Appellate Body refused to take a position on the

status of the principle in international law. In regard to its relationship with the SPS Agreement it made four additional points:

- That the principle has not been written into the Agreement as a basis for allowing measures that would otherwise contravene the Agreement
- That some reflection of the principle can be found in the Agreement, particularly where it allows states to apply more stringent measures than exist in the international standards
- That if a panel were to examine if 'sufficient scientific evidence' existed for a particular measure, it could take into account that 'governments commonly act from perspectives of prudence and precaution where risks of irreversible, e.g. life-terminating, damage to human health are concerned'
- That 'the precautionary principle does not, by itself, and without a clear textual directive to that effect, relieve a panel from the duty of applying the normal (i.e. customary international law) principles of treaty interpretation in reading the provisions of the SPS Agreement' (WTO, no date).

This does not resolve confusion over whether the precautionary principle may be applied to imports of GMOs, particularly since the third point seems to apply to threats only to human health, not to the environment.

Common Historical Development

As mentioned in Chapter 5, common historical development does not require the regulations to have been adopted at the same time, but that their principles and provisions have a common developmental history. To assess whether common development exists, documents on the regulations' history were examined. The main sources of these documents were international organisations, NGOs, academic groups and individual authors. The documents consulted were mainly fact sheets, journal articles and books.

Within some of the issue areas a common path of historical development can be identified. For example a common history can be identified for three of the arms control regulations and for the CBD and the Cartagena Protocol. This is not the case across the whole regulatory set, nor is it always the case within issue areas. Some key points in the historical development of the regulations are outlined below.

Analysis

Arms Control

A common historical development can be identified for the Geneva Protocol, the BWC and the Chemical Weapons Convention (CWC). The BWC and CWC were developed to reinforce and supplement the prohibitions of the Geneva Protocol. This is shown in the Conventions' preambles:

> *Recognizing* the important significance of the Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare
>
> *Recognizing* that an agreement on the prohibition of bacteriological (biological) and toxin weapons represents a first possible step towards the achievement of agreement on effective measures also for the prohibition of the development, production and stockpiling of chemical weapons, and determined to continue negotiations to that end,
>
> (BWC, Preamble)

> *Recognizing* that this Convention reaffirms principles and objectives of and obligations assumed under the Geneva Protocol of 1925, and the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction,
>
> (CWC, Preamble)

The Environmental Modification (EnMod) Convention does not have a strong connection to this historical development (although it is also grounded in the principles of international humanitarian law). It prohibits specific *uses* of weapons/methods of warfare, whereas the other three agreements prohibit the use of specific *types* of weapons.

Health

The disease control regulations developed separately in the areas of human, animal and plant health. They were, however, originally adopted within eleven years of each other (the Terrestrial Animal Health Code in 1968; the International Health Regulations in 1969; and the International Plant Protection Convention in 1979) and for the same basic motivation of protecting health while minimising trade disruptions. The World Health Organisation (WHO), which oversees the IHR, and the Office International des Epizooties (OIE), which oversees the Terrestrial Animal Health Code, both developed manuals to promote biosafety in laboratories as a further mechanism for preventing disease spread. The WHO developed a separate document dealing with guidelines for transport of infectious substances and diagnostic specimens – again to prevent disease spread. The OIE included sections on this subject in both its Terrestrial Code and Terrestrial Manual. The international organisations responsible for the IHR and International Plant Protection Convention (the WHO and Food and Agriculture Organisation) combined their efforts at promoting food safety through the creation of the Codex Alimentarius Commission in 1963. The Commission developed the principles and guidelines on assessing the safety of foods produced using modern biotechnology, which were adopted in 2003.

Environmental Protection

The two environmental agreements also have a closely shared history – the Cartagena Protocol was a direct development of and addition to the CBD. The potential need for such a protocol was outlined in Article 19 of the Convention – Handling of Biotechnology and Distribution of Its Benefits: 'The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have an adverse effect on the conservation and sustainable use of biological diversity.'

Trade

The SPS Agreement and the Technical Barriers to Trade Agreement have a common history in the development of free trade rules, outlined in Chapter 8. The other World Trade Organisation agreement of relevance to the control of biotechnology, the Trade Related Aspects of Intellectual Property Rights Agreement, does not share the same history. In fact, it has a closer historical connection to the Patent Cooperation Treaty and Patent Law Treaty of the World Intellectual Property Organisation, as they all relate to the international protection of intellectual property rights. Regulation of intellectual property did not extend into the free trade area until 1995. The International Convention for the Protection of New Varieties of Plants developed separately from the other rules on intellectual property and the rules governing access to genetic resources developed separately from the other trade rules.

Drugs Control

In the area of drugs control the two distinct sets of regulations have separate developmental histories. The United Nations Drugs Conventions were developed from 1961 to 1988 (built on agreements developed since the early twentieth century) and they focus on the control of illicit drugs in the international trade system. The international rules on anti-doping took longer to codify, only being formally approved by states in 2005; they focus on illicit use of performance-enhancing substances in sport, and are primarily directed at sports organisations.

Social and Ethical Impacts

The four international declarations in this area have a common history in the development of international human rights principles and rules. The Universal Declaration on the Human Genome and Human Rights, the International Declaration on Human Genetic Data and the Universal Declaration on Bioethics and Human Rights were all developed by the International Bioethics Committee and Intergovernmental Bioethics

Committee within the United Nations Educational, Scientific and Cultural Organisation (UNESCO). The United Nations Declaration on Human Cloning was developed within the UN General Assembly's Sixth Committee, using the principles of the Universal Declaration on the Human Genome and Human Rights as its basis. Article 11 of the Universal Declaration on the Human Genome and Human Rights specifically invited states to consider developing such an instrument: 'Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted. States and competent international organizations are invited to cooperate in identifying such practices and in taking, at national or international level, the measures necessary to ensure that the principles set out in this Declaration are respected.'

Summary

As a set the regulations applicable to the international control of biotechnology do not share a common developmental history, although within issue areas there are often many connections. The regulations largely developed separately from one another (or at least within different issue areas). They developed at different times, and thus in different historical contexts. The dates of adoption range across more than eighty years (from 1925 to 2008). Table 7.1 at the end of this chapter provides a full listing of adoption dates. Some of the regulations were adopted prior to even the scientific side of the biotechnology revolution occurring (mid-1970s) and several more before its full socio-economic implications began to be widely discussed.

Common Identity

Common identity was defined in Chapter 5 as external awareness of connections between the regulations. This identity would be established in the regulations themselves, or by the international organisation that oversees them, and would be evidenced in how the regulations are referred to by the public, media, governments and other groups and organisations – i.e. whether they are frequently referred to as a complete regulatory set. In order to assess this, evidence of external awareness was searched for in documents on the regulations, and on regional and national biotechnology regulations.

The biotechnology regulations lack such a common identity; however, there are indications that external awareness of the connections is gradually increasing. This awareness is still often limited to less than the full range of regulations. A common identity for the regulations has not yet gained general acceptance, but may be emerging.

Analysis

Some of the regulations share a common identity within an issue area. The clearest examples of this are the Single Convention on Narcotic Drugs, the

Convention on Psychotropic Substances and the Convention against Illicit Trade in Narcotic Drugs and Psychotropic Substances, which are commonly known as the 'UN Drugs Conventions'; and the Sanitary and Phytosanitary Agreement, Technical Barriers to Trade Agreement and Agreement on Trade Related Aspects of Intellectual Property Rights, which are all part of what are known as the 'World Trade Organisation agreements'.

The following studies have identified some of the regulations as biotechnology regulations:

- MacKenzie, R. (no date) *Globalisation and the International Governance of Modern Biotechnology – The International Regulation of Modern Biotechnology*.

This mentions: the International Plant Protection Convention; the Cartagena Protocol; the Codex Alimentarius (it was published prior to adoption of the principles and guidelines); the Sanitary and Phytosanitary Agreement; the Technical Barriers to Trade Agreement; the Trade Related Aspects of Intellectual Property Rights Agreement; those international standards referred to in the Sanitary and Phytosanitary Agreement (i.e. those of the Codex Alimentarius Commission, the International Plant Protection Convention and the Office International des Epizooties); and the World Trade Organisation's Dispute Settlement Understanding.

- United Nations Conference on Trade and Development (UNCTAD) (26 April 2001), *Panel on Legal and Regulatory Issues in Biotechnology: Summary Report*.

This mentions: the Trade Related Aspects of Intellectual Property Rights Agreement; the Convention for the Protection of New Varieties of Plants; the Convention on Biodiversity; the Cartagena Protocol; the Sanitary and Phytosanitary Agreement; the Technical Barriers to Trade Agreement; and the Codex Alimentarius Commission.

- Glowka, L. (2003) *Law and Modern Biotechnology: Selected Issues of Relevance to Food and Agriculture*, Rome: FAO Legal Office.

This mentions in its list of 'International Instruments Related to Modern Biotechnology': the Codex Principles and Guidelines (at this stage they were drafts); the International Treaty on Plant Genetic Resources; the International Plant Protection Convention; the Convention on Biodiversity; the Cartagena Protocol; the Sanitary and Phytosanitary Agreement; and the Technical Barriers to Trade Agreement.

- Blay, S. (2005) 'International Regulation of Biotechnology: Problems and Prospects', *Journal of International Biotechnology Law*, 02: 245–51.

This refers to: the Universal Declaration on the Human Genome and Human Rights; the International Declaration on Human Genetic Data; the United Nations Declaration on Human Cloning; the Convention on Biodiversity; the Cartagena Protocol; the International Plant Protection Convention; the International Treaty on Plant Genetic Resources; and the Trade Related Aspects of Intellectual Property Rights Agreement.

- Murphy, S. D. (Winter 2001) 'Biotechnology and International Law', *Harvard International Law Journal*, 42(1): 47–139.

This mentions: the World Intellectual Property Organisation; the Trade Related Aspects of Intellectual Property Rights Agreement; the Convention on Biodiversity; the Cartagena Protocol; the Sanitary and Phytosanitary Agreement; the Technical Barriers to Trade Agreement; the International Plant Protection Convention; and the World Trade Organisation.

Two further examples of awareness of the connections between the different areas of regulation in their relevance to control of biotechnology can be found in a guide to the UK's national biotechnology regulation – the *ibioUK Biotechnology Regulatory Atlas* (DTI/LGC Ltd, 2003) – which covers regulations in the areas of: strategy and society; intellectual property; safety and welfare; contained use of GMOs; deliberate release of GMOs; medical products; human genetics and therapy; environmental and chemical; and food and agriculture. And in a *Users Guide to European Regulation in Biotechnology* (LGC Ltd, 2005) which contains sections on: access to information; contained use of GMOs; release and commercialisation of GMOs; the genetically modified food and feed chain; transportation and international (transboundary) movement of GMOs; medicinal products and health care; and intellectual property.

Regulations at different levels (local, national, regional or international) will attach different importance to different issues, but both of these examples show awareness of the connections between the health, environmental, social and trade issues in the regulation of biotechnology.

Conclusion

The biotechnology regulations clearly fail to match the first four characteristics of coherent international regulation. They do not have a common purpose, and while some principles are shared by more than one regulation, there are none that extend across the full regulatory set. Shared historical development can be identified within some issue areas, but again it is not present for the set as a whole. There are positive signs of awareness of the connections between some of the regulations in their relevance to biotechnology, but they do not yet have a common identity.

Table 7.1 The Regulations, Their Oversight Bodies and Dates of Adoption and Entry into Force

Regulation	Oversight body	Date of adoption/ latest edition	Date of entry into force
1925 Geneva Protocol	n/a	1925	1928
Biological Weapons Convention	n/a	1972	1975
EnMod Convention	n/a	1976	1978
Chemical Weapons Convention	Organisation for the Prohibition of Chemical Weapons	1993	1997
International Health Regulations	World Health Organisation	2005	2007
Laboratory Biosafety Manual	World Health Organisation	2004	n/a
Laboratory Biosecurity Guidance	World Health Organisation	2006	n/a
Guidance on Regulations for the Transport of Infectious Substances	World Health Organisation	2009	n/a
Terrestrial Animal Health Code	Office International des Epizooties	18th edition, 2009	n/a
Aquatic Animal Health Code	Office International des Epizooties	12th edition, 2009	n/a
Manual of Diagnostic Tests and Vaccines for Terrestrial Animals	Office International des Epizooties	6th edition, 2008	n/a
Manual of Diagnostic Tests for Aquatic Animals	Office International des Epizooties	5th edition, 2006	n/a
International Plant Protection Convention	Food and Agriculture Organisation	1997	2005
Principles for the Risk Analysis of Foods Derived from Modern Biotechnology	Codex Alimentarius Commission	2003	As implemented by each member state
Guideline for Food Safety Assessment – Recombinant-DNA Microorganisms	Codex Alimentarius Commission	2003	As implemented by each member state
Guideline for Food Safety Assessment – Recombinant-DNA Plants	Codex Alimentarius Commission	2003	As implemented by each member state

Regulation	Oversight body	Date of adoption/ latest edition	Date of entry into force
Guideline for Food Safety Assessment – Recombinant-DNA Animals	Codex Alimentarius Commission	2008	As implemented by each member state
Convention on Biodiversity	Convention on Biodiversity Secretariat	1992	1993
Cartagena Protocol on Biosafety	Convention on Biodiversity Secretariat	2000	2003
Sanitary and Phytosanitary Agreement	World Trade Organisation	1995	1995
Technical Barriers to Trade Agreement	World Trade Organisation	1995	1995
Trade Related Aspects of Intellectual Property Rights Agreement	World Trade Organisation	1995	1995
Patent Cooperation Treaty	World Intellectual Property Organisation	1970	1978
Patent Law Treaty	World Intellectual Property Organisation	2000	2005
Budapest Treaty on the Deposit of Microorganisms for the Purpose of Patent Procedure	World Intellectual Property Organisation	1977	1980
International Convention for the Protection of New Varieties of Plants	Union for the Protection of New Varieties of Plant	1961/1991	1968
Bonn Guidelines on Access to Genetic Resources	Convention on Biodiversity Secretariat	2002	n/a
International Treaty on Plant Genetic Resources	Food and Agriculture Organisation	2001	2004
Single Convention on Narcotic Drugs	International Narcotics Control Board, Commission on Narcotic Drugs and UN Office on Drugs and Crime	1961	

(*Continued*)

Table 7.1 (*Continued*)

Regulation	Oversight body	Date of adoption/ latest edition	Date of entry into force
Convention on Psychotropic Substances	International Narcotics Control Board, Commission on Narcotic Drugs and UN Office on Drugs and Crime	1971	
Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances	International Narcotics Control Board, Commission on Narcotic Drugs and UN Office on Drugs and Crime	1988	
World Anti-doping Code	World Anti-doping Association	2009 edition	2009
International Convention against Doping in Sport	United Nations Educational, Scientific and Cultural Organisation	2005	2007
Universal Declaration on the Human Genome and Human Rights	United Nations Educational, Scientific and Cultural Organisation	1997	n/a
International Declaration on Human Genetic Data	United Nations Educational, Scientific and Cultural Organisation	2003	n/a
Universal Declaration on Bioethics and Human Rights	United Nations Educational, Scientific and Cultural Organisation	2005	n/a
United Nations Declaration on Human Cloning	United Nations General Assembly	2005	n/a

Table 7.2 The Main Purposes of the Regulations

Regulation	Summary of main purpose
1925 Geneva Protocol	Prevention of the use of biological or chemical weapons in war
Biological Weapons Convention	Prevention of the development, production, stockpiling and use of biological or toxin weapons at all times
EnMod Convention	Prevention of the use of certain techniques, at certain degrees, to modify the environment for warfare or other hostile use

Regulation	Summary of main purpose
Chemical Weapons Convention	Prevention of the development, production, stockpiling and use of chemical weapons, and destruction of existing weapons and production facilities
International Health Regulations	Prevention of the spread of serious human diseases through trade and travel routes, surveillance and response
Laboratory Biosafety Manual	Minimising the risk of disease transmission for people working in laboratories with dangerous pathogens and preventing transmission of disease to the public/release of pathogens into the environment
Laboratory Biosecurity Guidance	Minimising the risk of loss, theft or diversion of valuable biological materials including pathogenic agents
Guidance on Regulations for the Transport of Infectious Substances	Minimising the risk of disease transmission for people working in the transport of potentially dangerous pathogens and preventing transmission of disease to the public/release of pathogens into the environment
Terrestrial Animal Health Code	Prevention of the spread of serious animal diseases through trade and travel routes, surveillance and response
Aquatic Animal Health Code	Prevention of the spread of serious aquatic diseases through trade and travel routes, surveillance and response
Manual of Diagnostic Tests and Vaccines for Terrestrial Animals	Minimising the risk of disease transmission for people working in laboratories with or in the transport of potentially dangerous animal pathogens, preventing transmission of disease to the public or animals and the release of pathogens into the environment
Manual of Diagnostic Tests for Aquatic Animals	Minimising the risk of disease transmission during trade in aquatic animals and related products
International Plant Protection Convention	Prevention of the spread of serious plant diseases through trade and travel routes, surveillance and response
Principles for the Risk Analysis of Foods Derived from Modern Biotechnology	Ensuring effective and accurate risk analysis of the implications for human health and nutrition of genetically modified foods
Guideline for Food Safety Assessment – Recombinant-DNA Microorganisms	Ensuring effective and accurate safety assessment of foods produced using genetically modified microorganisms, including risk analysis and suggestion of risk management approaches
Guideline for Food Safety Assessment – Recombinant-DNA Plants	Ensuring effective and accurate safety assessment of foods derived from genetically modified plants, including risk analysis and suggestion of risk management approaches
Guideline for Food Safety Assessment – Recombinant-DNA Animals	Ensuring effective and accurate safety assessment of foods derived from genetically modified animals, including risk analysis and suggestion of risk management approaches

(*Continued*)

Table 7.2 (*Continued*)

Regulation	Summary of main purpose
Convention on Biodiversity	Protection and conservation of biodiversity, ensuring its sustainable use and the fair and equitable sharing of the benefits arising out of its utilisation
Cartagena Protocol on Biosafety	Protection of biodiversity from the potential risks posed by genetically modified organisms through a system of advanced informed agreement to imports
Sanitary and Phytosanitary Agreement	To limit to what is scientifically justifiable any human, animal or plant health-based restriction on trade and to harmonise such restrictions internationally
Technical Barriers to Trade Agreement	To limit to what is scientifically justifiable any technical barriers to trade and to harmonise such barriers internationally
Trade Related Aspects of Intellectual Property Rights Agreement	To internationalise standards of intellectual property protection
Patent Cooperation Treaty	To provide an optional system allowing a single international application for patent protection rather than requiring individual applications for each state
Patent Law Treaty	To enhance the international patent application scheme that was introduced in the Patent Cooperation Treaty
Budapest Treaty on the Deposit of Microorganisms for the Purpose of Patent Procedure	To allow single international deposits of microorganisms which support patent applications, rather than requiring individual deposits in each state
International Convention for the Protection of New Varieties of Plants	To provide intellectual property protection to new plant varieties
International Treaty on Plant Genetic Resources	To facilitate access to plant genetic resources of importance to food security
Bonn Guidelines on Access to Genetic Resources	To facilitate access to genetic resources under conditions that promote their sustainable use and ensure any benefits from their utilisation are shared equitably
Single Convention on Narcotic Drugs	To bring an end to the illicit international trade in narcotic drugs, while ensuring an adequate supply is maintained for medical and scientific purposes
Convention on Psychotropic Substances	To bring an end to the illicit international trade in psychotropic substances, while ensuring an adequate supply is maintained for medical and scientific purposes
Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances	To introduce further measures in support of the Single Convention on Narcotic Drugs and Convention on Psychotropic Substances

Regulation	Summary of main purpose
World Anti-doping Code	To prevent and penalise the misuse of drugs to confer unfair advantage in competitive sporting events
International Convention against Doping in Sport	To provide governmental support for the principles and objectives of the World Anti-doping Code
Universal Declaration on the Human Genome and Human Rights	To highlight particular human genetic techniques that pose risks to key principles, values and human rights and to declare certain uses of human genetics as unacceptable
International Declaration on Human Genetic Data	To declare that the collection and use of human genetic data should respect human dignity, human rights and fundamental freedoms
United Nations Declaration on Human Cloning	To acknowledge that human reproductive cloning is contrary to human dignity and human life and to declare its use as unacceptable
Universal Declaration on Bioethics and Human Rights	To outline international principles of bioethics

8. Coherence in the Biotechnology Regulations: Referencing, Definitions and Provisions

Coherent sets of regulation were shown in Chapter 5 to refer to each other where necessary, to share definitions of key terms, to contain some unifying provisions that strengthen their common identity and for their remaining provisions to be complementary to each other. The biotechnology regulations are assessed against these four characteristics in this chapter, with the method of analysis outlined before the results are discussed.

Self-referencing

Self-referencing is an indicator of internal awareness of connections among a regulatory set. A regulation may refer to others for example to avoid duplication or to make it clear that a particular issue is covered elsewhere in the set. Primarily the assessment here involved examining the texts of the regulations to identify any references to the other regulations (a summary of this is provided in Table 8.1 at the end of this chapter). A secondary examination of documents of the international organisations and meetings of the parties (MOPs) was also made to identify any indications of emerging awareness of connections.

There is self-referencing among some of the regulations both within and between issue areas, but not across the whole set, and there are significant omissions for example between trade and environmental rules. The self-referencing that does exist is not generally done in reference to biotechnology and is therefore not a reliable indicator of internal awareness of connections in relation to the regulations' relevance to the governance of biotechnology. Extending beyond the regulatory texts to interpretive statements of MOPs or their oversight bodies, there are some further indications of awareness of the connections. This awareness may come to be incorporated into future amendments, but it may not. Unless the statements of MOPs and oversight bodies have been formally adopted the regulations are not considered to be self-referencing. The analysis does not go further than this (into e.g. NGO or academic work) because this would indicate external rather than internal awareness of the connections.

Analysis

Examples of self-referencing within issue areas include the following:

- Reference in Article XIII of the Chemical Weapons Convention to the Biological Weapons Convention and the Geneva Protocol

  Nothing in this Convention shall be interpreted as in any way limiting or detracting from the obligations assumed by any state under the Protocol

for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare, signed at Geneva on 17 June 1925, and under the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) Weapons and on Their Destruction, signed at London, Moscow and Washington on 10 April 1972.

- Reference in the preamble to the Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances to the two earlier UN Drugs Conventions – 'Recognizing the need to reinforce and supplement the measures provided in the Single Convention on Narcotic Drugs, 1961 … and the 1971 Convention on Psychotropic Substances.'

There is, however, no consistency in self-reference patterns within issue areas.

Examples of self-referencing across issue areas include:

- Specific references in the Sanitary and Phytosanitary Agreement to the rules/standards adopted by the Codex Alimentarius Commission, the International Plant Protection Convention Secretariat and the Office International des Epizooties (OIE), as an appropriate basis for national trade measures for the protection of human, animal and plant health.

  International standards, guidelines and recommendations
  (a) for food safety, the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice;
  (b) for animal health and zoonoses, the standards, guidelines and recommendations developed under the auspices of the International Office of Epizootics;
  (c) for plant health, the international standards, guidelines and recommendations developed under the auspices of the Secretariat of the International Plant Protection Convention in cooperation with regional organizations operating within the framework of the International Plant Protection Convention;

  (SPS Agreement, Annex A.3)

Looking beyond the regulatory texts themselves and into interpretive documents produced by the relevant international organisations and meetings of the contracting parties, there are indications that awareness of the connections between the regulations in controlling some of the applications and impacts of biotechnology is growing, and may be incorporated into regulatory texts at a later stage. Examples include:

- Recognition of the World Health Organisation's role in disease surveillance as an important tool in the detection and identification of deliberate outbreaks of disease that may be caused by biological agents or toxins. In particular, this was recognised in two documents of the Fifty-fifth World Health Assembly – Resolution WHA55.16 (WHO, 2002a) and Report WHA55.20 (WHO, 2002b) – and in the 2004 update of the Organisation's guidance on *Public Health Responses to Biological and Chemical Weapons*.

- A document on the Cartagena Protocol (CBD Secretariat, June 2003) which states:

  Although the Cartagena Protocol on Biosafety is the only international instrument that deals exclusively with GMOs, it does not exist in a vacuum. The Convention on Biological Diversity, the 'parent' of the Protocol, itself requires governments to take measures to regulate, manage or control the risks associated with the use and release of GMOs. There are also a number of separate international instruments and standard setting processes that address various aspects of biosafety.

It then lists these as including the International Plant Protection Convention, the Codex Alimentarius Commission, the World Animal Health Organisation (OIE) and the Sanitary and Phytosanitary and Technical Barriers to Trade Agreements.

- The International Portal on Food Safety, Animal and Plant Health (IPFSAPH) which has been established by seven of the international organisations involved in the regulation of biotechnology, partly in recognition of the new challenges created by the use of biotechnologies in those areas (its database contains almost a thousand documents related to genetically modified organisms). It serves as a repository for all national, regional and international documents, guidelines and rules on food safety, animal and plant health, including those of the Codex Alimentarius. The seven organisations involved are: the Food and Agriculture Organisation; the Codex Alimentarius Commission; the International Plant Protection Convention Secretariat; the Office International des Epizooties; the World Trade Organisation; the Convention on Biodiversity Secretariat; and the World Health Organisation.

- A webpage produced by the Food and Agriculture Organisation on regulatory aspects of biotechnology in food and agriculture (FAO, no date b), which outlines rules in the areas of biosafety, food safety and intellectual property rights, specifically referring to the Cartagena Protocol, the International Plant Protection Convention, the work of the Codex Alimentarius Commission, the World Intellectual Property Organisation and the International Union for the Protection of New Varieties of Plants.

Shared Definitions

To assess this characteristic the regulatory texts were examined to identify any shared definitions, particularly of key terms, with either the same or very similar wording. The previously indicated divide between regulations within issue areas and regulations in different issue areas also exists here. Since the regulations do not have a common primary purpose the terms seen as important enough to be defined within the regulations are likely to vary accordingly. Therefore, it is not surprising that there are few shared definitions and none that extend across the full regulatory set.

Analysis

The following definitions are shared or very similar:

Sanitary measure (shared by the Terrestrial Animal Health Code and Sanitary and Phytosanitary Agreement):

> Sanitary measure
> Means a measure … designed to protect animal or human health or life within the territory of the OIE Member from risks arising from the entry, establishment and/or spread of a hazard.
>
> (Terrestrial Animal Health Code, Glossary)

> Sanitary or phytosanitary measure – Any measure applied:
> (a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;
> (b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or foodstuffs;
> (c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry establishment or spread of pests; or
> (d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.
>
> (SPS Agreement, Annex A.1)

Modern biotechnology (shared by the Cartagena Protocol and the Codex Principles):

The same wording is used in both the Cartagena Protocol (Article 3, Use of Terms) and the Codex Principles (Section 2 – Scope and Definitions): '(i) "Modern biotechnology" means the application of: a. *In vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organisms, or b. Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive

or recombination barriers and that are not techniques used in traditional breeding and selection.'

Conventional counterpart (shared by the Codex Principles and Guidelines):

The Codex Principles and Guidelines use similar definitions of 'conventional counterpart', for example: '"Conventional Counterpart" means a related organism/variety, its components and/or products for which there is experience of establishing safety based on common use as food' (Codex Principles, Section 2); and '"Conventional Counterpart" means a related plant variety, its components and/or products for which there is experience of establishing safety based on common use as food' (Codex Guideline RDNA Plants, Section 2).

Ex-situ conservation and *in-situ conservation* (shared by the Convention on Biodiversity and the International Treaty on Plant Genetic Resources):

These are found in Article 2 of the Convention on Biodiversity – '"*Ex-situ* conservation" means the conservation of components of biological diversity outside their natural habitats'; '"*In-situ* conservation" means the conservation of ecosystems and natural habitats and the maintenance and recovery of viable populations of species in their natural surrounding and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties.' And in Article 2 of the International Treaty on Plant Genetic Resources – '"*Ex-situ* conservation" means the conservation of plant genetic resources for food and agriculture outside their natural habitat.' '"*In-situ* conservation" means the conservation of ecosystems and natural habitats and the maintenance and recovery of viable populations of species in their natural surroundings and, in the case of domesticated or cultivated plant species, in the surroundings where they have developed their distinctive properties.'

These definitions are also shared with the Bonn Guidelines, which state that 'the terms as defined in Article 2 of the Convention shall apply to these Guidelines' (Bonn Guidelines, Part I, B).

Article 1 of the UN Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances uses the definitions of narcotic drugs and psychotropic substances from the earlier Conventions: '"Narcotic drug" means any of the substances, natural or synthetic, in Schedules I and II of the Single Convention on Narcotic Drugs, 1961 ... "Psychotropic substance" means any substance, natural or synthetic, or any natural material in Schedules I, II, III and IV of the Convention on Psychotropic Substances, 1971'.

The Laboratory Biosafety Manual and Laboratory Biosecurity Guidance share definitions of biosafety and biosecurity as they relate to laboratory facilities. The Terrestrial Animal Health Code defines biosecurity slightly

differently, with the term containment being closer to the World Health Organisation definition. The term biosafety in the Cartagena Protocol does not relate to laboratories.

Unifying Provisions

Coherent sets of regulation will have some provisions that are the same in each regulatory text. In order to assess this, the regulatory texts were examined to find such provisions. This did not require the same wording to be used and would also encompass provisions requiring the same action for the same objectives. It appears that regulations which share principles and self-reference are more likely to have provisions that can be viewed as unifying, but rarely to the extent of the identical wording found in the Geneva Conventions. There are no unifying provisions for the whole regulatory set; those which do occur are predominantly within issue areas.

Analysis

The most extensive unifying provisions (although the precise wording varies) are those on technical and financial assistance, scientific and technological cooperation, and capacity-building,[1] with a particular focus on assisting developing countries. Such provisions can be found in seventeen of the regulations: the International Health Regulations; the International Plant Protection Convention; the Codex Principles; the Convention on Biodiversity; the Cartagena Protocol; the Sanitary and Phytosanitary Agreement; the Technical Barriers to Trade Agreement; the Trade Related Aspects of Intellectual Property Rights Agreement; the Patent Cooperation Treaty; the International Treaty on Plant Genetic Resources; the Bonn Guidelines on Access to Genetic Resources; the Single Convention on Narcotic Drugs; the Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances; the Universal Declaration on the Human Genome and Human Rights; the International Declaration on Human Genetic Data; the Universal Declaration on Bioethics and Human Rights; and the UN Declaration on Human Cloning. There are also clauses in the Biological Weapons Convention and the Chemical Weapons Convention on not allowing their provisions to hamper development of states parties.

Examples include:

> The contracting parties agree to promote the provision of technical assistance to contracting parties, especially those that are developing contracting parties, either bilaterally or through appropriate international organisations, with the objective of facilitating implementation of this Convention.
>
> (IPPC, Article XX)

> Efforts should be made to improve the capability of regulatory authorities, particularly those of developing countries, to assess, manage and communicate risks, including enforcement, associated with foods derived from modern biotechnology or to interpret assessments undertaken by other authorities or recognised expert bodies, including access to analytical technology. In addition capacity building for developing countries either through bilateral arrangements or with assistance of international organisations should be directed toward effective application of these principles.
>
> (Codex Principles, point 27)

> Each Contracting Party shall promote technical and scientific cooperation with other Contracting Parties, in particular developing countries, in implementing this Convention.
>
> (CBD, Article 18.2)

> Members agree to facilitate the provision of technical assistance to other Members, especially developing country Members, either bilaterally or through the support of appropriate international organizations.
>
> (SPS Agreement, Article 9.1)

> In order to facilitate the implementation of this Agreement, developed country Members shall provide, on request … technical and financial cooperation in favour of developing and least developed country Members.
>
> (TRIPS Agreement, Article 67)

> The Contracting Parties agree to promote the provision of technical assistance to Contracting Parties, especially those that are developing countries or countries with economies in transition, either bilaterally or through the appropriate international organisations, with the objective of facilitating the implementation of this Treaty.
>
> (ITPGR, Article 8)

> States should … continue fostering the international dissemination of scientific knowledge concerning the human genome, human diversity and genetic research and, in that regard, to foster scientific and cultural cooperation, particularly between industrialized and developing countries.
>
> (UDHGHR, Article 18)

Complementary Provisions

Provisions of the different regulations are considered to be complementary if they work towards the same overall objectives and do not contradict

each other. To assess this, the texts were examined for provisions that complement each other in their application to biotechnology. They were also examined for any contradictory provisions, as clear examples of non-complementarity.

Despite having different purposes and principles many of the regulations' provisions can be viewed as complementary when applying the definition provided in Chapter 5 that they should extend protection over the different areas covered (in this case the different aspects of biotechnology that require regulation). However, the regulations also contain some contradictory provisions. There are also areas in which coverage is duplicated by separate regulations (e.g. coverage of access and benefit-sharing by the International Treaty on Plant Genetic Resources and the Bonn Guidelines).

Analysis

The regulations in the health area have provisions minimising their negative effects on trade that support the Sanitary and Phytosanitary Agreement which allows such restrictions where they are justified on health grounds and are not more trade restrictive than necessary. For example:

> In order to minimize interference with international trade, each contracting party … undertakes to act in conformity with the following:
>
> (a) Contracting parties shall not, under their phytosanitary legislation, take any of the measures specified in paragraph 1 of this Article, unless such measures are made necessary by phytosanitary considerations and are technically justified.
>
> (International Plant Protection Convention, Article VII.2)

> The purpose and scope of these Regulations are 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, and which avoid unnecessary interference with international traffic and trade.
>
> (International Health Regulations, Article 2)

There are some agreements in the trade area that have provisions that are complementary to provisions in agreements in the areas of arms control, health and disease control, and environmental protection. For example:

> Technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create. Such legitimate objectives are, *inter alia*: national security

> requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment.
>
> (TBT Agreement, Article 2.2)

> Nothing in this Agreement shall be construed:
> (a) to require a Member to furnish any information the disclosure of which it considers contrary to its essential security interests; or
> (b) to prevent a Member from taking any action which it considers necessary for the protection of its essential security interests;
>
> (TRIPS Agreement, Article 73)

> Each Contracting State recognizes that it is highly desirable that, if and to the extent which the export from or import into its territory of certain kinds of microorganisms is restricted, such restriction should apply to microorganisms deposited; or destined for deposit, under this Treaty only where the restriction is necessary in view of national security or the dangers for health or the environment.
>
> (Budapest Treaty, Article 5)

There are also complementary provisions between the Convention on Biodiversity, the Bonn Guidelines and the International Treaty for Plant Genetic Resources. These relate to their shared objectives:

> The objectives of this Convention … are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies
>
> (CBD, Article 1)

> The objectives of this Treaty are the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with the Convention on Biological Diversity
>
> (ITPGR, Article 1.1)

> E. Objectives
> 11. The objectives of the Guidelines are the following:
> a. To contribute to the conservation and sustainable use of biological diversity;
> b. To provide Parties and stakeholders with a transparent framework to facilitate access to genetic resources and ensure fair and equitable sharing of benefits;
>
> (Bonn Guidelines, Part I)

And to states' sovereign rights:

> States have … the sovereign right to exploit their own resources.
>
> (CBD, Article 3)

> The Contracting Parties recognize the sovereign rights of States over their own plant genetic resources for food and agriculture
>
> (ITPGR, Article 10.1)

> Nothing in these Guidelines should be interpreted to affect the sovereign rights of States over their natural resources;
>
> (Bonn Guidelines, Part I.A)

And between the Universal Declaration on the Human Genome and Human Rights, Universal Declaration on Bioethics and Human Rights and the arms control agreements in relation to the promotion of peaceful uses and prevention of non-peaceful uses of science:

> They [states] should seek to ensure that research results are not used for non-peaceful purposes.
>
> (UDBEHR, Article 15)

> States should take appropriate measures, both at the national and international levels, to combat bioterrorism and illicit traffic in organs, tissues, samples, genetic resources and genetic-related materials.
>
> (UDBEHR, Article 21.5)

> The States Parties to this Convention undertake to facilitate, and have the right to participate in, the fullest possible exchange of equipment, materials and scientific and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes.
>
> (BWC, Article X.1)

> The States Parties to this Convention undertake to facilitate, and have the right to participate in, the fullest possible exchange of scientific and technological information on the use of environmental modification techniques for peaceful purposes.
>
> (EnMod Convention, Article III)

However, just as the principles underlying some of the agreements appear contradictory, so too are some of their provisions, as shown in the previous chapter under the sub-heading Divergent Principles; these include provisions of the environmental and trade agreements and of the agreements on genetic resources and on intellectual property.

Conclusion

The biotechnology regulations fail to match the four characteristics of the coherent regulatory model covered in this chapter. There is some self-referencing among the regulations within and between issue areas, but not for the set as a whole and not always with relevance to the control of biotechnology. There are also some definitions shared among regulations within and across issue areas, but none for the full set. Seventeen of the regulations have similar provisions on assistance to developing states, which are the closest to the concept of unifying provisions – but again these do not extend across the full regulatory set. Finally, although some complementary provisions can be identified within and between issue areas, there are also contradictory provisions which should not exist within coherent regulatory sets.

Table 8.1 Self-referencing among the Biotechnology Regulations

Regulation	Refers to (regulation)	Refers to (organisation)
1925 Geneva Protocol		
Biological Weapons Convention	1925 Geneva Protocol	
Chemical Weapons Convention	1925 Geneva Protocol, Biological Weapons Convention	
EnMod Convention		
International Plant Protection Convention	Sanitary and Phytosanitary Agreement	
International Health Regulations		Food and Agriculture Organisation, Office International des Epizooties
Terrestrial Animal Health Code	Sanitary and Phytosanitary Agreement	World Trade Organisation
Aquatic Animal Health Code	Sanitary and Phytosanitary Agreement	World Trade Organisation
Laboratory Biosafety Manual		
Laboratory Biosecurity Guidance	Laboratory Biosafety Manual, Biological Weapons Convention, Universal Declaration on Bioethics and Human Rights, Convention on Biodiversity, Cartagena Protocol, International Health Regulations	Office International des Epizooties, World Health Organisation, Food and Agriculture Organisation

Regulation	Refers to (regulation)	Refers to (organisation)
Guidance on Regulations for the Transport of Infectious Substances		
Manual of Diagnostic Tests and Vaccines for Terrestrial Animals	Terrestrial Animal Health Code	Food and Agriculture Organisation, Codex Alimentarius Commission, World Health Organisation
Manual of Diagnostic Tests for Aquatic Animals		
Codex Principles for Risk Analysis of Foods Derived from Modern Biotechnology	Cartagena Protocol	
Codex Guideline on Food Safety Assessment – Recombinant-DNA Microorganisms	Codex Principles	
Codex Guideline on Food Safety Assessment – Recombinant-DNA Plants	Codex Principles	
Codex Guideline on Food Safety Assessment – Recombinant-DNA Animals	Codex Principles	
Convention on Biodiversity		
Cartagena Protocol	Convention on Biodiversity	
Sanitary and Phytosanitary Agreement	Technical Barriers to Trade Agreement, and standards of the Codex Alimentarius Commission, the Office International des Epizooties and the International Plant Protection Convention Secretariat	
Technical Barriers to Trade Agreement	Sanitary and Phytosanitary Agreement	
Trade Related Aspects of Intellectual Property Rights Agreement		World Intellectual Property Organisation
Patent Cooperation Treaty		
Patent Law Treaty	Patent Cooperation Treaty	
Budapest Treaty		

(*Continued*)

Table 8.1 (*Continued*)

Regulation	Refers to (regulation)	Refers to (organisation)
International Treaty for the Protection of New Varieties of Plants		
International Treaty on Plant Genetic Resources	Convention on Biodiversity	
Bonn Guidelines on Access to Genetic Resources	Convention on Biodiversity, International Treaty on Plant Genetic Resources	World Intellectual Property Organisation
Single Convention on Narcotic Drugs		
Convention on Psychotropic Substances	Single Convention on Narcotic Drugs	
Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances	Single Convention on Narcotic Drugs, Convention on Psychotropic Substances	
World Anti-doping Code	International Convention against Doping in Sport	
International Convention against Doping in Sport	World Anti-doping Code	World Anti-doping Association
Universal Declaration on the Human Genome and Human Rights	Biological Weapons Convention, Budapest Treaty, Trade Related Aspects of Intellectual Property Rights Agreement	
International Declaration on Human Genetic Data	Universal Declaration on the Human Genome and Human Rights, Trade Related Aspects of Intellectual Property Rights Agreement	
Universal Declaration on Bioethics and Human Rights	Universal Declaration on the Human Genome and Human Rights, International Declaration on Human Genetic Data, Convention on Biodiversity, International Treaty on Plant Genetic Resources, Trade Related Aspects of Intellectual Property Rights Agreement	Food and Agriculture Organisation, World Health Organisation
UN Declaration on Human Cloning	Universal Declaration on the Human Genome and Human Rights	

9. Coherence in the Biotechnology Regulations: Structure, Procedures, Mechanisms and Strength

This chapter assesses the biotechnology regulations on the characteristics of common structure, common administrative and review procedures, common enforcement and dispute settlement mechanisms and same strength of force. Coherent sets of international regulation are expected to clearly display these characteristics.

Common Structure

Common structure is found where related provisions are contained in the same articles in the different regulatory texts and/or where related provisions appear in the same order in each regulatory text. In order to assess this, the main structural elements of each regulatory text were identified, and listed so that the structures could be compared. The structural elements used for this analysis are: preamble/introductory text/foreword; basic provisions; substantive provisions; institutional provisions; and administrative provisions.[1]

Most of the regulations that take the form of treaties have a similar structure, generally consisting of a preamble, basic provisions, specific provisions, institutional provisions, administrative provisions and any annexes. The same structure can be found in most international treaties. Regulations that take the form of voluntary guidance or declarations are generally structurally different from the treaties, and often from each other. (Table 9.1, at the end of this chapter, indicates which of the regulations are legally binding and which are voluntary.) A common structure does not exist to the same extent that it does within the coherent regulatory sets identified in Chapter 5.

Analysis

There are certain commonalities of structure to the legally binding treaties that operate in this area. However, this is the case across most realms of international law. Treaties generally start with a non-binding preamble, followed by basic, then substantive provisions, institutional provisions and finally administrative provisions. This structure does not extend across the full range of regulations.

The following illustrates the structure of the regulations:

Legally binding treaties:

1925 Geneva Protocol
- Preamble
- Substantive Provisions

Biological Weapons Convention
- Preamble
- Basic Provisions (Article I)
- Substantive Provisions (Articles II–X)
- Administrative Provisions (Articles XI–XV)

EnMod Convention
- Preamble
- Basic Provisions (Articles I–III)
- Substantive Provisions (Articles IV–V)
- Administrative Provisions (Articles VI–X)
- One Annex

Chemical Weapons Convention
- Preamble
- Basic Provisions (Articles I–II)
- Substantive Provisions (Articles III–VII, IX–XII)
- Institutional Provisions (Article VIII)
- Administrative Provisions (Articles XIII–XXIV)
- Two Annexes

International Health Regulations
- Basic Provisions (Articles 1–4)
- Substantive Provisions (Articles 5–46)
- Administrative/Institutional Provisions (Articles 47–53)
- Administrative Provisions (Articles 54–66)
- Nine Annexes

International Plant Protection Convention
- Preamble
- Basic Provisions (Articles I–IV)
- Substantive Provisions (Articles V–X)
- Administrative/Institutional Provisions (Articles XI–XIII)
- Administrative Provisions (Articles XIV–XXIII)
- Annex – Model Phytosanitary Certificate

Convention on Biodiversity
- Preamble
- Basic Provisions (Articles 1–6)
- Substantive Provisions (Articles 7–19, 22)
- Institutional Provisions (Articles 20, 21, 23–25)
- Administrative Provisions (Articles 26–42)
- Two Annexes

Cartagena Protocol
- Preamble
- Basic Provisions (Articles 1–4)
- Substantive Provisions (Articles 5–18, 21–27)
- Institutional Provisions (Articles 19–20, 28–31)
- Administrative Provisions (Articles 32–40)
- Three Annexes

Sanitary and Phytosanitary Agreement
- Basic Provisions (Articles 1–4)
- Substantive Provisions (Articles 5–10)
- Administrative Provisions (Articles 11–14)
- Three Annexes

Technical Barriers to Trade Agreement
- Basic Provisions (Article 1)
- Substantive Provisions (Articles 2–12)
- Administrative/Institutional Provisions (Articles 13–15)
- Three Annexes

Trade Related Aspects of Intellectual Property Rights Agreement
- Preamble
- Basic Provisions (Articles 1–8)
- Substantive Provisions relating to different types of intellectual property rights (Articles 9–61)
- Substantive Provisions relating to all intellectual property rights (Article 62)
- Transitional Arrangements (Articles 65–67)
- Administrative and Institutional provisions (Articles 63, 64, 68–73)

Patent Cooperation Treaty
- Preamble
- Basic Provisions (Articles 1–2)
- Substantive Provisions (Articles 3–52)
- Administrative/Institutional Provisions (Articles 53–59)
- Administrative Provisions (Articles 60–69)

Patent Law Treaty
- Basic Provisions (Articles 1–2)
- Substantive Provisions (Articles 3–14)
- Administrative Provisions (Articles 15–27)

Budapest Treaty
- Basic Provisions (Articles 1–2)

- Substantive Provisions (Articles 3–9)
- Administrative/Institutional Provisions (Articles 10–12)
- Administrative Provisions (Articles 13–20)

International Convention for the Protection of New Varieties of Plants
- Basic Provisions (Articles 1–4)
- Substantive Provisions (Articles 5–22, 30–32)
- Institutional Provisions (Articles 23–27, 29)
- Administrative Provisions (Articles 28, 33–42)

International Treaty on Plant Genetic Resources
- Preamble
- Introductory Provisions (Articles 1–3)
- Basic Provisions (Articles 4–8)
- Substantive Provisions (Articles 9–17)
- Administrative and Institutional Provisions (Articles 18–35)
- Two Annexes

Single Convention on Narcotic Drugs
- Preamble
- Basic Provisions (Article 1)
- Substantive Provisions (Articles 2–4, 18–39)
- Institutional Provisions (Articles 5–17)
- Administrative Provisions (Articles 40–51)

Convention on Psychotropic Substances
- Preamble
- Basic Provisions (Articles 1–2)
- Substantive Provisions (Articles 3–16, 20–23)
- Institutional Provisions (Articles 17–19, 24)
- Administrative Provisions (Articles 25–33)

Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances
- Preamble
- Basic Provisions (Articles 1–2)
- Substantive Provisions (Articles 3–20)
- Institutional Provisions (Articles 21–23)
- Administrative Provisions (Articles 24–34)

World Anti-doping Code
- Introduction
- Basic Provisions (Article 1)
- Substantive Provisions (Articles 2–22 and 24)

- Administrative Provisions (Article 23)
- Appendix

International Convention against Doping In Sport
- Preamble
- Basic provisions (Articles 1–2)
- Substantive provisions (Articles 3–16, 19–27)
- Institutional provisions (Articles 17, 18, 28–32)
- Administrative provisions (Articles 33–43)

Non-binding agreements:

Terrestrial Animal Health Code
- Foreword and Users Guide
- Substantive Provisions

Aquatic Animal Health Code
- Foreword and Users Guide
- Substantive Provisions

Laboratory Biosafety Manual
- Foreword
- Basic Principles (Article 1)
- Substantive Provisions (Articles 2–21)
- Two Annexes

Laboratory Biosecurity Guidance
- Basic Provisions (pp. 1–6)
- Substantive Provisions (pp. 7–25)

Guidance on Regulations for the Safe Transport of Infectious Substances
- Basic Provisions
- Substantive Provisions

Manual of Diagnostic Tests and Vaccines for Terrestrial Animals
- Basic Provisions
- Substantive Provisions

Manual of Diagnostic Tests for Aquatic Animals
- Basic Provisions
- Substantive Provisions

Codex Principles
- Basic Provisions
- Substantive Provisions

Codex Guidelines R-DNA Microorganisms
- Basic Provisions
- Substantive Provisions
- One Annex

Codex Guidelines R-DNA Plants
- Basic Provisions
- Substantive Provisions
- Three Annexes

Codex Guidelines R-DNA Animals
- Basic Provisions
- Substantive Provisions
- One Annex

Bonn Guidelines
- Preamble (within the decision that the guidelines are annexed to)
- Basic Provisions (I.A–E)
- Substantive Provisions (II.A–C; III, IV.A–D, V.A–F)
- Two Appendices

Universal Declaration on the Human Genome and Human Rights
- Preamble
- Declaration of principles

International Declaration on Human Genetic Data
- Preamble
- Declaration of principles

UN Declaration on Human Cloning
- Preamble
- Declaration of principles

Universal Declaration on Bioethics and Human Rights
- Preamble
- Declaration of principles

Common Administrative and Review Procedures

In order to assess this characteristic, the administration and review procedures of each regulatory text were examined (where such existed) and then compared to see if any commonalities could be identified. Again there is some commonality between regulations in particular issue areas, but this does not extend across the set. The legally binding treaties usually have administration and review procedures that involve the formal input and consent of member states; review of the non-legally binding regulations

is generally more autonomous to the oversight body. This is one of the reasons that the voluntary regulations tend to be more frequently updated, since the amendment/revision procedures are less burdensome and time-consuming.

Analysis

While the majority of the regulations contain review procedures (the exceptions being: the Geneva Protocol; the Laboratory Biosafety Manual; the three Codex Guidelines; the International Declaration on Human Genetic Data; the UN Declaration on Human Cloning; and the Universal Declaration on Bioethics and Human Rights), none of these review procedures are shared, not even within issue areas. The regulations that come closest to having shared review procedures are the Convention on Biodiversity and the Cartagena Protocol as the Conference of the Parties to the Convention serves as the Meeting of the Parties to the Protocol (which are the bodies responsible for review). The regulations do not have common administrative procedures either; however, some of the regulations have similar provisions where they are overseen by the same international organisation (but this is not always the case).

Broadly speaking, the legally binding regulations share a degree of formality in their administrative and review procedures, involving the formal consent of member states for amendments for example. The same degree of formality is not found in the voluntary agreements. The legally binding regulations also often require member states to meet at set intervals for the purpose of review.

Examples of legally binding regulations requiring formal consent for amendment:

> Any State Party may propose amendments to this Convention. Amendments shall enter into force for each State Party accepting the amendments upon their acceptance by a majority of the States Parties to the Convention and thereafter for each remaining State Party on the date of acceptance by it.
>
> (Biological Weapons Convention, Article XI)

> 2. Amendments to this Convention shall be adopted at a meeting of the Conference of the Parties … The text of any proposed amendment to this Convention … shall be communicated to the Parties … by the Secretariat at least six months before the meeting at which it is proposed for adoption.
> 3. The Parties shall make every effort to reach agreement on any proposed amendment to this Convention … If all attempts at consensus have been exhausted, and no agreement reached, the amendment shall as a last resort be adopted by a two-third majority vote of the Parties … and shall be submitted by the Depositary to all Parties for ratification, acceptance or approval.
>
> (Convention on Biodiversity, Article 29)

3. All amendments to this Treaty shall only be made by consensus of the Contracting Parties present at the session of the Governing Body.
4. Any amendment adopted by the Governing Body shall come into force among Contracting Parties having ratified, accepted or approved it on the ninetieth day after the deposit of instruments of ratification, acceptance or approval by two-thirds of the Contracting Parties. Thereafter the amendment shall enter into force for any other Contracting Party on the ninetieth day that Contracting Party deposits its instrument of ratification, acceptance, or approval of the amendments.

(International Treaty on Plant Genetic Resources, Article 23)

Common Enforcement and Dispute Settlement Mechanisms

This characteristic was assessed in a similar way to administrative and review procedures. The enforcement and dispute settlement procedures of each regulatory text were examined (where such existed) and compared in order to identify any commonalities. There are no common enforcement and dispute settlement mechanisms for the regulations, but there are some similarities between some of the regulations in this regard. Significantly, in some cases there are large disparities in the mechanisms available.

Analysis

The regulations vary widely in regard to the enforcement and dispute settlement mechanisms that are available. Again there is a general difference between the legally binding regulations and the voluntary regulations, in that the latter do not contain enforcement mechanisms to the same degree, since states are not legally obliged to be bound by their provisions. Where regulations are overseen by the same international organisation some do have similar enforcement and dispute settlement procedures, for example the World Trade Organisation (WTO) agreements, which all make use of its Dispute Settlement Understanding, but this is not always the case.

The following regulations have no identifiable dispute settlement mechanism or enforcement procedure: the Laboratory Biosafety Manual; Guidance on Regulations for the Safe Transport of Infectious Substances; Laboratory Biosecurity Guidance; Manual of Diagnostic Tests and Vaccines for Terrestrial Animals; Manual of Diagnostic Tests for Aquatic Animals; the Codex Principles and Guidelines (though disputes may be resolved through the SPS Agreement); Patent Law Treaty; Budapest Treaty; International Convention for the Protection of New Varieties of Plants; International Convention against Doping in Sport; Universal Declaration on the Human Genome and Human Rights; International Declaration on Human Genetic Data; Universal Declaration on Bioethics and Human Rights; and UN Declaration on Human Cloning.

While the regulations that have dispute settlement mechanisms vary in their specific wording most provide a variety of options including negotiation, conciliation, arbitration, mediation and in many cases the option of submitting the dispute to the International Court of Justice. These options are specifically outlined in: the Convention on Biodiversity; the International Treaty on Plant Genetic Resources; the three UN Drugs Conventions; and the International Health Regulations.

Same Strength of Force

A variety of factors can be found that work against the regulations having the same strength of force, even for regulations within a specific issue area. Significant factors include: whether the regulation is legally binding or not (although note discussions in Chapter 4 on 'hard' and 'soft' laws); number of states parties; and enforcement and verification mechanisms available to promote compliance. These have been compared across the set. Summary information on some of these factors can be found in Table 9.1 at the end of this chapter.

Analysis

There are large discrepancies among the regulations in relation to the factors that contribute to strength of force. These include: the status of the regulation as legally binding, as voluntary guidance or as a declaration of principles; the number of parties to a treaty (this varies between 24 and 193); enforcement mechanisms; verification mechanisms; and support of key international states (e.g. the United States).

An illustration of this point can be found in the disparity between the enforcement capability of the WTO agreements and the environmental agreements. The WTO agreements carry the backing of potential imposition of trade sanctions for persistent non-compliance which provides a significant motivation for states to comply with these rules. There are no such sanctions incorporated into the environmental agreements.

A further example can be found in the different verification capacities of the Biological Weapons Convention (BWC) and the Chemical Weapons Convention (CWC). The CWC contains very strong and detailed provisions in this regard including the possibility of challenge inspections against states suspected of non-compliance. The BWC does not contain such provisions – although an attempt was made to supplement it with a verification protocol – resulting in a comparative weakness.

Conclusion

The biotechnology regulations fail to display the characteristics of common structure, common administrative and review procedures, common enforcement and dispute settlement mechanisms and same strength of force. There is a basic commonality of structure in the regulations that are legally

binding treaties, but it does not go deeper than this. Not all of the regulations incorporate administrative and review procedures and those that do vary in their requirements, although generally the legally binding treaties require formal input and approval from their member states for any amendments. Enforcement and dispute settlement mechanisms are not found in all of the regulations and they vary in strength – one of the factors which contribute to the regulations not having the same strength of force. They also vary on other relevant factors, including legal status and membership levels.

Table 9.1 The Regulations, Number of Parties and Type (information up-to-date March 2010)

Regulation	Number of parties	Type
1925 Geneva Protocol	132	Legally binding
Biological Weapons Convention	163	Legally binding
EnMod Convention	73	Legally binding
Chemical Weapons Convention	188	Legally binding
International Health Regulations	193	Legally binding
Laboratory Biosafety Manual	n/a	Voluntary guidance
Laboratory Biosecurity Guidance	n/a	Voluntary guidance
Guidance on Regulations for the Transport of Infectious Substances	n/a	Voluntary guidance
Terrestrial Animal Health Code	(The OIE has 174 member states)	Voluntary guidance
Aquatic Animal Health Code	(The OIE has 174 member states)	Voluntary guidance
Manual of Diagnostic Tests and Vaccines for Terrestrial animals	(The OIE has 174 member states)	Voluntary guidance
Manual of Diagnostic Tests for Aquatic Animals	(The OIE has 174 member states)	Voluntary guidance
International Plant Protection Convention	173	Legally binding
Principles for the Risk Analysis of Foods Derived from Modern Biotechnology	(The CAC has 182 member states)	Voluntary guidance
Guideline for Food Safety Assessment – Recombinant-DNA Microorganisms	(The CAC has 182 member states)	Voluntary guidance
Guideline for Food Safety Assessment – Recombinant-DNA Plants	(The CAC has 182 member states)	Voluntary guidance

Regulation	Number of parties	Type
Guideline for Food Safety Assessment – Recombinant-DNA Animals	(The CAC has 182 member states)	Voluntary guidance
Convention on Biodiversity	193	Legally binding
Cartagena Protocol on Biosafety	157	Legally binding
Sanitary and Phytosanitary Agreement	153	Legally binding
Technical Barriers to Trade Agreement	153	Legally binding
Trade Related Aspects of Intellectual Property Rights Agreement	153	Legally binding
Patent Cooperation Treaty	142	Legally binding
Patent Law Treaty	24	Legally binding
Budapest Treaty on the Deposit of Microorganisms for the Purpose of Patent Procedure	72	Legally binding
International Convention for the Protection of New Varieties of Plants	67	Legally binding
International Treaty on Plant Genetic Resources	123	Legally binding
Bonn Guidelines on Access to Genetic Resources	n/a	Voluntary guidance
Single Convention on Narcotic Drugs	184	Legally binding
Convention on Psychotropic Substances	183	Legally binding
Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances	184	Legally binding
World Anti-doping Code	634 sports organisations	Binding for sports organisations, not states
International Convention against Doping in Sport	124	Legally binding
Universal Declaration on the Human Genome and Human Rights	n/a	Non-binding
International Declaration on Human Genetic Data	n/a	Non-binding
Universal Declaration on Bioethics and Human Rights	n/a	Non-binding
United Nations Declaration on Human Cloning	n/a	Non-binding

10. Coherence in the Biotechnology Regulations: Organisation, Self-contained, Focus and Coverage

Coherent sets of international regulation tend to be overseen by a single international organisation; to require no reference to regulations outside of the set for their operation; to clearly focus on the issue that is their common purpose; and to comprehensively cover that issue. Assessment of the biotechnology regulations against the first of these four characteristics is straightforward, for the other three it is more complex.

Single International Organisation

Chapter 5 explains that in a coherent regulatory set a single international organisation will have responsibility for oversight, coordination, implementation, monitoring and development of the regulations. The existence of an international organisation was identified either through explicit mention in the regulatory text, or as the originator organisation of the text, having continued responsibility for the above roles.

Analysis

This characteristic can be easily assessed. There is no single international organisation common to all of the regulations. Some regulations (within and between issue areas) share international organisations, other regulations have no international organisation, and in total fifteen separate international organisations operate in this area. Some of the international organisations have cooperative relationships for certain issues relevant to governance of biotechnology.

The international organisations and the agreements they oversee are as follows:

- Organisation for the Prohibition of Chemical Weapons (Chemical Weapons Convention)
- World Health Organisation (International Health Regulations; Laboratory Biosafety Manual; Guidance on Regulations for the Transport of Infectious Substances; Laboratory Biosecurity Guidance)
- Office International des Epizooties (Terrestrial and Aquatic Animal Health Codes; Terrestrial and Aquatic Manuals)
- Food and Agriculture Organisation (International Plant Protection Convention; International Treaty on Plant Genetic Resources)
- Codex Alimentarius Commission (Codex Principles and Guidelines)
- Convention on Biodiversity Secretariat (Convention on Biodiversity; Cartagena Protocol; Bonn Guidelines)

- World Trade Organisation (SPS Agreement; TBT Agreement; TRIPS Agreement)
- World Intellectual Property Organisation (Patent Cooperation Treaty; Patent Law Treaty; Budapest Treaty)
- Union for the Protection of New Varieties of Plants (UPOV Convention)
- International Narcotics Control Board (UN Drugs Conventions)
- Commission on Narcotic Drugs (UN Drugs Conventions)
- United Nations Office on Drugs and Crime (UN Drugs Conventions)
- World Anti-doping Association (World Anti-doping Code)
- United Nations Educational, Scientific and Cultural Organisation (Universal Declaration on the Human Genome and Human Rights; International Declaration on Human Genetic Data; Universal Declaration on Bioethics and Human Rights; International Convention against Doping in Sport)
- United Nations General Assembly (UN Declaration on Human Cloning)

Three of these organisations cross issue areas in the regulations that they oversee: the Convention on Biodiversity Secretariat (environment and trade); the Food and Agriculture Organisation (health and trade); and the UN Educational, Scientific and Cultural Organisation (social and ethical impacts and drugs control).

There have been, and continue to be, efforts at coordination between some of these organisations. The Food and Agriculture Organisation and the World Health Organisation have jointly overseen the Codex Alimentarius Commission for more than forty years, but this institutional degree of cooperation is rare. There are now some limited efforts at coordination specifically for the area of biotechnology, for example between the World Intellectual Property Organisation and the Convention on Biodiversity Secretariat, on the issue of intellectual property rights relating to genetic resources used in modern biotechnology (CBD, April 2002, 16 January 2006; WIPO, no date) and the organisations are often invited to be present at each other's meetings. These are positive indications of cooperation but even these limited efforts have some way to go. The Convention on Biodiversity Secretariat has, for example, despite repeated applications not yet been granted observer status at the Council for Trade Related Aspects of Intellectual Property Rights, the Sanitary and Phytosanitary Committee or the Technical Barriers to Trade Committee at the World Trade Organisation, even though cooperative efforts are urgently required between these two organisations (CBD, no date).

Self-contained

This term was explained in Chapter 5 to mean that the regulations will be able to cover the particular issue that is their main focus (in this case control of biotechnology) without requiring reference to other regulations external to their set. The objectives identified in the regulatory texts for the analysis

of primary purpose have been used again here, in order to judge whether the provisions relevant to biotechnology operate independently of other international agreements. Here the analysis was difficult because of the way in which the regulations have been selected, that is because they have been selected for analysis specifically due to their relevance to the applications and impacts of biotechnology.

Analysis

Given that the regulations do not share a common purpose it is hard to make a comparable analysis of this element to the analysis of the Geneva Conventions made in Chapter 5. The question would be: do the regulations, by themselves, control biotechnology? However, since the regulations have been selected and examined precisely because they are the international regulations that cover biotechnology, this results in a circular argument. This issue is too ambiguous to allow a conclusive assessment. It is very difficult to make a comparative assessment between the international biotechnology regulations and the model of coherent regulatory sets in regard to this factor.

While all the regulations apply to the control of biotechnology, they mainly do so as part of agreements with a wider scope, on which the relevant clauses rely for their operation and in that sense they are not self-contained. This may become a problem, because if it is decided that, to meet a particular control need for biotechnology, a regulation needs to change, this may not be possible because the regulation, as it exists, is required for other purposes too. If new regulations were created that overlapped existing regulations this could also create interpretation problems and confusion.

However, the regulations do cover many of the important aspects of biotechnology that require international governance and while there are weaknesses, for example in the coverage of some social, ethical and developmental impacts, this is not because of reliance on other regulations to complete the coverage – it is because no regulations currently exist for these matters.

Clear Issue Focus

It should be clear from the text of each regulation that they focus on the particular issue that forms their common objective and this issue should be their primary focus. In order to assess this, first the regulatory texts were searched for specific indications of applicability to biotechnology (either referring to biotechnology in general or to one of its applications e.g. genetically modified organisms or genome studies). Then, if such were not found in the regulatory text, officially adopted documents on the regulations were examined for indications that such a focus existed or has developed. Given the different purposes of the regulations, it would perhaps be expected that a clear issue focus would be difficult to identify and indeed this function is not always explicit in the regulations, but in some it is, and documents of meetings of the states parties also indicate that this is the case.

Analysis

Because most of the regulations were not specifically designed to control biotechnology they generally do not have a clear focus on this issue. Often their scope is much broader and their relevance to biotechnology a side-issue to another purpose. This said there is, generally at least, recognition of their applicability to this area, shown in documents produced by their meetings of the parties and their associated international organisations. For example, the final documents produced by the five-yearly Review Conferences of the Biological Weapons Convention have repeatedly emphasised that the Convention's prohibitions on misuse of science extend to genetics, genomics and related technologies.

The following regulations contain no clear indication in their text or officially adopted documents of their relevance to biotechnology:

- The 1925 Geneva Protocol
- International Plant Protection Convention
- International Health Regulations
- Technical Barriers to Trade Agreement
- Sanitary and Phytosanitary Agreement
- Patent Law Treaty
- International Convention for the Protection of New Varieties of Plant
- Single Convention on Narcotic Drugs
- Convention on Psychotropic Substances
- Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances

All the other regulations have in their text or officially adopted documents some indication of relevance to modern biotechnology. Examples include:

- The Laboratory Biosafety Manual has a subsection focusing on risk assessment and genetically modified organisms and a section on biosafety and recombinant-DNA technology.
- The Manual of Diagnostic Tests and Vaccines for Terrestrial Animals has a chapter on Biotechnology in the Diagnosis of Infectious Diseases and Vaccine Development.
- The Convention on Biodiversity has a specific article (Article 19) on Handling of Biotechnology and Distribution on Its Benefits; biotechnology is mentioned in several other articles and biotechnology is specifically mentioned as being included in more general references to technology in the Convention.
- The Cartagena Protocol is specifically designed to ensure 'an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology' (Article 1).
- The preamble to the International Treaty on Plant Genetic Resources states: '*Acknowledging* further that plant genetic resources for food and agriculture are the raw material indispensable for crop genetic

improvement, whether by means of farmers' selection, classical plant breeding or modern biotechnologies'.

- Article 24(c) of the International Convention against Doping in Sport asks states to support research on 'the use of all emerging substances and methods resulting from scientific developments' and the prohibited list of the Convention and the World Anti-doping Code contains a prohibition on gene doping – 'The non-therapeutic use of cells, genes, genetic elements, or of the modulation of gene expression, having the capacity to enhance athletic performance is prohibited' (Prohibited List, M3).
- The Universal Declaration on the Human Genome and Human Rights, International Declaration on Human Genetic Data, Universal Declaration on Bioethics and Human Rights and UN Declaration on Human Cloning make many references to applications and impacts of biotechnology. For example: 'This Declaration addresses ethical issues related to medicine, life sciences and associated technologies as applied to human beings' (UDBEHR, Article 1.1) and '*Aware* of the ethical concerns that certain applications of rapidly developing life sciences may raise with regard to human dignity, human rights and the fundamental freedoms of individuals, *Reaffirming* that the application of life sciences should seek to offer relief from suffering and improve the health of individuals and humankind as a whole' (UNDHC, Preamble).

Comprehensive Coverage of the Issue

Coherent sets of regulations ought to provide comprehensive coverage of the issue on which they are focused and there should be no major gaps in this coverage, or imbalances that leave one area poorly covered. Coverage of the regulation of biotechnology is fairly comprehensive even though it is not coherent. However, this can be difficult to assess given the fragmentation of the regulations, contradictions and imbalances.

Analysis

The issue in this case is control of the applications and impacts of biotechnology. Although few of the regulations were designed specifically to control biotechnology, it would be beneficial for them to achieve comprehensive coverage of the issues that require international control. This coverage would have to be broad, and perhaps the demand is unrealistic in terms of what states will be willing to agree to.

In one sense the regulations do provide fairly comprehensive coverage. They cover the seven identified issue areas (although to varying degrees). However, significant gaps and weaknesses can be identified. In some areas, for example human cloning and development issues, there does at least seem to be awareness of this and faltering attempts to fill some of the gaps (e.g. the intended legal prohibition on reproductive human cloning that ended up as a political declaration), but other needs are still barely recognised.

The most prominent gaps are in the area of human genetics, which is weakly regulated internationally, there only being declarations of principles agreed so far. There are important social and ethical issues in this area that will need to be addressed partly at the international level. At present if national controls are placed on the use of these technologies, groups simply move to another country to conduct the work or people go to countries in which they can get the treatment they desire. For example, when the United Kingdom's Human Fertilisation and Embryology Authority (HFEA – the regulatory authority for reproductive technologies) declined a request for use of pre-implantation genetic diagnosis to create a sibling with a genetic match on the basis that the procedure would be of no benefit to the new child, the parents involved travelled to the United States for the procedure (Boseley, 20 June 2003). Obviously these are extremely complex and controversial issues, but some international direction is needed before the technologies race even further ahead of the social debates and democratic control.

Conclusion

Fifteen international organisations are associated with the biotechnology regulations, so they clearly fail to match the characteristic of having a single international organisation. In regard to the other characteristics covered in this chapter, the assessment is not as clear cut. The selection method makes analysis of self-containment problematic and also means that the regulations provide comprehensive coverage in relation to the issue areas of interest. The issue focus of the set will not be clear because they lack a common purpose, but the emerging awareness of connections outlined in Chapter 7 under 'common identity' and in Chapter 8 under 'self-referencing' should also contribute to increased understanding of the regulations as focusing (in part) on control of biotechnology.

11. Findings and Implications for the Effective Governance of Biotechnology

The international regulations of relevance to the governance of modern biotechnology do not form a coherent regulatory set and are currently fragmented. The analysis in the previous four chapters suggests that several factors lie behind this. These include that: the regulations were generally not designed with the specific intention of governing the applications and impacts of biotechnology; the regulations were developed at different times and in different historical contexts; the regulations largely developed separately from one another, or at least within distinct issue areas; and the regulations differ widely in their membership. Following a summary of the assessment of the degree of coherence among the biotechnology regulations, this chapter will outline the implications of this, particularly in regard to the effective functioning of the regulations, and will discuss policy options for increasing coherence.

Lack of Coherence among the International Regulations Relevant to the Control of Biotechnology

Assessed against the model of coherent international regulatory sets, which was outlined in Chapter 5, the biotechnology regulations fail to match twelve of the sixteen characteristics, and the assessment is ambiguous on the other four (see Table 11.1). There are signs that a common identity may be starting to emerge and internal awareness of connections between the regulations also seems to be improving.

Table 11.1 International Biotechnology Regulations and the Model of Coherent International Regulatory Sets

Characteristic	Displayed in the biotechnology regulations?
Common primary purpose	No
Common principles	No
Common historical development	No
Common identity	No, but signs it may be emerging
Self-referencing	No, but improving
Shared definitions	No
Unifying provisions	No
Complementary provisions	Yes, but also contradictory provisions

Characteristic	Displayed in the biotechnology regulations?
Common structure	No
Common administration and review procedures	No
Common enforcement and dispute settlement mechanisms	No
Same strength of force	No
Single international organisation	No
Self-contained	Not comparable
Clear issue focus	No
Comprehensive coverage of issue	Ambiguous

Problems in Fulfilling the Functions of International Regulation

Fifteen key functions of international regulation were identified in Chapter 4:

- Defining the rights and obligations of states
- Regulating conduct
- Coordinating behaviour
- Providing predictability and reducing uncertainty
- Reducing costs of individual action and increasing efficiency
- Authorising or prohibiting certain actions
- Facilitating cooperation
- Imposing constraints
- Realising values
- Establishing and shaping expectations
- Channelling conflict and providing mechanisms for its resolution
- Simplifying and facilitating transactions
- Assisting policy-making
- Dealing with common threats/problems
- Promoting peace

While the international biotechnology regulations assessed individually fulfil many of these functions, as a set they face several problems in doing so because of their lack of coherence. Several illustrative examples of these problems follow.

Example 1 – Lack of Clarity about Which Rules are Applicable

Lack of coherence among the regulations can leave it unclear which rules should be applied in particular cases. To illustrate this problem, when

deciding to allow the export of a genetically engineered bacterium, states may be unclear whether they should be applying rules on trade, on disease control, on arms control, on transport of dangerous goods or on conservation of biodiversity, or a combination of some or all of these regulations.

This is particularly problematic where there is no referencing between the regulations. It is, for example, made clear in the Cartagena Protocol that it does not cover 'living modified organisms which are pharmaceuticals for humans that are addressed by other relevant agreements and organisations' (Article 5), but it does not say what these agreements are, or whether any environmental impacts need to be taken into account when applying the other agreements. Referring back to Table 8.1 in Chapter 8, in relation to this example, it can be seen that there are no references from the arms control regulations to the other regulations; no references between the trade and the environmental regulations; and only limited references between the health regulations and trade regulations.

The implications of this are that states may be unaware of the full range of rules that apply, unclear which rules they should apply and unsure which rules other states will choose to apply to a particular case. This creates difficulties for defining rights and obligations, for coordinating behaviour and for providing predictability. Uncertainty is likely to increase in such situations as states cannot predict the behaviour of others. Joyner (2005, p. 7) explains the key role of certainty about behaviour in achieving predictability through international law:

> A lack of order often stems from uncertainty about the future conduct of others … decision makers need knowledge about the current state of affairs to make informed decisions. A government's decisions are intended to preclude unwanted future effects and to facilitate desired future ends and objectives. International law, framed by legal rules for state conduct, remains the principal channel for furnishing these expectations about future state behaviour.

Example 2 – Existence of Different Dispute Settlement Mechanisms

Where different dispute settlement mechanisms exist within a set of regulations – as they do in the international biotechnology regulations – then states could choose to move disputes to the forum which they believe best suits their side of the case. This could make the resolution of conflicts difficult. It may also be difficult for the dispute settlement body associated with one regulation to resolve conflicts between states on issues where another regulation contradicts or overlaps. There is the potential scenario of one body making a ruling that effectively goes against the provisions or principles of another regulation.

In the biotechnology area a problematic case might be a dispute on intellectual property rights and genetically engineered plants (this has already proved to be a controversial area). Such a dispute might, potentially, be dealt with by the World Trade Organisation's (WTO) dispute settlement body under the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement (Part V, Article 64); the dispute settlement procedures of the International Treaty on Plant Genetic Resources (Article 22); or the dispute settlement procedure suggested by the Bonn Guidelines (Section V, point E); or indeed of those incorporated into the future international regime on access and benefit-sharing, currently under negotiation under the Convention on Biodiversity's Conference of the Parties.

Example 3 – Competition over Values

Fragmentation of the regulations could encourage (particularly powerful) states or regional blocs to compete over values by forum-shifting (explained in Chapter 4). This creates uncertainty for other states and, where the principles that underlie the regulations are put in contention, fragmentation may increase. An illustration here is the different approaches to genetically modified foods taken by the United States and the European Union (EU) (which can be summarised as producer protection versus consumer protection). The US approach appears to be better reflected by the rules of the WTO; the EU's by the Codex Alimentarius (Ching, 2005).

Example 4 – Contradictory Provisions

Provisions in the regulations which are, or can be interpreted as, being contradictory will also leave states unclear as to which rules to apply, and will affect coordination and predictability of behaviour. This is also a problem in terms of shaping expectations. As Joyner explains 'rules provide expectations. If all governments follow the same rules in their relations, they would then know what to expect from one another' (2005, p. 15). Unfortunately this will often not be the case in the governance of biotechnology. A prominent example here is the treatment of living modified organisms (LMOs) – does a state have the right to block imports of LMOs on socio-economic grounds as implied by the Cartagena Protocol, or is this right precluded by the WTO agreements? Murphy (2001, p. 90), when discussing the role of the WTO agreements in addressing concerns about biotechnology, concluded that: 'The potential for conflict with other treaty regimes is significant.'

Example 5 – Overlap of Provisions

Partly as a result of the regulations developing separately from one another there are some areas of overlap, for example in provisions on scientific and technical assistance to developing countries. Such overlaps may result in duplication of efforts. For example, one state might provide scientific

knowledge under the technical assistance or benefit-sharing provisions of the International Treaty on Plant Genetic Resources (Articles 8 and 13) and another state might provide the same knowledge under the benefit-sharing provisions of the Bonn Guidelines (Appendix II) or under the technical assistance provisions of the International Plant Protection Convention (Article XX). Such duplication will undermine the functions of reducing costs and increasing efficiency.

Example 6 – Lack of Clarity on Prohibitions

Where one regulation can be interpreted as allowing an action that is prohibited by another regulation then activities may not be effectively constrained and again this will not reduce uncertainty or enhance predictability of state behaviour. For example, therapeutic human cloning appears to be permitted (subject to certain constraints) under Article 11 of the Universal Declaration on the Human Genome and Human Rights – 'Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted.' However, the prohibition on human cloning contained in the UN Declaration on Human Cloning is interpreted by many states as including therapeutic cloning as well as reproductive cloning – 'Member States are called on to prohibit all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life' (point b).

It is clear that the lack of coherence among the international biotechnology regulations challenges their ability to effectively fulfil several key functions of international regulation. In regard to those listed above, Table 11.2 provides a summary of likely areas of difficulty.

Table 11.2 Difficulty in Fulfilling the Functions of International Regulation

Function	Lack of coherence problematic?
Defining the rights and obligations of states	Yes
Regulating conduct	Yes
Coordinating behaviour	Yes
Providing predictability and reducing uncertainty	Yes
Reducing costs of individual action and increasing efficiency	Yes
Authorising or prohibiting certain actions	Yes
Facilitating cooperation	Yes
Imposing constraints	Yes

Function	Lack of coherence problematic?
Realising values	Not necessarily[a]
Establishing and shaping expectations	Yes
Channelling conflict and providing mechanisms for its resolution	Yes
Simplifying and facilitating transactions	Yes
Assisting policy-making	Yes
Dealing with common threats/problems	Yes
Promoting peace	Not necessarily[b]

[a] Fragmentation of regulations may provide states with more opportunities to realise their values, by expanding the number of fora in which they can promote them.
[b] While the existence of separate dispute settlement mechanisms may make the resolution of disputes more difficult, peaceful methods of resolution are generally available for the issues involved.

Problems in Fulfilling the Roles Required of International Biotechnology Regulations

Alongside the general functions of international regulation, four specific roles for biotechnology regulation were identified in Chapter 4:

- Promotion of benefits
- Identification, assessment and management of risks
- Prevention or minimisation of negative impacts
- Promotion of capacity-building

Again, the regulations examined individually will often fulfil these four roles, but the regulations as a set face difficulties in fulfilling the roles because of the problems faced in coordinating behaviour.

Promotion of Benefits

Just as there are contradictions in the provisions of the regulations, there are different perspectives on what ought to be prioritised as a benefit – and some of these may at times conflict. For example, should free trade (as outlined in the Sanitary and Phytosanitary and Technical Barriers to Trade Agreements) be prioritised over the protection of biodiversity (the focus of the Convention on Biodiversity and Cartagena Protocol)? Should providing rewards for innovation (as implied in the TRIPS Agreement) be prioritised over maintaining certain resources as the common heritage of mankind (as suggested in the International Treaty on Plant Genetic Resources)? When should freedom of scientific research be prioritised over the ethical, moral and cultural values of societies? These examples are all representative of ongoing wider debates between and within states and societies and it is perhaps unrealistic to expect regulation to have

resolved them – but some certainty needs to be provided if benefits are to be appropriately prioritised and promoted. It is also important that actions are coordinated. For example how should the potential benefit of increased food security through provision of genetically modified food aid be coordinated with environmental and health concerns?

Prevention or Minimisation of Negative Impacts

There are similar differences of perspective reflected in the regulations about what should be prioritised as negative impacts to be avoided. For example under the TRIPS Agreement innovators not being properly rewarded for the development of a novel (genetically engineered) crop would be a negative impact. However, under another agreement, the International Treaty on Plant Genetic Resources, the restriction of access to a plant genetic resource within its multilateral system that might result from a patent is viewed as a negative impact (Article 12.3(d)). There is no guidance as yet, as to how such issues ought to be balanced.

Identification, Assessment and Management of Risks

In trying to reach an optimal promotion of benefits and avoidance of negative impacts, effective risk identification, assessment and management are very important. Lack of coherence among the regulations could also pose problems here. It may be unclear to states what standards they should apply; how they should make their assessments; what types of assessments will be viewed as legitimate; whether they are allowed to use the precautionary principle; and whether they can include assessment of risks to social values or to economic development.

Promotion of Capacity-building

In order to be able to effectively identify, assess and manage risks, promote benefits and avoid negative impacts, states need to have the institutions, mechanisms, knowledge and funds to do so. This makes capacity-building very important for the effective governance of biotechnology. Many of the regulations have provisions that support capacity-building, particularly through financial and technical assistance, technology transfer and information exchange. However, there are still problems caused by the regulations' lack of coherence. If states are unclear about what their obligations are under the regulations, about what they should be promoting and avoiding, about what they are permitted and/or obliged to do in terms of risk assessment and management – then they are also likely to be unclear about what sort of mechanisms and institutions they need and what national legal measures they should put in place to implement the international regulations – particularly if they are worried that the legislation they put in place to implement one international regulation will be challenged under another international regulation.

Policy Proposals for Increasing the Coherence of the International Biotechnology Regulations

Any attempt to increase the coherence of the existing regulations will be difficult. It is clearer which routes cannot be taken successfully, than which might succeed.

Removing existing regulations and starting again with regulations specifically and primarily aimed at governing biotechnology will not be helpful. There are two major reasons for this: firstly, the existing regulations often have a much broader focus, and should not be withdrawn because of the other useful functions they fulfil; and secondly, this would take a long time to negotiate and without the existing regulations in place there would probably be an absence of control lasting for at least several years.

Similarly, creating one single treaty to combine all elements of biotechnology governance would be extremely problematic because there are so many issues to be covered. States may not agree to issues being taken out of existing treaty regimes – resulting in further duplications and overlaps. Negotiation of such an instrument would also take a long time.

Amendment of the existing regulations is a long-term possibility for the resolution of contradictions and imbalances, but will still be problematic because many amendment processes will be involved under the different review procedures. These would need to be closely coordinated if current problems are not to be perpetuated and again it is likely to be a very lengthy process, particularly in regard to the amendment of the legally binding treaties. Creating new agreements to fill in the gaps and strengthen weak areas is another possibility, but negotiators would need to be careful to avoid creating any more overlaps or contradictions – and this will not resolve the issue of coherence by itself.

Since the analysis shows that conflicting principles are associated with conflicting provisions (although no causal effect has been established), another proposal is establishment of an international framework of principles for international governance of biotechnology that would guide the development and implementation of the regulations. This has several advantages: prioritisation of principles is possible, although problematic – and importantly these principles would be ones that already exist and have been accepted by the international community; the framework need not be legally binding; and it may be easier to resolve contradictions by working at the level of principles, the moving up to the level of rules rather than the other way round. The international community would need to decide which principles it wishes to use as the basis of biotechnology regulation and then work from this basis towards amending or supplementing the regulations as necessary (the framework should indicate where this work needs to be done). This task too would be very difficult – for example, even within sets of internationally agreed principles there can be significant conflicts – but it is essential to find a way of enhancing coherence of the regulations. The

framework would also help raise awareness of the full range of the regulations, their connections and of the issues that need to be covered and the roles that need to be played by regulation.

More immediately, coherence at the stage of implementation of the regulations can be enhanced through increased cooperation between the international organisations responsible for the regulations. Several such initiatives are underway, but the extent and success of these depend fundamentally on the support of member states – where state support is lacking, even if the need for coordination is clearly recognised, it will be severely restrained. Positive examples can be seen, for example, where the World Intellectual Property Organisation has, on request, provided information to the World Health Organisation on patents relating to the avian influenza virus (WIPO, 2007), which informed a 2008 report by the World Health Organisation's Secretariat on Pandemic Influenza Preparedness (WHO, 2008c). An example of the limiting effects of member states' attitudes towards cooperative activities can be seen in the area of biofuels, where despite clear international recognition of the problems caused for food security and the environment from the recent massive increase in biofuel production and consumption, states have been unwilling to give necessary support to international cooperative initiatives – for example at the 2008 High Level Conference on World Food Security: The Challenges of Climate Change and Bioenergy hosted by the Food and Agriculture Organisation, states failed to produce more than a brief statement on possible future responses (FAO, 5 June 2008) despite the urgency of the problems, particularly those of food price rises, they were facing.

Conclusion

The key implication of the lack of coherence among the international regulations applicable to the applications and impacts of biotechnology is that at a time when such regulation is essential, it is presented with great difficulties in achieving coordination of state action. Separate action by individual states will be insufficient to address issues of common concern in the governance of biotechnology and the international dimensions of the revolution are unlikely to be effectively addressed by regulation as it currently stands, because it can neither fulfil the general functions of international regulation, nor the specific roles required of regulation of biotechnology. Moves towards greater coherence of the regulations will be problematic, but should not be viewed as impossible – and it is a task that the international community needs to act upon urgently, if it is to effectively manage the challenges and opportunities posed by modern biotechnology.

12. Conclusion

Examination of the origins of the field of biotechnology clearly shows that a series of scientific advances combined to produce a major scientific and technological revolution. The rapid and widespread application of these scientific and technological developments in agriculture, health care and a range of other industries has produced a socio-economic revolution which is still in its infancy. A range of examples of current and potential socio-economic impacts were outlined in Chapter 3, which showed that there will be both positive and negative impacts resulting from the biotechnology revolution. Some of the negative outcomes could be severe and in this event are likely to be very difficult, if not impossible, to reverse. They will not necessarily be inadvertent – there is significant potential for biotechnology to be used with malign intent. There remains a great deal of uncertainty about the precise outcomes of the revolution – a variety of unpredictable factors will influence the revolution's course and many impacts will be seen only in the long term. However, it is still clear that there are particular benefits to be promoted, risks to be identified and managed, as well as negative impacts to be avoided, and regulation can play an important role in achieving these aims.

The context in which the revolution is occurring is one of high international interdependence across a range of interconnected fields (politics, economics, environment, health, etc.) and of great inequalities and large-scale human suffering. The governance *needs* outlined in this book include the need to effectively manage biotechnology in order to promote positive impacts, manage risks and minimise or prevent negative impacts. Importantly, biotechnology has the potential to significantly contribute to the alleviation of poverty and associated suffering. However, this potential is currently hampered by distortions in world markets that disadvantage the interests of the poor and short-term political and economic policies that fail to recognise the implications of interdependence or act appropriately upon imperatives of sustainable development. Unless effectively directed, rather than the benefits reaching those who have the most urgent need of them, the biotechnology revolution may instead exacerbate existing inequalities. This would represent a serious failure of international governance. There is, therefore, also an urgent need for capacity-building to enable more equitable distribution of benefits.

Because of this background, regulation at the international level will be essential if the revolution is to be effectively governed. Many of the revolution's impacts are in areas in which there is a need for coordinated state action due to high international interdependence, where separate action by individual states will be insufficient to address common concerns. Chapter 4 identified seven issue areas in which the revolution has significant applications and impacts and which are areas of high interdependence – arms control,

health and disease control, environmental protection, trade, drugs control, development, and social and ethical impacts.

International regulation helps to coordinate state action through the performance of certain key functions, which include for example, providing predictability, reducing uncertainty, facilitating cooperation, and establishing and shaping expectations. Where there are sets of international regulations addressing a particular matter, coherence of the regulations is important in enabling them to fulfil these functions. Regulatory sets which, on the other hand, lack coherence present various *problems* – such as contradictions, gaps and imbalances – for the effective functioning of international regulation.

Chapter 5 introduced a model of coherent international regulatory sets illustrated with reference to the Geneva Conventions and Protocols. Sixteen key characteristics of coherent international regulatory sets were identified:

- Common (primary) purpose
- Common principles
- Common historical development
- Common identity (external awareness of connections)
- Self-referencing (international awareness of connections)
- Shared definitions
- Unifying provisions
- Complementary provisions
- Common structure
- Common administration and review procedures
- Common enforcement and dispute settlement mechanisms
- Same strength of force
- Single international organisation
- Self-contained
- Clear issue focus
- Comprehensive coverage of the issue

Coherent international regulatory sets will not necessarily display all of these characteristics, but they are expected to display a majority of them.

Within the seven issue areas identified as relevant to the governance of biotechnology there are currently thirty-seven applicable international regulations; these are:

In the area of arms control

- The Geneva Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare
- Biological Weapons Convention
- Chemical Weapons Convention
- Convention on the Prohibition of Military or Any Other Hostile Use of Environmental Modification Techniques

Together these regulations prohibit the hostile use of biotechnological tools and techniques in the development, production or use of biological and toxin weapons against humans, animals or plants, or as a form of environmental modification in warfare. They also promote beneficial, peaceful uses and development of such tools and techniques.

In the area of health and disease control

- The International Health Regulations
- Terrestrial and Aquatic Animal Health Codes
- International Plant Protection Convention
- Laboratory Biosafety Manual
- Biorisk Management: Laboratory Biosecurity Guidance
- Guidance on Regulations for the Transport of Infectious Substances
- Manual of Diagnostic Tests and Vaccines for Terrestrial Animals
- Manual of Diagnostic Tests for Aquatic Animals
- Codex Principles for the Risk Analysis of Foods Derived from Modern Biotechnology
- Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants;
- Codex Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms
- Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals

The International Plant Protection Convention, International Health Regulations and Terrestrial and Aquatic Animal Health Codes aim to prevent the international spread of serious human, plant and animal diseases. Biotechnology can help in the identification, surveillance and treatment of these diseases; its use may also, deliberately or inadvertently, result in outbreaks of novel diseases that could require international control. The Laboratory Biosafety Manual, Guidance on Regulations for the Transport of Infectious Substances, Manual of Diagnostic Tests and Vaccines for Terrestrial Animals and Manual of Diagnostic Tests for Aquatic Animals also aim to prevent disease spread, with a particular focus on minimising the risk of infection to those working in laboratories with, or in the transport of, infectious substances. The Codex Principles and Guidelines deal specifically with the safety assessment of foods produced with or consisting of genetically modified organisms, to minimise risks to human health.

In the area of environmental protection

- The Convention on Biodiversity
- Cartagena Protocol on Biosafety

The Convention on Biodiversity aims to protect the earth's biodiversity in all its forms. It specifically recognises biotechnology as both a potential tool

to assist conservation of biodiversity and as a potential threat to biodiversity. The Cartagena Protocol specifically aims to allow states to restrict imports of living modified organisms (produced using genetic engineering) where they may pose a threat to biodiversity.

In the area of trade

- The Sanitary and Phytosanitary Agreement
- Technical Barriers to Trade Agreement
- Trade Related Aspects of Intellectual Property Rights Agreement
- Patent Cooperation Treaty
- Patent Law Treaty
- Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure
- International Convention for the Protection of New Varieties of Plants
- International Treaty on Plant Genetic Resources for Food and Agriculture
- Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilisation

The Agreement on Technical Barriers to Trade and the Agreement on the Application of Sanitary and Phytosanitary Measures aim to limit technical barriers to those which are scientifically justified. Various technical barriers, for example in the form of quality/safety standards and labelling rules, are applied to biotechnology products.

Novel biotechnology products and processes may be eligible for intellectual property protection, particularly through patents or plant variety rights. The Agreement on Trade Related Aspects of Intellectual Property Rights, Patent Cooperation Treaty, Patent Law Treaty and Budapest Treaty on the International Recognition of the Deposit of Microorganisms all form part of the international system for patent protection. The International Convention for the Protection of New Varieties of Plants provides an internationally recognised system of plant variety right protection.

The International Treaty on Plant Genetic Resources and the Bonn Guidelines on Access to Genetic Resources cover access to and benefit-sharing from genetic resources. Such resources often form the basis for the development of novel biotechnology products, particularly pharmaceutical and agricultural products.

In the area of drugs control

- The Single Convention on Narcotic Drugs
- Convention on Psychotropic Substances
- Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances
- World Anti-doping Code
- International Convention against Doping in Sport

Biotechnology can be used in the development and production of novel pharmaceutical drugs which can enter illicit markets or be produced specifically for illicit use. It may be particularly useful in designing drugs to be undetectable in current tests for doping in sport. There is also a suggestion that direct genetic interventions may be used in the future to enhance athletic performance (referred to by the World Anti-doping Association as 'gene doping'). The three UN Drugs Conventions aim to restrict the trade in and use of narcotic drugs and psychotropic substances to licit medical and scientific purposes. The International Convention against Doping in Sport and World Anti-doping Code aim to limit, prevent and punish the use of banned drugs to enhance athletic performance.

In the area of development

The application of biotechnology may both hinder and assist development. For example, food security may be improved through the production of nutritionally enhanced crops, but the concentration of biotechnology research and development in the developed world may exacerbate the global gaps between rich and poor. There are development-related clauses – particularly on scientific and technological exchange and capacity-building – in many of the regulations identified in the other issue areas, but no international regulation solely applicable to the development impacts of modern biotechnology was identified.

In the area of social and ethical impacts

- The Universal Declaration on the Human Genome and Human Rights
- International Declaration on Human Genetic Data
- Universal Declaration on Bioethics and Human Rights
- United Nations Declaration on Human Cloning

The biotechnology revolution has a range of social and ethical impacts, particularly in the area of human genetics. So far there are four international declarations that set out ethical principles for the use of human genetic technologies, but there are not yet any international agreements containing prescribed rules for this area.

The international biotechnology regulations largely developed separately from each other, at different times, for different purposes and based on different principles. They were generally not specifically designed to govern the applications and impacts of biotechnology. Comparison of the regulations to the model of coherent international regulatory sets clearly demonstrates that they display few of its characteristics and they are still a long way from meeting the model. A summary of the assessment follows.

Some of the regulations within issue areas had similar primary purposes but the regulations do not share a *common primary purpose*. Some *common principles* were identified both within and between the issue areas. However,

contradictory principles were also identified and there are no principles common to all the regulations. Within issue areas there is some common regulatory development, but there is no *common historical development* in relation to the full set of regulations. As yet, there is no established *common identity* for the regulations, although there are signs that it might be emerging as external awareness of the connections among the regulations grows.

There is *self-referencing*, which indicates internal awareness of connections, between some of the regulations both within and between issue areas, but there are also significant omissions. The self-referencing that is done is often not in relation to biotechnology. Some indications of increasing international awareness were found in documents of the meetings of the parties to the regulations or of their related international organisations, but these are not yet incorporated into the regulatory texts. There are no *shared definitions* used throughout the regulatory set, and only very few shared between some of the regulations. Where *unifying provisions* occur it is mainly within issue areas and their use does not extend across the full regulatory set. Some *complementary provisions* were identified in the sense that the regulations extend protection over different issue areas, but contradictory provisions were also identified and these should not be present in coherent sets of regulation.

Some of the regulations, particularly those that are legally binding, have elements of *common structure*, but this is not displayed to the extent expected in coherent regulatory sets. While some of the regulations within issue areas share similar or *common administrative and review procedures*, this does not extend across the full regulatory set. Despite there, again, being some similarities among regulations within issue areas, there are also significant disparities and there are no *common enforcement and dispute settlement mechanisms* for the regulations. In assessment of the characteristic of *same strength of force*, various factors were identified as problematic, including differences in the number of states parties, in legal status and in the availability of enforcement and verification mechanisms.

It was not possible to make a comparable assessment on the characteristic of being *self-contained* as the regulations were specifically selected because they cover control of biotechnology. Rather than there being a *single international organisation* for the biotechnology regulations, there are fifteen, some of which cover more than one regulation, including across issue areas. In some of the regulations it was possible to identify that they focus on the issue of control of biotechnology, but not in all of them, so they do not match the characteristic of *clear issue focus*. The regulations may be said to display *comprehensive coverage of the issue*, in the sense that they cover all the issue areas relevant to international governance of biotechnology. However, this coverage is hampered by contradictions, imbalances, weaknesses and gaps, which should not occur in coherent regulation.

A significant implication of the regulations' lack of coherence is that, as a set, they will have difficulty fulfilling the key functions of international regulation and the key roles that international regulation of biotechnology needs to play in order to contribute to effective governance of biotechnology. Finding a timely solution to this is problematic. Provision of a framework of principles and enhanced cooperative activities among the relevant international organisations hold some *potential* for promoting coherence at the stage of implementation and for guiding future development and adaptation of the regulations.

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Glossary

adenine One of the four acid bases or nucleotides that make up the genetic code in DNA. Often abbreviated to A.

amino acids These are a type of molecule that makes up proteins.

atomic weight/molecular weight This is the weight given to atoms originally relative to the value of 16 being given to oxygen. The weight of molecules is worked out according to the weight of the atoms in them.

autocatalytic 'A compound that catalyses its own chemical transformation' (Lackie and Dow, 10 October 2001). DNA catalyses its own replication and is therefore autocatalytic.

bacteriophage A form of virus that attacks bacteria.

base pairs The pairs of DNA bases that match up in the double strands of DNA: adenine to thymine; thymine to adenine; guanine to cytosine; and cytosine to guanine.

base sequence The sequence made up of the four bases of DNA: adenine (A); thymine (T); cytosine (C); and guanine (G).

cell division The process by which cells either replicate themselves to produce two identical cells or divide further into four cells containing half the chromosomes of the original cell.

chromosomes Structures present in cells that contain DNA.

codon A triplet set of DNA bases that code for the production of a particular amino acid or a halt in the translation process.

codon dictionary A list or chart of the sixty-four different codons and the amino acids or stops that they code for.

crossing-over This is where sections of DNA exchange places on pairs of chromosomes during meiosis leading to genetic variations or mutations.

cytology The science of studying cells.

cytoplasm The area of a cell surrounding its nucleus.

cytosine One of the four acid bases or nucleotides that make up the genetic code in DNA. Often abbreviated to C.

dideoxynucleotides These can be used to stop the process of DNA replication at particular points corresponding to the nucleotide used, because the next nucleotide in the sequence cannot attach to the dideoxynucleotide. They are used in a gene-sequencing technique developed by Frederick Sanger.

DNA Deoxyribonucleic acid. This carries the genetic code and is located in the nuclei of cells.

DNA bases The four nucleic acids that carry the genetic code: adenine (A); thymine (T); cytosine (C); and guanine (G).

DNA ligase An enzyme which can 'stick' together fragments of DNA. It is used in the creation of recombinant DNA.

electrophoresis A method of analysing complex molecules by using an electrical charge to separate them. 'Each kind of molecule travels … at a different rate depending on its electrical charge and size' (Indiana Institute for Molecular and Cellular Biology, 2 July 2002). This can be used to separate DNA molecules.

enzymes 'Proteins that act as catalysts, speeding the rate at which biochemical reactions proceed but not altering the direction or nature of the reactions' (Indiana Institute for Molecular and Cellular Biology, 2 July 2002).

gamete cells Cells that are involved in reproduction and that contain half the number of chromosomes of the other cells of an organism.

gene expression This occurs when a particular gene (section of DNA) is translated into the relevant protein.

gene therapy The use of genetic engineering to correct 'faults' in the DNA code.

genetically modified crops Crops that have been genetically engineered to improve or confer desired traits.

genome The collective name for all the genes contained in the DNA of a particular life form.

genome sequence The sequence of DNA bases on a genome.

genome sequencing The process of deciphering the DNA base sequence of a particular genome.

guanine One of the four acid bases or nucleotides that make up the genetic code in DNA. Often abbreviated to G.

Human Genome Project A public project started in 1990 to sequence and map the human genome.

linkage To do with the distance between particular genes on a chromosome. Where genes are close together on a chromosome they will be separated less often by the process of crossing-over. The approximate distance between and relative location of genes can thus be worked out from the frequency with which they are inherited together.

linkage/chromosome map Map showing the relative locations of genes on chromosomes, often worked out by studying the frequency of inheritance of certain characteristics.

meiosis The form of cell division that produces four daughter cells with only half of the set of chromosomes contained in the parent cell. Occurs only during the creation of reproductive cells.

mitosis Cell division that occurs in all cells except those involved in the creation of reproductive cells. This form of cell division produces two daughter cells with identical sets of chromosomes to the parent cell.

molecular structure The way in which atoms are arranged within molecules.

mRNA One of the three forms of ribonucleic acid (RNA) present in cells. Messenger RNA (mRNA) carries the code from the DNA in the nucleus out to the cytoplasm of the cell where it is translated into amino acids.

mutation Name given to a genetic change such as a missing base or an 'error' in the genetic sequence.

nucleic acid There are two types of nucleic acid present in cells, deoxyribonucleic acid (DNA) and ribonucleic acid (RNA).

nucleotide sequence The sequence of the four nucleotides or bases of DNA or RNA.

nucleotides The individual bases of adenine, thymine, cytosine and guanine (and uracil in RNA) are also known as nucleotides.

paper chromatography A method of analysing the constituents of substances. A solvent is added to a drop of the substance on paper and the solvent carries the constituents along the paper at different rates and to different distances. The four bases of DNA move at different speeds, so this method can be used to analyse fragments of DNA.

periodic table A table/chart that contains a specific arrangement of elements arranged according to their atomic number and grouped within 'families' that share particular properties.

phlogiston theory A chemical theory of the eighteenth century, which postulated that flammable materials released a substance known as phlogiston when burnt.

plasmid DNA structures which are present in a cell independently of the chromosomes. They are most often found in bacterial cells and are commonly used as vectors in genetic engineering.

polymerase chain reaction (PCR) A method of amplifying, i.e. multiplying, fragments of DNA. Once one piece is replicated, the next stage of the process can replicate both pieces and so on.

polypeptide chain Name given to a chain of amino acids that make up a protein.

recombinant DNA (rDNA) DNA that has had foreign DNA inserted into it.

rennet An enzyme used in the cheese-making process. Traditionally sourced from calves' stomachs it can now, due to genetic engineering techniques, be 'manufactured' by bacteria, producing cheese suitable for vegetarians.

restriction enzymes Enzymes that can 'cut' DNA at particular points in the sequence.

RNA Ribonucleic acid. Similar to DNA but usually present in single strands and with the base uracil replacing thymine. Present within cells in three types: messenger RNA; ribosomal RNA; and transfer RNA.

rRNA Ribosomal RNA. Present in ribosomes within the cytoplasm of cells where the amino acids coded for by DNA are built into proteins.

stop codon Three of the DNA triplet codons do not code for an amino acid but instead for a stop in the translation of the code.

synthesis Building larger chemical compounds from smaller ones. This includes the creation of proteins from amino acids which occurs within the cells of living organisms.

tetranucleotide hypothesis This wrongly asserted that the four bases of DNA made up a repetitive sequence that could not hold the genetic code. This was disproved in 1948.

thymine One of the four acid bases or nucleotides that make up the genetic code in DNA. Often abbreviated to T.

transgenic Containing genes from an unrelated organism inserted using recombinant-DNA techniques.

translation The turning of the DNA code into amino acids.

tRNA Transfer RNA. This is present within the cytoplasm of cells and is used in the process of building amino acids.

uracil An acid base that is not present in DNA but which replaces thymine in RNA.

X-ray crystallography A technique that allows 'photographs' of molecules to be taken based on the differing refraction of X-rays on the crystals of the atoms that make up the molecule.

Notes

Chapter 3 The Uncertain Consequences of the Biotechnology Revolution

1 When discussed in this book, development has broader connotations than simply economic growth, referring to other factors that can contribute to the worsening or alleviation of poverty, including food security, health, sanitation, innovative capacities and modes of ownership.

2 Note on use of terms – In discussion of crops which have had their genetic codes manipulated through modern biotechnological techniques there are three key terms used:
- Genetically engineered (GE) – This refers to all crops that have had their genetic codes altered through direct intervention at the genetic level.
- Transgenic – This term refers to those crops that have received genetic information from an unrelated organism.
- Genetically modified (GM) – This refers to food products derived from GE crops.

3 For details of such work, see for example: work undertaken at the Malaria Research Institute at Johns Hopkins University http://www.malaria.jhsph.edu; Marshall, J. M. and Taylor, C. E. (10 February 2009), 'Malaria Control with Transgenic Mosquitoes', *PLOS Med*, 6(2): e.1000020; Webster, D. and Hill, A. V. S. (2003), 'Progress with New Malaria Vaccines', *Bulletin of the World Health Organisation*, 81(12): 902–8; and Cumberland, S. (2009), 'Mosquito Wars', *Bulletin of the World Health Organisation*, 87: 167–9.

4 'Conventional counterpart' is in this context defined by the Codex Alimentarius Commission as 'a related organism/variety, its components and/or products for which there is experience of establishing safety based on common use as food' (CAC, 2003b).

Chapter 4 Regulatory Needs

1 'International custom, as evidence of a general practice accepted as law' is one of the sources of international law recognised by the International Court of Justice (Article 38.b, Statute of the ICJ).

2 Issue areas: These involve broad issues that have been recognised to be of international significance. The term is used in a similar way to Deutsch and Hoffman's term 'international matters', which they have defined as: 'matters which by their nature, or by the nature of economic, political, technological, military, and other realities, cannot be dealt with on the national scale. They are the matters which cannot be "settled" singly by any state, however powerful' (1971, p. 155).

3 See, *inter alia*: Art and Jervis (1992), Cassesse (1986), Deutsch and Hoffman (1971), Holsti (1994), Joyner (2005), Kegley and Wittkopf (1995), Sands (2005) and Wallace (1986).

4 Coherence: having a 'logical or natural connection or consistency' (HarperCollins, 1999, p. 285).

5 Forum-shifting: Moving between different international fora, in order to achieve particular goals in international relations. Here it would be different fora involved in setting regulation. Four strategies for forum-shifting have been

identified by Braithwaite and Drahos (2000, p. 29): 'moving a regulatory agenda from one organization to another'; 'abandoning an organization'; 'pursuing the same agenda in more than one organization'; and 'preventing an international organization from acting as a forum for regulatory development in the first place'. They noted that this is a tactic used predominantly by strong states or regional blocs (especially the US and EU) which 'forum-shift to fora that embed the principles most valued by them for the relevant regulatory problems'.

Chapter 6 The Regulations

1 Technically justified is defined in Article II of the International Plant Protection Convention as 'justified on the basis of conclusions reached by using appropriate pest risk analysis'.
2 The ICAO Technical Instructions for the Safe Transport of Dangerous Goods by Air, the OTIF Regulations Concerning the International Carriage of Dangerous Goods by Rail, the European Agreement Concerning the International Carriage of Dangerous Goods by Road, and the International Maritime Dangerous Goods Code.
3 Based on Principle 15 of the Rio Declaration on Environment and Development (UNGA, 12 August 1992) – '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'.

Chapter 8 Coherence in the Biotechnology Regulations: Referencing, Definitions and Provisions

1 In this context, capacity-building relates to activities/actions that increase capacity – generally in developing countries and economies in transition – in administrative, regulatory, technical and scientific areas relevant to the particular regulation. For example, this may involve construction of the necessary national legal and administrative structures to implement the regulation and the technical capacity to monitor and report on its implementation.

Chapter 9 Coherence in the Biotechnology Regulations: Structure, Procedures, Mechanisms and Strength

1 Basic provisions include, for example, scope, objectives, principles and use of terms. Substantive provisions will be specific to the particular treaty, but will generally direct states to take certain measures or prohibit certain actions. Institutional provisions include, for example, details of committees, assemblies, meetings of the parties, executive, secretariat and funding structures/mechanisms. Administrative provisions include, for example, procedures for dispute settlement, ratification, acceptance, review and amendment, withdrawal and entry into force.

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