Rhodes, Catherine. "Introduction." *International Governance of Biotechnology: Needs, Problems and Potential*. London: Bloomsbury Academic, 2010. 1–7. Science Ethics and Society. *Bloomsbury Collections*. Web. 26 Apr. 2023. <<http://dx.doi.org/10.5040/9781849661812.ch-001>>.

Downloaded from Bloomsbury Collections, www.bloomsburycollections.com, 26 April 2023, 04:57 UTC.

Copyright © Catherine Rhodes 2010. You may share this work for non-commercial purposes only, provided you give attribution to the copyright holder and the publisher, and provide a link to the Creative Commons licence.

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.