Rhodes, Catherine. "Conclusion." *International Governance of Biotechnology: Needs, Problems and Potential*. London: Bloomsbury Academic, 2010. 173–180. Science Ethics and Society. *Bloomsbury Collections*. Web. 26 Apr. 2023. <<http://dx.doi.org/10.5040/9781849661812.ch-012>>.

Downloaded from Bloomsbury Collections, www.bloomsburycollections.com, 26 April 2023, 09:40 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.

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 malignant 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.

This page intentionally left blank