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Health in the International Governance of Biotechnology – The Real, the Ideal and the Achievable

Catherine Rhodes

Introduction

Biotechnology has great potential to fulfil health needs worldwide. Governance of biotechnology in the health area can help shape its ability to fulfil this potential. By examining the ability of current international governance efforts to promote benefits, identify, assess and manage risks, minimize negative impacts and promote capacity building for health (the ideal), this chapter highlights problems, flaws and weaknesses in the current situation (the real) and points to ways in which it can be improved, given the realities of the international system (the achievable).

Health and biotechnology

Health is one of the main areas in which modern biotechnology is applied and in which it has great potential. New knowledge and techniques enhance understanding of disease processes and susceptibilities and can be applied to assist diagnosis, treatment and prevention of disease and surveillance of infectious disease outbreaks. Biotechnologies also pose potential hazards to health. Concern has, for example, been expressed about: nutritional and other health implications of genetically modified foods; side-effects of gene therapies; and release of genetically modified pathogens into the environment. There is also potential for the new knowledge and technologies to be misused – the production of novel biological warfare agents would be a significant negative impact.

Health is an area of great inequalities within and between nations in regard to research and development (R&D), healthcare systems and infrastructure and availability of and access to treatments. Application of biotechnologies thus raises concerns about the likelihood that the concentration of research

and development activities in developed countries¹ will mean that their interests will dominate and benefits will fail to reach those who need them most:

Fears that the unequal distribution of the potential medical benefits which may be generated by genomics research could exacerbate current inequalities in the provision of healthcare among nations are well founded. Although some progress is being made towards improving the situation, many problems remain, particularly in the areas of infrastructure, biotechnological development, patenting DNA, benefit-sharing, and the commercial implications of large population data collections.²

This produces a substantial need for capacity-building and highlights a significant negative impact that could result from advances in biotechnology – that rather than meeting their potential they will simply serve to further entrench existing inequalities.

Taken in isolation of other rules and fully and appropriately implemented, the health rules would contribute significantly to promoting benefits by advancing scientific, health and regulatory capacities. Governance of biotechnology within the health area is adequate for dealing with many of the risks associated with accidental or deliberate disease outbreaks. However, scant attention is given to a major negative impact associated with advances in biotechnology – that of entrenching inequalities between developed and developing countries in regard to knowledge and expertise, scientific and technological capacities, research and development capabilities and supporting infrastructures. This is despite high-level recognition of the problems this situation will cause. There is room for improvement then – but how far this can go towards achieving what is desirable in governance of biotechnology is questionable.

An additional issue is that the health area has substantial interactions with other regulatory areas – both generally and within the governance of biotechnology. While some of these connections are supportive others impede the effective and intended operation of the health rules.

Use of terms

Biotechnology

Biotechnology can refer to any application of the biosciences, however, most references relate to use of modern tools and techniques, for example in genetic

- 1 The United Nations Educational, Scientific and Cultural Organisation (UNESCO) provides figures on global research and development expenditure (GERD), the most recent figures (2008) indicate that science and R&D activities remain overwhelmingly concentrated in developed countries – which account for less than 20 per cent of the global population, but 76 per cent of GERD and 75 per cent of scientific publications. UNESCO, *UNESCO Science Report 2010: The Current Status of Science in the World* (Paris: UNESCO, 2010), <http://unesdoc.unesco.org/images/0018/001899/189958e.pdf>.
- 2 WHO, *Genomics and World Health* (Geneva: WHO, 2002), 146.

engineering and genomics. Modern biotechnologies have applications across a range of sectors including healthcare, agriculture, environmental remediation and related industries.

International governance

Global governance refers to rules, mechanisms, procedures and other arrangements which, in the absence of an overarching supranational authority, govern relations between actors in the international system. International governance refers to a subset of these that occurs between states. Finkelstein describes global governance as: ‘Any purposeful activity intended to ‘control’ or influence someone else that either occurs in the arena occupied by nations or, occurring at other levels, projects influence into that arena.’³

International regulation

These are rules agreed between states to govern their relations and actions. The term is used to cover both the ‘hard’ and ‘soft’ elements of international law – that is legally binding treaties and voluntary standards, guidelines and codes – because both influence state behaviour. It refers here only to those rules that are potentially universal – that is open to any state to subscribe to.

International organizations

Often associated with particular rules, these are organizations of states that serve to facilitate cooperation, provide forums for discussion and negotiation and oversee and support implementation of rules. Again, the term refers to those which are open to all states, having potentially universal membership.

The need to govern biotechnology

As in the area of health – where it has potential to bring great benefits, carries risks, will give rise to negative impacts (some of which may be severe and irreversible), and can impact inequalities – biotechnology has similar implications for a range of other areas, including conservation of biodiversity, food security and agricultural production. These outcomes are not inherent to the technology but result from how it is applied, under which conditions and in

3 Lawrence S. Finkelstein, ‘What is Global Governance?’, *Global Governance*, 1995, 1(3): 363–72.

which context. This can be shaped by governance measures such as regulation. The dimensions of benefits, risks, negative impacts and inequity produce four key roles for governance of biotechnology:

- 1 Promotion of benefits
- 2 Identification, assessment and management of risks
- 3 Minimization or avoidance of negative impacts
- 4 Promotion of capacity-building⁴

As an illustration – regulation of a genetically modified food could fulfil these roles by: promoting the benefit of enhanced nutritional value; requiring the identification and assessment of any risks to human health resulting from the changes made to the food and their management, for example by setting a recommended daily intake; banning types of changes that produce too high a risk to human health, for example insertion of genetic material from known allergenic sources; and promoting capacity-building in the conduct of effective risk assessment.⁵ This fits quite closely the current international regulatory approach to such foods.⁶

In the context of this chapter governance that fulfils these four roles will be viewed as the ‘ideal’.

International governance of biotechnology

The applications and impacts of biotechnology are not limited by national boundaries. Knowledge, technology material resources and people are highly mobile and the governance mechanisms of a single state can easily be

4 Catherine Rhodes, *International Governance of Biotechnology: Needs, Problems and Potential* (London: Bloomsbury Academic, 2010), 49.

5 *Ibid.*, 50.

6 See, Codex Alimentarius Commission, *Codex Principles for the Risk Analysis of Foods Derived from Modern Biotechnology* (2003a). Accessed 31 October 2011 through <http://codexalimentarius.org/standards/list-of-standards/en/>; Codex Alimentarius Commission, *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* (2003b). Accessed 31 October 2011 through www.codexalimentarius.org/standards/list-of-standards/en/. Codex Alimentarius Commission, *Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms* (2003c). Accessed 31 October 2011 through www.codexalimentarius.org/standards/list-of-standards/en/. Codex Alimentarius Commission, *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals* (2008). Accessed 31 October 2011 through www.codexalimentarius.org/standards/list-of-standards/en/.

circumvented by locating activities elsewhere. Murphy makes this point in relation to xenotransplantation:⁷

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.

The impacts of biotechnology are shaped by the global context in which it is being applied. As previously mentioned, this is a context of great inequalities. It is also one of deep interdependence between states which provokes a need for cooperative action on issues of common concern.

International governance efforts have 'greater potential than those at other levels to contribute to a more even distribution of benefits and to establish measures to ameliorate negative impacts', they can 'play a role in introducing accountability and responsibility for transnational risks; help balance the varying needs and interests of different countries; and to promote transfer of technology, financial assistance, information and skills for capacity-building'.⁸

In any area in which there is a high degree of international interdependence – where separate actions by individual states will be insufficient to address issues of common concern – there is a need for rules and other governance mechanisms in order to coordinate state action. In coordinating state action, international regulation and other forms of governance fulfil several core functions such as: establishing and shaping expectations; defining rights and obligations; simplifying and facilitating transactions; reducing uncertainty; authorizing or prohibiting certain actions; guiding policy-making; reducing the costs of individual actions; and channelling conflict and providing mechanisms for its resolution.⁹

Biotechnology has significant applications and impacts in several areas in which international interdependence is high, these include:

- Arms control

Biotechnology has the potential for misuse in production of novel warfare agents and can also be applied to biodefence research. In the arms control area there are rules which prohibit non-peaceful uses of biology and that promote scientific and medical research for peaceful purposes.

7 Sean D. Murphy, 'Biotechnology and International Law', *Harvard International Law Journal*, 2001, 42(1): 47–139, 60.

8 Rhodes, *International Governance of Biotechnology*, 51.

9 *Ibid.*, 57–8.

- Development

Biotechnology – in the way it is applied and the uses to which it is put – has significant implications for several aspects of development. Rather than there being separate regulations relevant to the development implications of biotechnology, there are development-related clauses within about half of the other regulations. These include, for example, clauses on provision of scientific and technical advice, financial resources and training, and various forms of capacity-building, for example in infrastructure and administration.

- Drugs control

This includes control of the illicit international drugs trade and prohibitions on the use of doping in sport. In both cases biotechnology could be applied to produce novel drugs that may be misused; it can also assist in producing sufficient supplies of (e.g. pain relieving) drugs for medical and scientific purposes – something that is promoted by rules in this area.

- Environmental protection

Biotechnologies could have both protective and damaging effects on the environment, with a particular area of international concern being their impacts on biodiversity. This concern is most strongly raised in relation to planting of genetically engineered crops which may reinforce monocultural agricultural practices, push out wild relatives and result in gene transfer to other crops and weeds.¹⁰

- Health

As mentioned earlier, biotechnology has many applications and impacts of relevance to health. Relevant international governance efforts include those on disease control (for plant, animal and human health), food safety, and laboratory biosafety and biosecurity.

- Social impacts of human genetics

There are four international declarations which deal with the human rights and other social implications of human genetics research and its applications.

- Trade

10 See, for example, John Madeley, *Yours for Food: Plant Genetic Resources and Food Security* (London: Christian Aid, 1996); David Zilberman, Holly Ameden and Martin Qaim, 'The Impact of Agricultural Biotechnology on Yields, Risks and Biodiversity in Low Income Countries', *Journal of Development Studies Special Issue – Transgenics and the Poor: Biotechnology in Development Studies*, 2007, 43(1): 63–78.

The products of biotechnology and their constituent parts are traded internationally. Relevant rules include those on free trade, intellectual property rights and access to genetic resources.

There are currently 37 regulations relevant to biotechnology within these areas and 15 international organizations directly associated with these rules. These are listed in Table 10.1 at the end of this chapter. Most of the rules were not developed with the specific aim of addressing the applications and impacts of biotechnology, but do so as part of a wider purpose. They developed largely in separation from one another, at different times (ranging from 1925–2010) and for different purposes. It is not surprising, therefore, to find that these regulations lack coherence – a point which has implications for the effective operation of the health rules.

Health in the International Governance of Biotechnology (The ‘Real’)

There are three strands of health regulations that have particular relevance to the governance of biotechnology – those on disease control, on laboratory biosafety and biosecurity, and on food safety.

Disease control rules have been created in the domains of human, animal and plant health. These rules aim to limit the spread of disease through international travel and trade links. Biotechnology is particularly relevant to these rules because it can assist in the detection, identification, surveillance, tracking and response to disease outbreaks. The key rules and their associated organizations are:

- The International Health Regulations – World Health Organisation (WHO).
- The Terrestrial Animal Health Code, Aquatic Animal Health Code, Manual of Diagnostic Tests and Vaccines for Terrestrial Animals and Manual of Diagnostic Tests for Aquatic Animals – World Animal Health Organisation (OIE).
- The International Plant Protection Convention – Food and Agriculture Organisation (FAO).

These rules will also be relevant to the control of any disease outbreaks caused by accidental or deliberate release of pathogens that have been genetically modified or otherwise used within biotechnological processes. This is not a remote possibility – the 2007 Foot-and-Mouth disease outbreak in the United

Table 10.1 International regulations relevant to biotechnology and their associated international organizations

Regulation	Associated organization
<i>Arms Control</i> 1925 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	Organisation for the Prohibition of Chemical Weapons
<i>Drugs Control</i> Single Convention on Narcotic Drugs Convention on Psychotropic Substances Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances World Anti-Doping Code International Convention against Doping in Sport	United Nations (UN) Office on Drugs and Crime; International Narcotics Control Board; Commission on Narcotic Drugs UN Office on Drugs and Crime; International Narcotics Control Board; Commission on Narcotic Drugs UN Office on Drugs and Crime; International Narcotics Control Board; Commission on Narcotic Drugs World Anti-Doping Association UN Educational, Scientific and Cultural Organisation
<i>Environmental Protection</i> Convention on Biodiversity Cartagena Protocol on Biosafety	Convention on Biodiversity Secretariat Convention on Biodiversity Secretariat
<i>Health</i> International Health Regulations Terrestrial Animal Health Code Aquatic Animal Health Code International Plant Protection Convention Manual of Diagnostic Tests and Vaccines for Terrestrial Animals	World Health Organisation World Animal Health Organisation World Animal Health Organisation Food and Agriculture Organisation World Animal Health Organisation

Manual of Diagnostic Tests for Aquatic Animals	World Animal Health Organisation
Laboratory Biosafety Manual	World Health Organisation
Laboratory Biosecurity Guidance	World Health Organisation
Guidance on Regulations for the Safe Transport of Infectious Substances	World Health Organisation
Codex Principles for Risk Analysis of Foods Derived from Modern Biotechnology	Codex Alimentarius Commission
Codex Guideline for Safety Assessment of Foods Derived from Recombinant-DNA Plants	Codex Alimentarius Commission
Codex Guideline for Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms	Codex Alimentarius Commission
Codex Guideline for Safety Assessment of Foods Derived from Recombinant-DNA Animals	Codex Alimentarius Commission
<i>Social Impacts of Human Genetics</i>	
Universal Declaration on the Human Genome and Human Rights	UN Educational, Scientific and Cultural Organisation
International Declaration on Human Genetic Data	UN Educational, Scientific and Cultural Organisation
Universal Declaration on Bioethics and Human Rights	UN Educational, Scientific and Cultural Organisation
United Nations Declaration on Human Cloning	UN General Assembly
<i>Trade</i>	
Agreement on the Application of Sanitary and Phytosanitary Measures	World Trade Organisation
Agreement on Technical Barriers to Trade	World Trade Organisation
Agreement on Trade Related Aspects of Intellectual Property Rights	World Trade Organisation
Patent Law Treaty	World Intellectual Property Organisation
Patent Cooperation Treaty	World Intellectual Property Organisation
Budapest Treaty on the Deposit of Microorganisms for the Purpose of Patent Procedure	World Intellectual Property Organisation
Convention on the Protection of New Varieties of Plants	World Intellectual Property Organisation
International Treaty on Plant Genetic Resources	Union for the Protection of New Varieties of Plants
Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising Out of their Utilisation	Food and Agriculture Organisation Convention on Biodiversity Secretariat

Kingdom was almost certainly caused by the release of a virus strain used in the production of vaccines in a laboratory facility.¹¹

These long-standing rules¹² are based on the need to protect life and health from infectious disease with minimal interference in travel and trade.

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 trade.¹³

Safety of 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.¹⁴

They prescribe mechanisms for surveillance, communication, reporting and import and travel controls. The importance of capacity-building is acknowledged in the IHR, particularly in relation to surveillance, reporting, risk analysis and regulation.¹⁵ The International Plant Protection Convention (IPPC) asks its contracting parties to provide technical assistance to developing countries to assist their implementation of the Convention.¹⁶

Laboratory biosafety and biosecurity rules aim to protect the health and safety of workers involved in the transport, handling and use of infectious substances and to protect human and animal health and the environment from disease outbreaks that might originate from laboratory facilities. The following extract from the WHO Laboratory Biosafety Manual¹⁷ explains the distinction between biosafety and biosecurity in this context:

‘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

11 Brian G. Spratt, *Independent (Spratt) Review of the Safety of UK Facilities Handling Foot-and-Mouth Disease Virus* (Defra: UK, 2007), http://archive.defra.gov.uk/foodfarm/farmanimal/diseases/atoz/fmd/documents/spratt_final.pdf.

12 The first version of the International Health Regulations was adopted in 1951, the first version of the Terrestrial Animal Health Code in 1968 and the first version of the International Plant Protection Convention in 1952.

13 World Health Organisation, *International Health Regulations (2005)* (Geneva: WHO, 2008), Article 2, http://whqlibdoc.who.int/publications/2008/9789241580410_Eng.pdf.

14 Office International des Epizooties, *Terrestrial Animal Health Code* (20th edn) (Paris: OIE, May 2011), Article 5.1.1., www.oie.int/international-standard-setting/terrestrial-code/access-online/.

15 World Health Organisation, *International Health Regulations (2005)*, para 5.

16 Food and Agriculture Organisation, *International Plant Protection Convention* (Rome: FAO, 1997), Article XX, www.ippc.int/file_uploaded/publications/13742.New_Revised_Text_of_the_International_Plant_Protection_Convention.pdf.

17 World Health Organisation, *Laboratory Biosafety Manual* (Geneva: WHO, 2004), 47, www.who.int/csr/resources/publications/biosafety/Biosafety7.pdf.

to institutional and personal security measures designed to prevent the loss, theft, misuse, diversion or intentional release of pathogens and toxins.

The Laboratory Biosecurity Guidance broadens this to cover ‘the safekeeping of all valuable biological materials (VBM), including not only pathogens and toxins, but also scientifically, historically and economically important biological materials’.¹⁸ This was done to highlight the fact that there are many reasons to secure these materials, not just prevention of misuse.

The World Health Organisation has a biosafety programme which includes three key publications: the Laboratory Biosafety Manual; Biorisk Management: Laboratory Biosecurity Guidance; and Guidance on Regulations for the Safe Transport of Infectious Substances. The Laboratory Biosecurity Guidance and Laboratory Biosafety Manual both have specific guidance relating to genetically modified organisms (Chapter 16 of the Manual and p. 17 of the Guidance) as well as applying more generally to all laboratory work.

Laboratory biosafety is also covered in a section of the Terrestrial Animal Health Code (Chapter 5.8) and is addressed in more detail in Chapter 1.1.2 – Biosafety and Biosecurity in the Veterinary Microbiology Laboratory and Animal Facilities – of the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals.

The WHO and OIE guidance take a very similar approach, advising on risk analysis and assignment of pathogens to one of four risk groups. Particular containment and handling requirements apply to four biosafety levels to which different pathogens are assigned (these levels ‘relate’ but don’t ‘equate’ to the risk groups¹⁹ because local conditions, e.g. levels of immunity in the population and availability of treatments also have to be taken into account).

In 1963 the WHO and FAO formed a joint body to take forward their work developing standards and guidelines for safety in the international food trade – known as the Codex Alimentarius Commission (CAC). The CAC has since produced more 300 standards and set nearly 3000 maximum residue limits for pesticides and around 440 maximum residue limits for veterinary drugs in food (see²⁰ and www.codexalimentarius.org).

In 2003, the Commission adopted a set of Principles for Risk Analysis of Foods Derived from Modern Biotechnology. These were viewed as a necessary supplement to its standard risk analysis principles because these did not deal with assessment of whole foods. At the same time, CAC adopted the two sets of guidelines on assessment of foods derived from recombinant-DNA plants

18 World Health Organisation, *Biorisk Management: Laboratory Biosecurity Guidance* (Geneva: WHO, 2006), 5, www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6.pdf.

19 World Health Organisation, *Laboratory Biosafety Manual*, 1.

20 FAO/WHO, *Understanding the Codex Alimentarius*, (Rome: FAO, 2006), [ftp://ftp.fao.org/codex/Publications/understanding/Understanding_EN.pdf](http://ftp.fao.org/codex/Publications/understanding/Understanding_EN.pdf).

and produced using recombinant-DNA microorganisms. In 2008, guidelines for assessment of foods derived from recombinant-DNA animals were added.

The Principles present a reasoned modification of and supplement to the CAC's standard risk analysis approach and aim to 'provide a framework for undertaking risk analysis on the safety and nutritional aspects of foods derived from modern biotechnology'.²¹ They cover the steps of risk assessment (relative to a 'conventional counterpart'), risk management and risk communication. The three guidelines give more specific recommendations on the structure and content of food safety assessments. The assessments are intended to identify any new or altered hazards. If such hazards are determined to be a risk to human health, this should then be dealt with under the risk management considerations outlined in the Principles.²² The Principles outline a need for capacity-building in capabilities to assess and manage risks:

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.²³

The above health rules, taken in isolation and implemented as intended, could serve the four roles quite well, promoting benefits while using science-based risk assessment and management processes, and supporting effective and rapid response to any disease outbreaks. They also have some capacity-building clauses, which, if fully implemented, could make a significant contribution.

The health rules do not operate in isolation of other rules. There are significant interactions with other rules in the governance of biotechnology – some of these are complementary and supportive but some (and in fact often the same) rules can also conflict and/or impede the effective operation of the health rules. Not all of these interactions are outlined here, instead examples from the areas of trade and arms control are provided.

Trade

There are three types of trade rule relevant to the governance of biotechnology – those on reduction of barriers to trade, on protection of intellectual property rights and on access to and benefit-sharing from the use of genetic resources – all three have implications for the operation of the health rules.

21 Codex Alimentarius Commission, *Codex Principles for the Risk Analysis of Foods Derived from Modern Biotechnology*, point 7.

22 See, Codex Alimentarius Commission, *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants*, point 5.

23 Codex Alimentarius Commission, *Codex Principles for the Risk Analysis of Foods Derived from Modern Biotechnology*, point 27.

The World Trade Organisation's Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) aims to limit trade measures put in place for health reasons to those that are scientifically justified. Health-based trade restrictions must also not be applied in a discriminatory manner. The Agreement promotes harmonization of international standards and use of those standards as the basis for health-related trade rules.

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.²⁴

Sanitary or phytosanitary measures which conform to international standards, guidelines or recommendations shall be deemed necessary to protect human, animal or plant life or health, and presumed to be consistent with the relevant provisions of this Agreement.²⁵

It refers specifically to standards associated with the World Animal Health Organisation, Codex Alimentarius Commission and International Plant Protection Convention as acceptable sources of international standards. The SPS Agreement also promotes capacity building in relation to the application of health measures.²⁶

Rules on protection of intellectual property rights influence the operation of health rules in various ways. For example, they have implications for access to medicines and for benefit-sharing from research on viral genetic resources. Relevant rules include: the WTO's Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement), the Patent Cooperation Treaty and Patent Law Treaty of the World Intellectual Property Organisation (WIPO) and the Convention for the Protection of New Varieties of Plants. It is the TRIPS Agreement that has had the most notable impacts through its provisions requiring harmonized minimum standards for patenting, which must extend to pharmaceutical products. This is because it requires that patents 'be available for any inventions, whether products or processes, in all fields of technology'.²⁷

This has undermined generic production in developing countries and made many medicines unaffordable to their populations. It should be noted that the Agreement itself contains flexibilities intended to avoid such problems, for example allowing compulsory licensing subject to certain conditions in Article 31.

There has also been subsequent work by WTO member states to promote use of these flexibilities and interpretation of the Agreement in ways supportive of the

24 World Trade Organisation, *Agreement on the Application of Sanitary and Phytosanitary Measures* (Geneva: WTO, 1995a), Article 2, www.wto.org/english/tratop_E/sps_E/spsagr_E.htm.

25 Ibid., Article 3.2.

26 Ibid., Article 9.1.

27 World Trade Organisation, *Agreement on Trade Related Aspects of Intellectual Property Rights* (Geneva: WTO, 1995b), Article 27.1, www.wto.org/english/docs_E/legal_E/27-trips.pdf.

right to health, including the 2001 Doha Declaration on the TRIPS Agreement and Public Health, which emphasized that the Agreement should be applied in ways supportive of public health and access to medicines and that states are free to ‘determine the grounds’ under which they grant compulsory licenses.²⁸ Paragraph 6 of the Declaration instructed the Council for TRIPS (a body within WTO) to find a solution to the problem that ‘members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing’.²⁹ This led to a 2003 Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health which created the ‘paragraph six mechanism’, allowing import of generic medicines manufactured under compulsory licensing, where the importing country lacks domestic manufacturing capability.³⁰ The provisions of this decision were incorporated in an amendment to the TRIPS Agreement adopted by the WTO General Council in December 2005.³¹ This will take effect once two-thirds of WTO’s members have accepted it.

There are also two international rules on access to genetic resources that have relevance to health. Both focus on plant genetic resources, some of which have potential uses in medicine, but the main link to health is their connection to food security. International exchange of plant genetic resources assists in maintaining their diversity, which in turn provides greater resilience to disease and changing environmental conditions. There are very strong connections between health and nutrition. Research involving plant genetic resources that, for example, increases yields of key food crops, or enhances their micronutrient value, could help to reduce incidence of calorie and micronutrient deficient malnutrition. The Food and Agriculture Organisation’s most recent estimates are that over 925 million people worldwide are undernourished;³² more than twice this number suffer from micronutrient deficiencies.³³

28 World Trade Organisation, *Declaration on the TRIPS Agreement and Public Health* (Geneva: WTO, November 2001a), para 4, www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

29 Ibid., para 6.

30 World Trade Organisation, *Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health* (Geneva: WTO, 2003), www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm.

31 World Trade Organisation, *Amendment of the TRIPS Agreement* (Geneva: WTO, 2005), www.wto.org/english/tratop_e/trips_e/wtl641_e.htm.

32 Food and Agriculture Organisation, Press Release ‘World Hunger Report 2011: High, Volatile Prices Set to Continue’ (Rome: FAO, 10 October 2011), www.fao.org/news/story/en/item/92495/icode/.

33 World Health Organisation, *Worldwide Prevalence of Anaemia Report 1993–2005* (Geneva: WHO, 2008), www.who.int/vmnis/anaemia/prevalence/en/; World Health Organisation, *Micronutrient Deficiencies: Vitamin A Deficiency* (Geneva: WHO, no date a), www.who.int/nutrition/topics/vad/en/index.html; Food and Agriculture Organisation, *The Scourge of ‘Hidden Hunger’: Global Dimensions of Micronutrient Deficiencies* (Rome: FAO, 2003), <ftp://ftp.fao.org/docrep/fao/005/y8346my8346m01.pdf>.

The International Treaty on Plant Genetic Resources was adopted by the FAO in 2001, to promote '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'.³⁴ It covers a core set of plant genetic resources that are considered to be important to food security and created a 'multilateral system of access and benefit-sharing' through which they can be exchanged.

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of the Benefits Arising out of their Utilisation was adopted by the states parties to the Convention on Biodiversity in 2010.³⁵ It sets out a system for prior informed consent of countries of origin (and also local and indigenous groups) to use of their genetic resources. Its coverage is limited to those genetic resources that fit within Article 15 of the Convention on Biodiversity – those being accessed for 'environmentally sound purposes'.

There is a strong connection between the rules on intellectual property rights and on access and benefit-sharing. Article 27.3b of the TRIPS Agreement (a clause which has been controversial since its drafting) states that:

Members may also exclude from patentability: . . .

(b) plants and animals other than microorganisms, and essentially biological processes for the production of plants and animals other than non-biological and microbiological processes.³⁶

Whether and how this applies to genetic resources (and of which types) is somewhat ambiguous, and there are large controversies over the patenting of genetic material, particularly that which is related to disease.

The relationship between intellectual property rights and access and benefit-sharing has been raised within the World Health Organisation in relation to viral genetic resources. The WHO first became concerned about this issue in 2003 during the SARS (severe acute respiratory syndrome) outbreak and faced significant problems during an avian influenza outbreak in 2007 when Indonesia stopped sharing viral samples with its collaborating research centres due to concerns that private companies were patenting products based on the research conducted on these resources and would price them at a level

34 Food and Agriculture Organisation, *International Treaty on Plant Genetic Resources for Food and Agriculture* (Rome: FAO, 2001), Article 1, <http://ftp.fao.org/docrep/fao/011/i0510e/i0510e.pdf>.

35 Convention on Biodiversity Secretariat, *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of the Benefits Arising Out of their Utilisation* (Montreal: CBD Secretariat, 2010), www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf.

36 World Trade Organisation, *Agreement on Trade Related Aspects of Intellectual Property Rights*, Article 27.3b.

unaffordable to its population.³⁷ WHO stated that ‘there has been a breakdown in trust in this essential system of the international collaboration and collective action’ relating to ‘sharing of viruses and specimens, the development and production of preventive and curative measures such as vaccines and antivirals’ and that ‘the current system does not deliver the desired level of fairness, transparency and equity’.³⁸ Its member states have developed various mechanisms and guidance on sharing viruses including adoption of a Pandemic Influenza Preparedness Framework: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits in May 2011 (WHA64.5).³⁹ However, the issue of intellectual property rights has been largely excluded from these outputs and it remains to be seen whether the problem will re-occur in future.

The SPS Agreement seems largely supportive of the health rules; TRIPS – in the way it is currently implemented – poses various problems for their effective operation; and rules on access- and benefit-sharing may generally be supportive of health, but also have significant omissions in relation to human, viral and other disease-related genetic resources.

Arms control

Many of the health rules are supportive of the Biological Weapons Convention. Effective implementation of laboratory biosafety and biosecurity measures will close one route to accessing dangerous pathogens. The Laboratory Biosecurity Guidance also recommends that laboratories’ risk management culture involve consideration of bioethics; ethics education has been recommended as part of national implementation measures for the Biological Weapons Convention. The surveillance and monitoring capacities promoted in the disease control rules will also be useful in the event of any deliberate disease outbreaks. The International Health Regulations, for example, cover any disease ‘irrespective of origin or source, that presents or could present significant harm to humans’ (Article 1). The connection is recognized by the World Health Organisation – for example in its work on preparedness for deliberate epidemics⁴⁰ and within

37 World Health Organisation, *Patent Applications for SARS Virus and Genes* (Geneva: WHO, 2003), www.who.int/ehitics/topics/sars_patents/en/print.html; World Health Organisation, Press Release ‘Indonesia to resume sharing H5N1 avian influenza virus samples following a WHO meeting in Jakarta’ (Geneva: WHO, 27 March 2007), www.who.int/mediacentre/news/releases/2007/pr09/en/index.html.

38 World Health Organisation, *Interim Statement of the Intergovernmental Meeting on Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits* (Geneva: WHO, 23 November 2011), www.who.int/gb/pip/pdf_files/IGM_PIP_Int_Statement_En.pdf.

39 World Health Assembly, WHA65.4. *Pandemic Influenza Preparedness Framework: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits* (Geneva: WHO, May 2011), http://apps.who.int/gb/ebwha/pdf_files/WHA64/A64_8-en.pdf.

40 World Health Organisation, *Preparedness for Deliberate Epidemics* (Geneva: WHO, no date b), www.who.int/csr/resources/publications/preparedness/en/.

the Laboratory Biosecurity Guidance – the Food and Agriculture Organisation and the World Animal Health Organisation (OIE) and by states parties to the Biological Weapons Convention. The three organizations have given presentations and participated as observers in recent meetings of states parties to the Biological Weapons Convention.⁴¹

The problem of deliberate misuse is addressed within some of the health rules which support provisions of the Biological Weapons Convention, both at the stage of prevention (the rules on laboratory biosafety and biosecurity) and in the event of any use (through provisions for tracking and containing disease outbreaks in the disease control rules). There are concerns about the robustness of the current biological weapons control regime, but these are not due to weaknesses in the health rules.

Assessment against the ideal (four roles)

In relation to the ‘ideal’ of fulfilling the four roles, these examples suggest that:

The health rules do not specifically promote benefits of biotechnology but they have the potential to facilitate benefits by providing for products of biotechnology to be researched, handled, traded and consumed safely. All of the health rules incorporate processes for risk assessment and management approaches, as does the Sanitary and Phytosanitary Agreement. There is, however, a lack of reflection on the risks that arise due to the inequitable context in which biotechnology is being applied.

The negative impact of entrenched inequalities is not adequately addressed. A need for capacity-building is recognized in some of the rules and by their associated organizations but action remains small-scale and provisions are not fully implemented by states. The adequacy of the provisions on capacity-building is questionable. There is high demand for capacity-building activities and finance, but effective support and enforcement mechanisms are lacking. Other

41 See, for example, World Health Organisation, *WHO's response in the case of an alleged use of a biological agent* (Geneva: BWC Implementation Support Unit, 2010), [www.unog.ch/80256EDD006B8954/\(httpAssets\)/CA61BD8F4B4AA1B7C125778B0046A0DF/\\$file/1_WHO.pdf](http://www.unog.ch/80256EDD006B8954/(httpAssets)/CA61BD8F4B4AA1B7C125778B0046A0DF/$file/1_WHO.pdf); Office International des Epizooties, *Statement for the Biological and Toxin Weapons Convention Meeting of States Parties* (Geneva: BWC Implementation Support Unit, 2010), [www.unog.ch/80256EDD006B8954/\(httpAssets\)/89A67AFC0499190BC12577F20039690B/\\$file/BWC_MSP_2010-OIE-101206.pdf](http://www.unog.ch/80256EDD006B8954/(httpAssets)/89A67AFC0499190BC12577F20039690B/$file/BWC_MSP_2010-OIE-101206.pdf); Food and Agriculture Organisation, *Current FAO Mechanisms for Dealing with the Deliberate Release of Detrimental Biological Agents – Biological Weapons Convention (BWC) Meeting of States* (Geneva: BWC Implementation Support Unit, 2007), [www.unog.ch/80256EDD006B8954/\(httpAssets\)/56FF617B870F4D12C12573AF0051BF53/\\$file/BWC_MSP_2007_Statement-FAO-071210AM.pdf](http://www.unog.ch/80256EDD006B8954/(httpAssets)/56FF617B870F4D12C12573AF0051BF53/$file/BWC_MSP_2007_Statement-FAO-071210AM.pdf).

negative health impacts, for example the introduction and spread of infectious diseases are addressed adequately by the rules.

The achievable – signs of progress

There are some initiatives and activities that indicate improvements in some of the deficient areas are likely. Examples include:

- Collaboration among international organizations

For example, the World Intellectual Property Organisation has, on request, been sharing information with the WHO on patent landscapes for avian influenza which has supported its work on access and benefit-sharing for viral genetic resources.⁴²

- Development agendas

The WTO's member states adopted a development agenda in the Doha Ministerial Declaration of 2001 providing a work programme for the organization in which developing countries' needs and interests are to be central.⁴³ The World Intellectual Property Organisation's member states adopted a development agenda in 2007 to promote consideration of development issues across the organization's activities and established a Committee on Development and Intellectual Property.

- Capacity-building funds/programmes

These include the Standards and Trade Development Facility which provides project grant funding to support capacity-building for the implementation of sanitary and phytosanitary standards. It is a partnership of the FAO, OIE, World Bank, WHO and WTO. Three of the organizations have also established journal access initiatives providing free online access to many journals for developing countries including: Hinari (Access to Research in Health Programme) linked to

42 World Intellectual Property Organisation, *Patent Issues Related to Influenza Viruses and their Genes* (Geneva: WIPO, 19 October 2007), www.who.int/csr/disease/avian_influenza/WIPO_IP_%20paper19_10_2007.pdf; World Intellectual Property Organisation, *Patent Landscape for the H5 Virus: Interim Report* (Geneva: WIPO, November 2007), www.who.int/csr/disease/influenza/avian_flu_landscape.pdf.

43 World Trade Organisation. *Doha Ministerial Declaration* WT/MIN(01)/DEC/1 (Geneva: WTO, November 2001b), www.wto.org/english/thewto_E/minist_E/min01_E/mindecl_E.htm.

the WHO;⁴⁴ Agora (Access to Global Online Research in Agriculture) linked to FAO;⁴⁵ and aRDI (Access to Research for Development and Innovation) linked to WIPO.⁴⁶ WIPO has also recently launched 'Re:Search' in partnership with WHO, major pharmaceutical companies, the US National Institutes of Health and non-profit research organizations. This initiative has been set up to 'share valuable intellectual property (IP) and expertise with the global health research community to promote development of new drugs, vaccines, and diagnostics to treat neglected tropical diseases, malaria and tuberculosis'.⁴⁷

The achievable – obstacles remaining

Various obstacles to progress remain. The biggest problems are in the area of capacity-building for science and technology, health research and development, effective regulation, technology and risk assessment and related infrastructure. States still generally perceive their national interest in narrow terms largely related to economic competitiveness and short-term gain rather than cooperative action in pursuit of long-term welfare improvements. As Dresner explains:

In a world of competing states, each has an incentive to go for the maximum growth and become dominant. The societies that fail to grow . . . end up losing their influence to those who do grow. So each state has an incentive to follow the path of modernity in the short to medium term, even if it is likely to lead to global disaster in the long term.⁴⁸

Combined with power relations this means that the short-term interests of developed states continue to dominate international relations and 'there are still considerable doubts about the will of governments of developed countries to help solve problems which do not appear directly germane to their own populations'.⁴⁹ With the result that, for example: cooperative activities between international organizations are curtailed; issues are dropped from negotiating agendas even when their value is fully recognized; and flexibilities provided

44 World Health Organisation, Health Internetwork Access to Research Initiative, www.who.int/hinari/en.

45 Food and Agriculture Organisation, Access to Global Online Research in Agriculture, www.aginternetwork.org/en.

46 World Intellectual Property Organisation, Access to Research for Development and Innovation, www.wipo.int/ardi/.

47 World Intellectual Property Organisation, Press Release PR/2011/699. 'Leading Pharmaceutical Companies and Research Institutions Offer IP and Expertise for use in Treating Neglected Tropical Diseases as Part of WIPO Re:Search' (Geneva: WIPO, October 2011), www.wipo.int/pressroom/en/article_0026.html.

48 Simon Dresner, *The Principles of Sustainability* (London: Earthscan, 2002), 170.

49 World Health Organisation, Genomics and World Health, 105.

in trade agreements are circumvented by the application of bilateral pressures (the paragraph 6 mechanism has, for example, only been used once since its creation). Funding commitments are also under-fulfilled. For example, although the Standards and Trade Development Facility has a relatively small annual budget of \$5 million, donations between 2007 and 2010 contributed only an average of 86 per cent of this target.⁵⁰

Power relations are unlikely to change significantly in the near future, but can be balanced to an extent by developing countries working together – indeed without such efforts the development agendas of the WTO and WIPO are unlikely to have been created.

Lessons

The design and implementation of health rules needs to take into account the impacts of rules in other areas that might support or hinder their operation. Likewise, the design and implementation of rules in other areas of biotechnology governance ought to take into account the impact they might have on the operation of health rules. The global context needs to be adequately taken into account with far more effort being made to ensure that inequalities are not entrenched by scientific advances being concentrated in developed countries and that biotechnologies can fulfil their beneficial potential for those with greatest need.

50 Standards and Trade Development Facility, *Donor Support* (no date), www.standardsfacility.org/en/AUDonorSupport.htm.