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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 indirectly, 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.1). 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 approach³ 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	<ul style="list-style-type: none"> – Report on access applications – Ensure that approved uses do not prevent traditional uses – Encourage participation of indigenous and local communities (II.C.1)
Users	<ul style="list-style-type: none"> – ‘seek informed consent prior to access’ – ‘respect customs, traditions and values’ – maintain documents on access and use (II.C.2)
Contracting states	<ul style="list-style-type: none"> – 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	<ul style="list-style-type: none"> – 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 UNHDC, 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).