# GENOMICS MONITOR

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## Aims of the Monitor

- To provide regularly updated information and analysis on developments in the international regulations relevant to the control of the biotechnology revolution.
- To highlight the connections, in applicability to biotechnology, between regulations in the areas of arms control, health and disease control, environmental protection, trade, drugs control, development, and social and ethical impacts of human genetics.
- To raise awareness of the scope and limitations of the current regulation in this area.

## Aims of the Introductory Issue

To provide an overview of the international standards, guidelines, codes and treaties that are relevant to the control of the biotechnology revolution.

## Importance of this Area

Current information sources on the international regulation of biotechnology are very limited. Four years ago a website (www.genomics-gateway.net) was established to bring together, in one central location, information on all the international regulations in this area, with links provided to the official texts. A more thorough study of developments in this area is now provided through the Monitor, to inform all those working in this area of current issues and debates and of the status of the regulations. Its value lies in the range of information it provides on the regulations, its emphasis on the interconnections between the regulations, and highlighting of debates that cut across regulatory areas. It will provide a central authoritative source for anyone interested in this area.

## Acknowledgements

The development and production of the Monitor is made possible through a grant from the Carnegie Corporation of New York, as part of the work of the Bradford Disarmament Research Centre, based in the Department of Peace Studies at Bradford University. The Department and Centre have a long history of work in this area, producing over the last ten years series of Briefing Papers, Review Conference Papers, Evaluation Papers, and Science and Technology Reports connected to the project on Strengthening the Biological Weapons Convention. Recognising the links between regulation of biotechnology in the arms control area and wider international regulation of biotechnology, work on exploring these connections began four years ago with the development of the Genomics Gateway Website.

## Structure of the Introductory Issue

As the inaugural issue of the Genomics Monitor, this issue will focus on introducing the international regulations applicable to the control of biotechnology. First, a general section will provide an overview of the regulations, and then the key aims and provisions of each regulation will be outlined, within seven issue areas. Future issues will focus predominantly on developments in the regulations, cross-cutting work by international organisations, emerging issues, and relevant work by other groups. As this issue is being launched just before the Sixth Review Conference of the Biological Weapons Convention, a section is included which summarises the document *Strengthening the Biological Weapons Convention Key Points for the Sixth Review Conference*[2]. Towards the end of the issue information on forthcoming events and recent publications is provided.

[2] Graham S. Pearson, Nicholas A. Sims & Malcolm R. Dando (eds), *Strengthening the Biological Weapons Convention: Key Points for the Sixth Review Conference, University of Bradford, Department of Peace Studies*, September 2006. Accessible through: http://www.brad.ac.uk/acad/sbtwc.

# PART I – REGULATORY DEVELOPMENTS

## 1) AN OVERVIEW OF INTERNATIONAL REGULATION OF BIOTECHNOLOGY

The term regulation is used in the Monitor to cover a range of 'hard' and 'soft' international legal instruments including voluntary standards, guidelines and codes, and legally-binding treaties. All of these documents have relevance for the guidance of state policy on biotechnology.

The biotechnology revolution and its impacts are global, and international regulation is an essential part of its effective control because it facilitates coordinated state action. There are seven main international issue areas in which biotechnology has significant applications and impacts, for which such coordinated action is vital. They are: arms control; health and disease control; environmental protection; trade; drugs control; development; and the social and ethical impacts of human genetics. These issue areas form the structure of the main sections of the Monitor – although there are not regulations specific to the development aspects of biotechnology, instead many of the regulations in the other issue areas incorporate development related clauses.

Within these issue areas there are currently around 35 international regulations applicable to biotechnology. These regulations largely developed in separation from one another. They also developed at different times (from 1925 to the present). Of those which are legally-binding, state participation varies from 14 to 192. There are also fourteen international organisations that operate across the issue areas. There is some awareness of the connections between some of the regulations, but not necessarily in terms of their applicability to biotechnology. In addition the connections across the full range of regulations are rarely recognised. It is important that this awareness is increased because currently there are a number of tensions, imbalances, gaps and weaknesses that need to be addressed – and which cannot be fully seen without examining the regulations as a whole set.

## 2) ARMS CONTROL

### Relevance of the Area to Control of Biotechnology

For any state to feel secure in limiting its own capabilities, it needs assurances that others are doing the same. For this reason, much arms control takes place at the international level. Alongside the many benefits of modern biotechnology, there is potential for deliberate misuse. This is a significant concern in regard to the development and production of biological agents for hostile purposes. The international arms control agreements of relevance to preventing the hostile use of biotechnology (while facilitating peaceful research) 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;
- The Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction;
- The Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on Their Destruction; and
- The Convention on the Prohibition of Military or Any Other Hostile Use of Environmental Modification Techniques.

Each is outlined below.

### The 1925 Geneva Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous, or Other Gases, and of Bacteriological Methods of Warfare

*Key Aims and Provisions*

This brief document noted that a prohibition on the use in war of "asphyxiating, poisonous or other gases, and of all analogous liquids, materials or devices" was already contained in international treaties, and it extended this prohibition to "bacteriological methods of warfare". The Protocol, despite being adopted over eighty years ago, remains relevant today, because it bans the use of biological weapons – the later Biological Weapons Convention does so only through reference to the Protocol.

*Development and Current Status*

The Protocol entered into force in 1928 and has 132 States Parties. It is now generally accepted to be part of customary international law, which makes it binding on all states whether they are parties to it or not, and most previous reservations to the Protocol (which rendered it essentially a 'no-first-use' treaty) have now been withdrawn.

**Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction**

*Key Aims and Provisions*

The Biological and Toxin Weapons Convention (BTWC) prohibits the development, production, stockpiling, acquisition, retention, and – through reference to the Geneva Protocol – use of:

> "(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."
> (Article 1)

States also agree to destroy or convert to peaceful use all such agents, toxins and equipment (Article 2) and not to permit their transfer (Article 3). The provisions of the BTWC apply equally to agents and toxins produced by or consisting of genetically engineered organisms, or through other biotechnology techniques – as can be seen in the following section.

*Development and Current Status*

It was recognised during negotiation that new scientific developments might have an effect on the operation of the Convention and Article 12 instructs that the parties "take into account any new scientific and technological developments relevant to the Convention." The Review Conferences (with the exception of the 5th) through the production of final declarations have built up understandings on the Convention's provisions. In terms of scientific developments, the Final Declaration of the 4th Review Conference stated:

> "The Conference, conscious of apprehensions arising from relevant scientific and technological developments, inter alia, in the fields of microbiology, biotechnology, molecular biology, genetic engineering, and any applications resulting from genome studies, and the possibilities of their use for purposes inconsistent with the objectives and the provisions of the Convention, reaffirms that the undertaking given by the States Parties in Article I applies to all such developments."

The Review Conferences have also established confidence building measures (CBMs) to enhance confidence in compliance with the Convention. Through this, states are invited to submit annual declarations covering such matters as: national biological defence programmes; infectious disease outbreaks; legislative measures; past activities; and vaccine production facilities.

A further attempt to enhance confidence in the Convention has been in the investigation of potential verification mechanisms (by the VEREX Group of Technical Experts in 1992 and 1993) and subsequent negotiation of a protocol to strengthen the BTWC (through the Ad Hoc Group of Governmental Experts from 1994-2001). While a Protocol was negotiated, the US withdrew its support from this process in 2001 and it was not adopted, as intended, at the 5th Review Conference in November that year. The 5th Review Conference was reconvened in November 2002, but the process of negotiating an appropriate instrument was not renewed. Instead a set of three Inter-Review Conference meetings was agreed discussing:

> "i. the adoption of necessary national measures to implement the prohibitions set forth in the Convention, including the enactment of penal legislation;
> ii. national mechanisms to establish and maintain the security and oversight of pathogenic microorganisms and toxins;
> iii. enhancing international capabilities for responding to, investigating and mitigating the effects of cases of alleged use of biological or toxin weapons or suspicious outbreaks of disease;
> iv. strengthening and broadening national and international institutional efforts and existing mechanisms for the surveillance, detection, diagnosis and combating of infectious diseases affecting humans, animals, and plants;
> v. the content, promulgation, and adoption of codes of conduct for scientists."

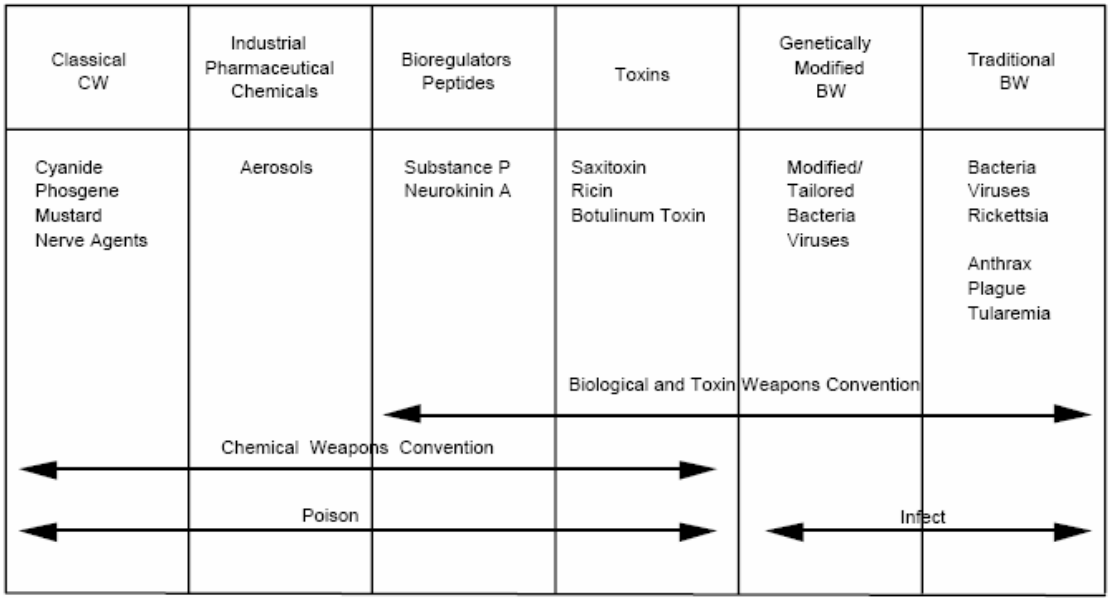
The Sixth Review Conference meets from the 20th November – 8th December 2006 and it is expected to produce a Final Declaration that reviews the Convention's provisions. A summary of *Key Points for the Sixth Review Conference*, is provided in a separate section of the Monitor.

The BTWC was adopted in 1972 and entered into force in 1975. It has 155 States Parties.

**Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on Their Destruction**

*Key Aims and Provisions*

The provisions of the Chemical Weapons Convention (CWC) are also relevant to the control of biotechnology because they cover toxins, which can be produced through biological processes. Graham Pearson (2001, p.6) set out the overlapping coverage of the CWC and BTWC in the CBW Spectrum:




The CWC prohibits the development, production, stockpiling, acquisition, retention, use or preparation to use chemical weapons. Chemical weapons being defined as:

> "the following, together or separately:
> (a) Toxic chemicals and their precursors, except where intended for purposes not prohibited under this Convention, as long as the types and quantities are consistent with such purposes;

(b) Munitions and devices, specifically designed to cause death or other harm through the toxic properties of those toxic chemicals specified in subparagraph (a), which would be released as a result of the employment of such munitions and devices;

(c) Any equipment specifically designed for use directly in connection with the employment of munitions and devices specified in subparagraph (b)."

(Article II.1)

Peaceful uses of toxic chemicals and their precursors are allowed under the Convention's general purpose criterion (Article II.9).

The CWC has detailed provisions on monitoring compliance. States are required to give declarations on any chemical weapons and production facilities held prior to their adopting the Convention, and on their destruction (Article III). Declarations are also required on scheduled chemicals, their precursors and related facilities (Article VI). (Dual-use chemicals are listed in three schedules in an annex to the Convention.) All declarations are made to the Organisation for the Prohibition of Chemical Weapons – and oversight and administration body established by the Convention.

The Convention also has detailed verification provisions and mechanisms for on-site inspections. An Annex on Verification gives further details on the declaration requirements and guidance on the conduct of verification activities.

*Development and Current Status*

The CWC was adopted in 1993 and entered into force in 1997; it has 180 States Parties.

## Convention on the Prohibition of Military or Any Other Hostile Use of Environmental Modification Techniques

*Key Aims and Provisions*

In the Convention on the Prohibition of Military or Any Other Hostile Use of Environmental Modification Techniques (EnMod Convention) states agreed:

> "not to engage in 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."

The Convention, in Article 2, defines environmental modification techniques as:

> "any technique for changing – through the deliberate manipulation of natural processes – the dynamics, composition or structure of the Earth, including its biota, lithosphere, hydrosphere and atmosphere, or of outer space."

In contrast to the Geneva Protocol, BTWC and CWC, the EnMod Convention does not prohibit a particular type of weapon, but a particular use of weaponry. Although the Convention was adopted in 1977, it applies to scientific developments since then, its preamble specifically recognising "that scientific and technical advances may open up new possibilities with respect to modification of the environment."

*Development and Current Status*

The EnMod Convention has received only limited international support, which may be due to flaws in the Convention (among other things its definition of environmental modification techniques gives it very restricted scope). It was

adopted in 1977 and entered into force in 1978. It has 70 States Parties. Review conferences, which under Article VIII of the Convention should have taken place every five years, have only been held twice – in 1986 and 1992.

**References/Links:**

***Official Texts:***

1925 Geneva Protocol – http://www.sussex.ac.uk/Units/spru/hsp/Genev-Prot.html.

Biological Weapons Convention – access through http://www.opbw.org/.

Biological Weapons Convention Review Conference Documents – access through http://www.opbw.org/.

Existing Confidence Building Measures for the Biological Weapons Convention – access through http://www.opbw.org/.

Chemical Weapons Convention – access through http://www.opcw.org/.

EnMod Convention – http://www.fas.org/nuke/contro/enmod/text/environ2.htm.

Chemical Weapons Convention Review Conference Documents – access through http://www.opcw.org/.

***Official Organisations:***

Organisation for the Prohibition of Chemical Weapons – http://www.opcw.org/.

***Others:***

Genomics Gateway Website, http://www.genomics-gateway.net.

Harvard Sussex Programme on Chemical and Biological Weapons, http://www.sussex.ac.uk/Unites/spru/hsp/.

International Committee of the Red Cross, Biotechnology, Weapons and Humanity Appeal, http://www.icrc.org/Web/Eng/siteeng0.nsf/htmlall/bwh?OpenDocument.

Organisation for the Prohibition of Biological Weapons – site administered by the Department of Peace Studies, University of Bradford – http://www.opbw.org.

Pearson, Graham, S., “New Scientific and Technological Developments of Relevance to the Fifth Review Conference”, SBTWC Review Conference Paper No. 3, http://www.brad.ac.uk/acad/sbtwc/briefing/rcp3.pdf.

Project on Strengthening the Biological Weapons Convention, http://www.brad.ac.uk/acad/sbtwc/.

Rhodes, Catherine, (May 2005), International Control of the Biotechnology Revolution – Working Paper 1 – International Arms Control Agreements of Relevance to the Control of the Biotechnology Revolution, http://www.brad.ac.uk/acad/sbtwc/gateway/ARMS/workingpaper1.htm.

SIPRI Chemical and Biological Warfare Project, http://www.sipri.org/contents/cbwarfare/.

## 3) HEALTH AND DISEASE CONTROL

### Relevance of the Area to the Control of Biotechnology

Biotechnology has many applications in the area of health care and international regulation can help to promote the international exchange of beneficial knowledge, research, technology and end products. Disease control rules can assist in the identification, containment and response to any serious infectious disease outbreaks, including any that involve genetically engineered pathogens, whether deliberate or unintentional. Also for the protection of health, certain aspects of food safety are regulated internationally, and rules that cover genetically modified foods are relevant.

### *Disease Control Regulations*

### International Health Regulations

*Key Aims and Provisions*

The International Health Regulations (IHR) aim to protect human health on an international basis by limiting the international spread of infectious diseases. The 1969 version, which is currently in force, focuses on the reporting of outbreaks of cholera, plague and yellow fever. The scope of the IHR has been significantly expanded in the 2005 Revised Version – in force from May 2007 – to cover all "public health emergencies of international concern". A public health emergency of international concern is defined in Article 1 of the IHR 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."

States are instructed to establish ‘core capacities’, including: surveillance; detection; verification; notification; determination of control measures; and response to public health emergencies (these are detailed in Annex 1 of the IHR). They include capacities at ports, airports and ground-crossings. On receiving notification of a public health emergency the World Health Organisation (WHO) will take action to determine whether such is occurring, how to respond, and when the emergency can be considered to have ended (Article 12). Measures will always be designed to be the least restrictive possible, particularly with a view to minimising disruption to travel and trade.

*Development and Current Status*

The process of revising the International Health Regulations began in 1995 and was completed in May 2005 when a revised version was adopted. This will enter into force in May 2007 and states are expected to have established the core capacities by 2012. There are currently 192 States Parties to the IHR. They are overseen by the World Health Organisation.

**The Terrestrial and Aquatic Animal Health Codes**

*Key Aims and Provisions*

These two regulations aim to control the international spread of animal diseases for the protection of both animal and human health. They include general guidance on how to treat imports and exports of animals and animal products. They operate on the basis of listed diseases, outbreaks of which must be reported to the Central Bureau of the Office International des Epizooties (OIE – also known as the World Animal Health Organisation).

States should apply risk analysis to imports of animals and animal products. This analysis is expected to include: hazard identification; assessment of the probability of release; assessment of the probability of exposure following release; and assessment of the consequences and their probability. This

should result in a risk estimation, and suggested measures for risk management. All imports are to be accompanied by international veterinary certificates that indicated freedom from any disease specified by the importing state.

*Development and Current Status*

The Codes are voluntary but membership of the international organisation which oversees them (the OIE) is currently 167 states. The Codes are regularly revised: the Terrestrial Animal Health Code is in its 15th Edition; the Aquatic Animal Health Code in its 9th Edition.

**The International Plant Protection Convention**

*Key Aims and Provisions*

The International Plant Protection Convention (IPPC) is designed to control the international spread of plant pests and diseases, while minimising disruption to international trade. It particularly focuses on the control of 'quarantine pests' – those that are "of potential economic importance to the area endangered thereby and not yet present, or present but not widely distributed and being officially controlled." The precise definition will therefore be locally specific.

National measures are implemented through National Plant Protection Organisations (NPPOs) established under the Convention. NPPOs are responsible for, inter alia:

- issuing phytosanitary certificates;
- surveillance and inspection of plant products during cultivation, storage and transport (particularly international transport);
- reporting outbreaks; imposing control measures; and
- conducting pest risk analyses (Article IV.2).

Pest risk analysis is to be used in decisions on implementing appropriate phytosanitary measures. Phytosanitary certificates accompany all exports of plants and plant products, and are designed to indicate compliance with the standards of the importing state.

The IPPC is recognised by the World Trade Organisation as an acceptable basis for protection measures under its Agreement on the Application of Sanitary and Phytosanitary Measures. Standard-setting under the IPPC is undertaken by a Commission for Phytosanitary Measures (CPM).

*Development and Current Status*

The first version of the IPPC was adopted in 1951 and a revised version in 1979. The IPPC was revised again and a new version adopted in 1997. The 1997 version entered into force in October 2005. The Commission on Phytosanitary Measures held its first meeting in April 2006. Between 1997 and 2005 its work was conducted under an Interim CPM. 27 International Standards for Phytosanitary Measures (ISPMs) have been adopted by the CPM. ISPM No. 11 on Pest Risk Analysis for Quarantine Pests gives guidance on the scope of the IPPC in relation to living modified organisms and how to determine whether they constitute a pest. The Convention is legally-binding and has 159 States Parties.

**WHO Laboratory Biosafety Manual**

*Key Aims and Provisions*

The World Health Organisation's Laboratory Biosafety Manual aims to minimise the risk of disease spread through accidental or deliberate release from laboratories. The Manual has eight main sections covering: biosafety guidelines; laboratory biosecurity; laboratory equipment; good microbiological techniques; introduction to biotechnology; chemical, fire and electrical safety; safety organisation and training; and safety checklists.

The Manual uses four risk groups to classify agents:

> "**Risk Group 1** (no or low individual and community risk)
> A microorganism that is unlikely to cause human or animal disease.
> **Risk Group 2** (moderate individual risk, low community risk)
> A pathogen that can cause human or animal disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment. Laboratory exposures may cause serious infection, but effective treatment and preventive measures are available and the risk of spread of infection is limited.
> **Risk Group 3** (high individual risk, low community risk)
> A pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another. Effective treatment and preventive measures are available.
> **Risk Group 4** (high individual and community risk)
> A pathogen that usually causes serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly. Effective treatment and preventive measures are not usually available."
> (Reproduced from Table 1. Classification of infective microorganisms by risk group, page 1, Laboratory Biosafety Manual.)

The classification of agents into the risk groups is to be done on a national or regional basis, as risk will vary depending on local conditions. According to the risk group that an agent is in – work with that agent must take place in a laboratory designed and equipped to Biosafety Level 1, 2, 3 or 4, with cumulatively stringent biosafety requirements applying to each level.

Special consideration should be given to, “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.” (Chapter 2). There is also a specific chapter in the Manual that focuses on Biosafety and Recombinant-DNA Technology (Chapter 16) and another that deals with Laboratory Biosecurity Concepts (Chapter 9).

*Development and Current Status*

The Laboratory Biosafety Manual is a voluntary guidance document, published as part of the WHO’s Biosafety Programme. The 3rd Edition was published in 2004. It expanded coverage of biotechnology issues. The advice on biosecurity was new to the 2004 Edition, it has now been supplemented with a document, Laboratory Biosecurity Guidance, published by the WHO in September 2006 – which will be further discussed in the next issue of the Genomics Monitor. The WHO has 192 member states.

**WHO Guidance on Regulations for the Transport of Infectious Substances**

*Key Aims and Provisions*

This document aims to minimise the risk of disease spread from accidental release of infectious substances during transport. It provides a synthesis of requirements from modal dangerous goods regulations (e.g. the International Maritime Dangerous Goods Code) which are all based on the UN Model Regulations on the Transport of Dangerous Goods.

Infectious substances are divided into two categories for the purpose of the Guidance. Category A covers any substance “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”. Substances that do not meet this definition come under Category B.

The Guidance focuses on ensuring that infectious substances are correctly identified, packaged and labelled for transport. Substances are assigned UN numbers and shipping names, used in labelling to allow rapid identification. For example a substance in Category A that affects only humans is 'UN 2814 INFECTIOUS SUBSTANCE, AFFECTING HUMANS'. The packing guidance for Category A and B substances closely matches UN Packing Instructions P620 and P650 respectively, and these are reproduced in annexes to the Guidance. In both cases, a basic triple packaging system is used as the starting point.

Any personnel involved in the packaging, handling and/or transport of infectious substances should receive appropriate training. Effective coordination between sender, carrier and receiver is vital to ensuring biosafety during transport, and the Guidance outlines specific responsibilities for each party.

*Development and Current Status*

The Guidance, with which compliance is voluntary, forms part of the WHO's Biosafety Programme. The WHO had 192 member states. The Guidance was significantly revised and republished in September 2005. It was previously titled Biosafety Guidelines for the Safe Transport of Infectious Substances and Diagnostic Specimens.

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

*Key Aims and Provisions*

These documents are designed to accompany the Terrestrial and Aquatic Animal Health Codes. They are mainly concerned with quality management but also provide advice on human safety in veterinary microbiology

laboratories. The Terrestrial Manual also contains sections on biotechnology in the diagnosis of infectious diseases and vaccine development (Chapter I.1.8) and on licensing of products derived through biotechnology, classification of biotechnology derived vaccines, and release of live recombinant-DNA products (Chapter I.1.7). The second part of each Manual contains guidance specific to each OIE listed disease.

*Development and Current Status*

The Manual of Diagnostic Tests and Vaccines for Terrestrial Animals is in its 5th Edition, published in 2004. The online version of the Manual has been updated more recently. The Manual of Diagnostic Tests for Aquatic Animals is also in its 5th Edition, published in 2006. Both Manuals are voluntary guidance and are overseen by the OIE. The OIE has 167 member states.

## *Food Safety Regulations*

### The Codex Alimentarius Principles and Guidelines on Food Derived From Modern Biotechnology

*Key Aims and Provisions*

The Codex Alimentarius Commission is an international standard-setting body concerned with harmonising food safety rules. In 2003 the Commission adopted three documents relating to safety aspects of foods derived from or produced using modern biotechnology:

- Codex Principles for the Risk Analysis of Foods Derived from Modern Biotechnology;
- Codex Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms; and
- Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived From Recombinant-DNA Plants.

The principles form “a framework for undertaking risk analysis on the safety and nutritional aspects of foods derived from modern biotechnology.” (Point 7). The Principles explain, specific to the particular context, what risk assessment is and describe its potential components – including hazard identification, risk management, risk communication, and post-market monitoring. The general guidance they provide is applied more specifically in the two guidelines.

The guidelines concern the conduct of food safety assessments. They identify the information that is needed for an effective assessment and operate using a conventional counterpart to compare the novel food to. The conventional counterpart will have history of safe use as a food, and therefore risk assessment is only concerned with additional or altered hazards. A hazard is defined in the Codex Working Principles for Risk Analysis as “A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.” (Point 2). The assessment will, at least, consider the characteristics of the recombinant-DNA plant/ microorganism, host plant/microorganism, and donor plant/microorganism; identify all transferred genetic material and expressed substances; and identify any toxic or allergenic effects and the impact of any nutritional modification.

There is a particular concern, reflected in annexes to both guidelines, about potential allergenicity. For recombinant-DNA microorganisms the immunological effects of interaction with gut microorganism must also be assessed, and the use of antibiotic resistant genetic material that might transfer to gut microorganisms is discouraged.

*Development and Current Status*

The Codex Alimentarius Commission was established by the Food and Agriculture Organisation (FAO) and WHO in 1963 to oversee the development of harmonised international food safety standards. It has developed over 4800 standards, codes and recommendations over the past forty years.

Previous Codex principles for risk analysis focused on individual food components rather than whole foods, and so it was decided that separate guidance was required for genetically-modified foods. This led to the adoption of the Principles and Guidelines in 2003. The standards of the Codex Alimentarius are voluntary. The Codex Alimentarius Commission has 170 member states and one regional member (the EU).

**References/Links**

***Official Texts:***


International Health Regulations – http://www.who.int/csr/ihr/en/.

Terrestrial Animal Health Code – http://www.oie.int/eng/normes/en_mcode.htm.

Aquatic Animal Health Code – http://www.oie.int/eng/normes/en_acode.htm.

International Plant Protection Convention – https://www.ippc.int/servlet/BinaryDownloaderServlet/13742_1997_English.pdf?filename=/publications/13742.New_Revised_Text_of_the_International_Plant_Protectio.pdf&refID=13742.

Agreement on the Application of Sanitary and Phytosanitary Measures – http://www.wto.org/english/docs_e/legal_e/15-sps.doc.

Laboratory Biosafety Manual – http://www.who.int/csr/resources/publications/biosafety/en/Biosafety7.pdf.

Guidance on Regulations for the Transport of Infectious Substances – http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2005_22%20.pdf.

International Maritime Dangerous Goods Code – restricted access through http://www.imo.org/Safety/index.asp?topic_id=158.

UN Model Regulations on the Transport of Dangerous Goods – http://www.unece.org/trans/danger/publi/unrec/rev14/14files_e.html.

Terrestrial Manual – http://www.oie.int/eng/normes/en_mmanual.htm.

Aquatic Manual – http://www.oie.int/eng/normes/en_amanual.htm.

Codex Principles – http://www.codexalimentarius.net/download/standards/10007/CXG_044e.pdf.

Codex Guideline Recombinant-DNA Microorganisms – http://www.codexalimentarius.net/download/standards/10025/CXG_046e.pdf.

Codex Guideline Recombinant-DNA Plants – http://www.codexalimentarius.net/download/standards/10021/CXG_045e.pdf.

***Official Organisations:***

World Health Organisation – http://www.who.int/.

Office International Des Epizooties – http://www.oie.int/.

Food and Agriculture Organisation – http://www.fao.org/.

International Plant Protection Convention Secretariat – http://www.ippc.int/.

Commission on Phytosanitary Measures – https://www.ippc.int/servlet/CDSServlet?status=ND0xMzMzMCY2PWVuJjMzPSomMzc9a29z.

Codex Alimentarius Commission – http://www.codexalimentarius.net/.

***Others:***

WHO's Biosafety Programme – http://www.who.int/csr/labepidemiology/projects/biosafety/en/.

Laboratory Biosecurity Guidance – http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6/en/index.html.

## 4) ENVIRONMENTAL PROTECTION

### Relevance of the Area to Control of Biotechnology

Biotechnology has applications that may be beneficial to the environment, for example by reducing the amount of pesticides used on crops. Other, and even the same, applications pose threats to the environment and particularly to biodiversity, due to potential effects on other plants, to untargeted insects and species further up the food chain.

### The Convention on Biodiversity

*Key Aims and Provisions*

The Convention on Biodiversity (CBD) is a broad framework convention, dealing with all aspects of the protection of biodiversity:

> "The objectives of this Convention… are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources."
> (Article 1)

It recognises that all technologies have the potential to contribute to biodiversity conservation but also that many pose threats. Biotechnology is specifically included in its definition of technology in this context (Article 2). A key tool for the protection of biodiversity recommended by the Convention is environmental impact assessment for any "proposed projects that are likely to have significant adverse effects on biological diversity" (Article 14). This approach is more specifically applied to certain biotechnology applications in a Protocol to the Convention – the Cartagena Protocol on Biosafety.

*Development and Current Status*

The CBD was adopted in 1992 at the United Nations Conference on Environment and Development. It entered into force in 1993. The Conference of the Parties, responsible for review and development of the Convention, has met eight times since then, most recently in March 2006. The Convention is legally-binding and has 189 States Parties.

**The Cartagena Protocol on Biosafety to the Convention on Biodiversity**

*Key Aims and Provisions*

The Cartagena Protocol gives practical application to the principles of the CBD in relation to transboundary movements of living modified organisms, which are defined as: “any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology” (Article 3.g).

It principally operates through an advanced informed agreement mechanism through which states must give prior consent to transboundary movements of LMOs. The notification given by the potential exporter contains details on the LMO and risk assessment of it. Annex II to the Protocol gives full details on the content and conduct of risk assessments. The importing state acknowledges receipt of the notification and is expected to reach a decision within 270 days, however failure to do so may not be read as implying consent. Decisions are reported both to the exporter and to the Biosafety Clearing House (BCH). The BCH is a mechanism established by the Protocol to facilitate information exchange – access is open to all online. Where risks are identified in the assessment the importing state is expected to put measures in place to deal with them. All states should have measures in place to prevent and penalise illegal transboundary movements.

For the purposes of the Protocol LMOs are divided into three categories: LMOs for deliberate release into the environment; LMOs for direct use in food or feed or food processing; and LMOs for contained use. Each is treated differently in terms of the advance informed agreement procedure.

*Development and Current Status*

Article 19.3 of the CBD instructed states to:

> "consider the need for and modalities of a protocol setting out appropriate procedures… in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity."

The Cartagena Protocol on Biosafety was adopted in 2000 and entered into force in 2003. Three Meetings of the Parties to the Protocol have been held so far, in February 2004, May-June 2005, and March 2006. The Conference of the Parties to the CBD serves as the Meeting of the Parties to the Protocol. The Protocol is legally-binding and has 135 States Parties.

**References/Links**

***Official Texts:***

Convention on Biodiversity – http://www.biodiv.org/convention/convention.shtml.

Cartagena Protocol – http://www.biodiv.org/biosafety/protocol.shtml.

Documents of the Conference of the Parties to the Convention on Biodiversity – http://www.biodiv.org/convention/cops.shtml.

Documents of the Meeting of the Parties to the Cartagena Protocol – http://www.biodiv.org/biosafety/cop-mop/search.aspx?menu=mop3.

***Official Organisations:***

Convention on Biodiversity Secretariat – http://www.biodiv.org/.

***Other:***

Biosafety Clearing House – http://bch.biodiv.org/.

## 5) TRADE

### Relevance of the Area to Control of Biotechnology

There are three main trade-related areas that are of relevance to the international control of biotechnology. First are rules on the reduction of barriers to trade which will apply to many biotechnology products. Second are rules on intellectual property protection for innovative products and processes. Third are rules on access to genetic resources which form the basis of many biotech products.

### *Agreements for the Reduction of Barriers to Trade*

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

*Key Aims and Provisions*

Various quality standards and technical regulations may be applied to biotech products, for example labelling rules for genetically modified foods or quality standards for pharmaceuticals. These standards and rules are referred to by the World Trade Organisation (WTO) as technical barriers to trade. In many cases, such technical barriers will be justified, for example to prevent deceptive practices, but they can also be used as unjustified barriers to trade. The Technical Barriers to Trade Agreement (TBT Agreement) of the WTO aims to remove these unjustified barriers and to encourage harmonisation of legitimate technical barriers in order to further facilitate trade.

Where such technical regulations and standards are in place for the protection of human, animal or plant health they come under the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). This Agreement also aims to remove unjustified barriers to trade and to harmonise legitimate standards and rules.

Technical regulations and standards are specifically defined in Annex 1 of the TBT Agreement. SPS measures are defined in Annex A of SPS Agreement.

Both agreements incorporate the requirement for all rules to be scientifically justified, i.e. based on scientific risk assessment. Where international standards exist states are encouraged to use them as the basis for their national measures which will then be considered compliant with the Agreements. The SPS Agreement particularly refers to standards produced by the Codex Alimentarius Commission, Office International des Epizooties and the Secretariat of the International Plant Protection Convention (Article 3.4 and Annex A.3).

*Development and Current Status*

The WTO was established in 1995 and the SPS and TBT Agreements were part of its founding Agreements. They are legally-binding for all WTO members, it currently has 149.

### *Agreements on Intellectual Property Protection*

#### Agreement on Trade Related Aspects of Intellectual Property Rights

*Key Aims and Provisions*

The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) provides for minimum standards of protection for intellectual property rights. It covers a range of intellectual property rights, but its provisions on patents are most relevant to the field of biotechnology. All states are expected to have national measures to implement and enforce intellectual property rights. In regard to patents, developing and least developed country members are granted extensions to the time periods in which they must apply such measures (see *Declaration on the TRIPS Agreement and Public Health*, WTO, 20/11/01).

Patents are granted for “any inventions, whether products or processes, in all fields of technology, as long as they are novel, involve an inventive step and are capable of industrial application” (Article 27.1). Certain exclusions are allowed, particularly for the protection of public order, life, health, the environment and essential security interests (Article 29 and 73); “diagnostic, therapeutic and surgical methods”; and “plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes” (Article 27.3). The application of Article 27.3 is being kept under review by the Council for TRIPS.

*Development and Current Status*

International protection of intellectual property began in 1883 with the Paris Convention for the Protection of Industrial Property. Since then most of the work in this area has been conducted by the World Intellectual Property Organisation (WIPO – known from 1893 to 1970 as the United International Bureaux for the Protection of Intellectual Property), which currently administers 23 treaties, and works closely with the WTO. Rules on intellectual property were separate to those on reduction of barriers to trade until the Uruguay Round of the General Agreement on Tariffs and Trade. TRIPs was adopted as one of the WTO’s founding agreements in 1995. It is legally-binding for all WTO members, there are currently 149.

**The Patent Law Treaty and Patent Cooperation Treaty**

*Key Aims and Provisions*

These treaties facilitate applications for patents in more than one country. The Patent Cooperation Treaty (PCT) created a single international application system; the Patent Law Treaty (PLT) contains additional provisions on the application process. Both have accompanying sets of

regulations that provide further details of the system and process. Under the PCT, an application can be filed as an international application in any of its member states, for as many member states as the applicant chooses (Article 3). The PCT system uses International Search Authorities (ISAs) to ensure the invention is novel. Applicants also have the option of having an international preliminary examination conducted prior to making international applications. This preliminary examination will inform them about whether their invention meets the patenting criteria (Article 33).

*Development and Current Status*

The PCT was adopted in 1970 (and amended in 1979, 1984 and 2001) and the PLT was adopted in 2000. They are both administered by the World Intellectual Property Organisation. They are legally-binding. The PCT has 133 States Parties and the PLT has 14.

**The Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure**

*Key Aims and Provisions*

When filing for a patent on novel microorganisms it will often be necessary to submit samples of the microorganism as part of the examination process. This is in order to meet disclosure criteria, i.e. sufficient detail needs to be provided for the invention to be reproduced. A written description alone might not allow this in regard to novel microorganisms. Under the Budapest Treaty, which also covers plasmids and tissue cultures, applicants may leave the sample(s) with a single International Depositary Authority, rather than needing to make separate deposits in each state in which patent applications are being made.

*Development and Current Status*

The Budapest Treaty was adopted in 1977 and is administered by the World Intellectual Property Organisation. There are currently 37 International Depositary Authorities. The Treaty is legally-binding and has 65 States Parties.

## The International Convention for the Protection of New Varieties of Plants

*Key Aims and Provisions*

The International Convention for the Protection of New Varieties of Plants (UPOV Convention) provides a system of intellectual property protection for plant varieties in the form of plant variety or plant breeders' rights. Plants may alternatively be patented under other agreements. Plant variety rights operate in a similar way to patents, allowing the developer to benefit from their commercial exploitation. A plant variety is defined in the Convention as:

> "a plant grouping within a single botanical taxon of the lowest known rank, which grouping…can be
> - defined by the expression of the characteristics resulting from a given genotype or combination of genotypes,
> - distinguished from any other plant grouping by the expression of at least one of the said characteristics and
> - considered as a unit with regard to its suitability for being propagated unchanged"
> (Article 1)

Plant varieties must fulfil four criteria of novelty, distinctness, uniformity, and stability, to be eligible for plant variety protection (Article 5). These terms are given full definition in Articles 6-9 of the Convention. Applications for protection are made to a designated authority in whichever member state the applicant wishes to use first. That authority examines the application on

compliance with the four criteria. The protection provided by the plant variety right extends to: production; reproduction; conditioning for propagation; sale or offering for sale; export; import; and stocking for any of those purposes (Article 14). It does not cover private, non-commercial or experimental use (Article 15). The operation of the Convention is overseen by the International Union for the Protection of New Varieties of Plants.

*Development and Current Status*

The UPOV Convention was adopted in 1961 and entered into force in 1968. It has been amended in 1972, 1978 and 1991. It is legally-binding and has 61 States Parties.

## *Agreements on Access to Genetic Resources*

### The International Treaty on Plant Genetic Resources for Food and Agriculture

*Key Aims and Provisions*

The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR) is designed to ensure the maintenance and sustainable use of a broad range of plant genetic resources, which are vital to food security. Its objectives are stated in Article 1 as:

> "the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security."

The main mechanism used by the treaty is the Multilateral System of Access and Benefit-Sharing. It covers selected plant genetic resources (PGR) that are important for food security (listed in Annex 1 to the Treaty). States are

expected to grant access to the resources, over which they have sovereign rights, through this system for the purposes of research or breeding for food and agriculture. Access is not to be granted for "chemical, pharmaceutical and/or other non-food/feed industrial uses" (Article 12.3.g). If it were to result in restricted access to the system's PGR, intellectual property rights must not be claimed (Article 12.3.d).

Benefits from the use of the system's PGR are to be:

> "shared fairly and equitably through the following mechanisms: the exchange of information, access to and transfer of technology, capacity-building, and the sharing of the benefits arising from commercialization"
> (Article 13.2)

*Development and Current Status*

The Food and Agriculture Organisation (FAO) initiated work on PGR with two resolutions in 1983 which adopted an International Undertaking on Plant Genetic Resources and established the Commission on Genetic Resources for Food and Agriculture (CGRFA). Work to revise the Undertaking began in 1993 and the ITPGR was adopted in 2001. It entered into force in 2004 and has 106 States Parties.

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

*Key Aims and Provisions*

The Bonn Guidelines provide guidance to states and other stakeholders on access to genetic resources and benefit-sharing, particularly for states in creating policy, legislative or administrative measures, and for other stakeholders in negotiation of access and benefit-sharing agreements. The Guidelines also contain provisions on capacity-building, technology transfer

and poverty alleviation. A system of written prior informed consent is recommended for access to genetic resources, and mutually agreed terms should be negotiated for benefit-sharing. States are advised to establish national information points to respond to queries on access and benefit-sharing.

*Development and Current Status*

A key objective of the 1992 Convention on Biodiversity was "the fair and equitable sharing of benefits arising out of the utilization of genetic resources" (CBD, Article 1). The CBD's Conference of the Parties decided to examine the development of guidance in 2000 and adopted the Guidelines in 2002. They are not legally-binding.

**References/Links**

***Official Texts:***

SPS Agreement – http://www.wto.org/english/docs_e/legal_e/15-sps.doc.

TBT Agreement – http://www.wto.org/english/docs_e/legal_e/17-tbt.doc.

TRIPS Agreement – http://www.wto.org/english/docs_e/legal_e/27-trips.doc.

Declaration on the TRIPS Agreement and Public Health – http://www.wto.org/english/thewto_e/minist_e/mindecl_trips_e.htm.

Patent Cooperation Treaty – http://www.wipo.int/pct/en/texts/articles/atoc.htm.

Regulations Under the Patent Cooperation Treaty – http://www.wipo.int/pct/en/texts/rules/rtoc1.htm.

Patent Law Treaty – http://www.wipo.int/treaties/en/ip/plt/trtdocs_wo038.html.

Regulations Under the Patent Law Treaty – http://www.wipo.int/treaties/en/ip/plt/trtdocs_wo039.html.

Budapest Treaty – http://www.wipo.int/treaties/en/registration/budapest/trtdocs_wo002.html.

List of International Depositary Authorities Under the Budapest Treaty – http://www.wipo.int/treaties/en/registration/budapest/idalist.doc.

UPOV Convention – http://www.upov.int/en/publications/conventions/index.html.

ITPGR – ftp://ftp.fao.org/ag/cgrfa/it/ITPGRe.pdf.

Bonn Guidelines – http://www.biodiv.org/programmes/socio-eco/benefit/bonn.asp.

***Official Organisations:***

World Trade Organisation – http://www.wto.org/.

World Intellectual Property Organisation – http://www.wipo.int/.

Union for the Protection of New Varieties of Plants – http://www.upov.int/.

Food and Agriculture Organisation – http://www.fao.org/.

Convention on Biodiversity Secretariat – http://www.biodiv.org/.

***Other:***

Work on Article 27.3 of TRIPS – http://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm.

## 6) DRUGS CONTROL

### Relevance of the Area to the Control of Biotechnology

Biotechnology is enabling the development and production of many novel drugs, with huge potential benefits to human health. It is important to ensure adequate international supply of drugs for medical and scientific purposes but there is a long history of diversion to illicit channels, which requires coordinated international efforts to control. Misuse of drugs, including in sport, causes harm to both the individual involved and to societies as a whole.

### United Nations Drugs Conventions

*Key Aims and Provisions*

The three United Nations Drugs Conventions – the Single Convention on Narcotic Drugs, the Convention on Psychotropic Substances, and the Convention Against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances – all aim to reduce the illicit international drugs trade, while ensuring a sufficient supply for licit uses. The Convention on Narcotic Drugs and the Convention on Psychotropic Substances contain provisions on monitoring and countering the illicit drugs trade, including punishment and deterrence of drugs offences. They operate on the basis of Schedules (lists) of controlled substances and preparations, which can be regularly updated. The manufacture, trade and distribution of scheduled substances require licensing. Both Conventions require states to submit regular reports and estimates of national drug production and requirements, and any imports/exports, which are used by the International Narcotics Control Board to construct a picture of the international drug supply and demand situation.

The Convention Against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances extends coverage to additional materials and equipment (contained within the ‘Red List’) and to additional offences, listed in detail in

Article 3, including “possession, purchase or cultivation of narcotic drugs or psychotropic substances for personal consumption” and possession, transfer, conversion or use of property gained through other offences.

*Development and Current Status*

The United Nations Economic and Social Council established the Commission on Narcotic Drugs in 1946 to oversee international drugs control policy. The Single Convention on Narcotic Drugs was developed to replace a range of earlier agreements and was adopted in 1961, and entered into force in 1975. Coverage was extended in the Convention on Psychotropic Substances, which was adopted in 1971 and entered into force in 1976. The third Convention (Against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances) extended coverage to trafficking offences and was adopted in 1988, entering into force in 1990. Two organisations work alongside the Commission on Narcotic Drugs – the International Narcotics Control Board (created under the 1961 Convention) and the United Nations Office on Drugs and Crime (established in 1997). The Conventions are all legally-binding. There are 180 States Parties to both the 1961 and 1988 Conventions, and 179 States Parties to the 1971 Convention.

**The World Anti-Doping Code**

*Key Aims and Provisions*

The World Anti-Doping Code (WADC) aims to deter, prevent, and punish the use of banned substances and methods to confer competitive advantage in sporting events. It is aimed at athletes and athlete support personnel, and is expected to be used by national, regional and international sporting bodies. It sets out offences and sanctions and establishes routines and procedures for testing, with a particular emphasis on the use of no-advance-notice testing. The Code uses a Prohibited List of banned substances and methods, which is updated annually by the World Anti-Doping Association (WADA). The

Prohibited List includes the method of 'gene-doping' – "The non-therapeutic use of cells, genes, genetic elements, or of the modulation of gene expression, having the capacity to enhance athletic performance," (Point M3, the 2007 Prohibited List).

*Development and Current Status*

The International Olympic Committee established a list of banned substances in 1967 and began testing athletes at the 1968 Olympic Games. Some other sports bodies also conducted tests for certain substances, but it was not until the end of the 20th century that efforts to coordinate international standards took place. In 1999 the WADA was established and immediately began work on producing an anti-doping code, which was adopted in 2003, and operational in time for the 2004 Olympic Games. Its signatories are sporting organisations rather than governments, and currently 580 organisations are listed as having accepted the Code.

**International Convention Against Doping in Sport**

*Key Aims and Provisions*

The International Convention Against Doping in Sport (ICADS) is designed to provide formal governmental support for the rules of the World Anti-Doping Code. It incorporates the WADC's Prohibited List. States agree to provide the necessary legislative and administrative support to national sports organisations for fulfilment of their obligations under the Code.

*Development and Current Status*

In March 2003 governments signed up to the Copenhagen Declaration on Anti-Doping in Sport. This expressed political support for the WADC but was not legally-binding. The United Nations Educational, Scientific and Cultural Organisation began work on drafting a legally-binding convention in support of

the Code and the ICADS was adopted in October 2005. It currently has 18 States Parties but requires 30 for entry into force.

**References/Links:**

***Official Texts:***

Convention on Narcotic Drugs – http://www.unodc.org/pdf/convention_1961_en.pdf.

List of Narcotic Drugs Under International Control, 46th Edition, December 2004, http://www.incb.org/incb/yellow_list.html.

Convention on Psychotropic Substances – http://www.unodc.org/pdf/convention_1971_en.pdf.

List of Psychotropic Substances under International Control, 23rd Edition, December 2003, http://www.incb.org/incb/green_list.html.

Convention Against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances – http://www.unodc.org/pdf/convention_1988_en.pdf.

List of Precursors and Chemicals Frequently Used in the Illicit Manufacture of Narcotic Drugs and Psychotropic Substances Under International Control, 10th Edition, January 2006 – http://www.incb.org/incb/red_list.html.

World Anti-Doping Code – http://www.wada-ama.org/rtecontent/document/code_V3.pdf.

Prohibited List of the World Anti-Doping Code – http://www.wada-ama.org/rtecontent/document/2006_LIST.pdf.

International Convention Against Doping in Sport – http://portal.unesco.org/en/ev.php-URL_ID=31037&URL_DO=DO_TOPIC&URL_SECTION=201.html.

***Official Organisations:***

Commission on Narcotic Drugs – http://www.unodc.org/unodc/en/cnd.html.

International Narcotics Control Board – http://www.incb.org/incb/index.html.

United Nations Office on Drugs and Crime – http://www.unodc.org/.

World Anti-Doping Association – http://www.wada-ama.org/.

United Nations Educational, Scientific and Cultural Organisation – http://www.unesco.org/.

***Other:***

Report of the INCB for 2005 – http://www.incb.org/incb/annual_report_2005.html.

Issue 1 2005 Play True – Gene Doping – http://www.wada-ama.org/rtecontent/document/Play_True_01_2005_en.pdf.

## 7) SOCIAL AND ETHICAL IMPACTS OF HUMAN GENETICS

### Relevance of the Area to the Control of Biotechnology

Research and development in human genetics carries great promise, particularly for the treatment and prevention of disease, but many of the techniques involved raise serious ethical issues, and challenge social values. Many questions are raised, for example:

- To what extent should selection of embryos be allowed?
- When are essentially eugenic choices acceptable?
- Who will control the knowledge produced?
- Are we open to new forms of discrimination?
- Will new technologies be available to all?

Some degree of international leadership is needed on these issues and regularly coordination is required, as currently activities banned in one country/region are easily relocated elsewhere.

### Universal Declaration on the Human Genome and Human Rights

*Key Aims and Provisions*

The main aim of the Universal Declaration on the Human Genome and Human Rights (UDHGHR) is to establish principles for the protection of human rights during the development and application of human genetic technologies. It particularly emphasises that people's rights are to be respected regardless of their genetic characteristics (see for example Article 2a). Any research involving an individual's genome must have that person's prior informed consent, and all data gathered must be kept confidential. Any research and practices "contrary to human dignity" should not be allowed – human reproductive cloning is given as an example of such research (Article

11). Freedom of research is supported (Article 14) and its applications should be aimed at relieving suffering and improving health, with benefits available to all (Article 12).

*Development and Current Status*

The development of the four declarations covered in this section is outlined at the end of the section.

**International Declaration on Human Genetic Data**

*Key Aims and Provisions*

Picking up on the principles outlined in the UDHGHR the International Declaration on Human Genetic Data (IDHGD) focuses more specifically on how data gathered in human genetics research, application and use should be treated. It covers human genetic data, human proteomic data and the samples from which they are derived. It covers collection, processing, storage and use. Human genetic data are granted special status because:

> "(i) they can be predictive of genetic predispositions concerning individuals;
> (ii) they may have a significant impact on the family, including offspring, extending over generations, and in some instances on the whole group to which the person concerned belongs;
> (iii) they may have cultural significance for persons or groups." (Article 4a)

The need for prior informed consent is emphasised, and it should be up to the individual whether or not they receive the research results. Data must be kept confidential and discrimination avoided. Any benefits from human genetic research are to be shared with "society as a whole and the international community" (Article 19).

*Development and Current Status*

The development of the four declarations covered in this section is outlined at the end of the section.

**Universal Declaration on Bioethics and Human Rights**

*Key Aims and Provisions*

The Universal Declaration on Bioethics and Human Rights (UDBEHR) aims to establish key ethical principles to guide governmental and societal responses to developments in medicine and the life sciences, particularly as they relate to humans. The key principles include:

- Protection of human rights;
- Respect for human dignity;
- Equitable access to scientific and technological developments;
- Recognition of the importance of freedom of scientific research;
- Minimisation of harm and maximisation of benefits;
- Respect for privacy, equality and justice;
- Avoidance of discrimination on biological grounds (including genetic);
- Sharing of benefits;
- Promotion of health;
- Assessment and management of risks; and
- Prevention of illegal activities.

In regard to promoting health, scientific and technological development should aim towards improving access to medicines and health care; providing adequate nutrition and water; improving living conditions; and reducing poverty, illiteracy and marginalisation (Article 14).

*Development and Current Status*

The development of the four declarations covered in this section is outlined at the end of the section.

**United Nations Declaration on Human Cloning**

*Key Aims and Provisions*

The United Nations Declaration on Human Cloning (UNDHC) applies the principles of the UDHGHR to the area of human cloning, which it recognises as a threat to human dignity, human rights and fundamental freedoms. States are to take all necessary measures to protect human life "in applications of the life sciences" (point a) and prohibit "all forms of human cloning" (point b) and other applications which are "contrary to human dignity" (point c). Controversially, the UNDHC does not distinguish between reproductive and therapeutic cloning, and this has resulted in limited international support for the Declaration.

*Development and Current Status of the Four Declarations*

The UDHGHR, IDHGD and UDBEHR were all developed by UNESCO. The UNDHC was adopted by the United Nations General Assembly but used the principles of the UDHGHR as its basis. UNESCO established a bioethics programme within its social and human sciences sector in 1993 and work on the UDHGHR also began at this time. It was adopted in 1997. Work on the IDHGD began in 2001 and it was adopted in 2003. Drafting of the UDBEHR began in 2004 and it was adopted in 2005. While all three declarations were adopted unanimously by UNESCO's General Conference, they are not legally-binding.

Work on drafting the UNDHC began within the UN General Assembly's 6th Committee in 2001. It was originally intended to take the form of a legally-

binding prohibition but consensus could not be reached on the issue of therapeutic human cloning, and in 2004 the General Assembly instructed the 6th Committee to draft a non-binding political declaration instead. The Declaration was adopted by the General Assembly in March 2005 in Resolution 59/280. The vote, of those states present, was 84 for, 34 against and 37 abstentions. The for figure accounts for less than half of the UN's 191 member states.

**References/Links**

***Official Texts:***

Universal Declaration on the Human Genome and Human Rights – http://portal.unesco.org/en/ev.php-URL_ID=13177&URL_DO=DO_TOPIC&URL_SECTION=201.html.

International Declaration on Human Genetic Data – http://portal.unesco.org/en/ev.php-URL_ID=17720&URL_DO=DO_TOPIC&URL_SECTION=201.html.

Universal Declaration on Bioethics and Human Rights – http://portal.unesco.org/shs/en/ev.php-URL_ID=1372&URL_DO=DO_TOPIC&URL_SECTION=201.html.

United Nations Declaration on Human Cloning – http://www.un.org/law/cloning/.

***Official Organisations:***

United Nations Educational Scientific and Cultural Organisation – http://www.unesco.org/.

International Bioethics Committee – http://portal.unesco.org/shs/en/ev.php-URL_ID=1879&URL_DO=DO_TOPIC&URL_SECTION=201.html.

Intergovernmental Bioethics Committee – http://portal.unesco.org/shs/en/ev.php-URL_ID=1878&URL_DO=DO_TOPIC&URL_SECTION=201.html.

United Nations General Assembly – http://www.un.org/ga/61.

United Nations General Assembly 6th Committee – http://www.un.org/law/cod/sixth/61/sixth61.htm.

***Other:***

"General Assembly adopts United Nations Declaration on Human Cloning by vote of 84-34-37", *Press Release GA/10333*, 08/03/05, http://www.un.org/News/Press/docs/2005/ga10333.doc.htm.

# PART II

## KEY POINTS FOR THE SIXTH REVIEW CONFERENCE

The Sixth Review Conference for the BTWC takes place in Geneva from 20th November – 8th December 2006. This Review Conference provides an extremely important opportunity for States Parties to review the operation of the Convention and promote its effective implementation. No Final Declaration reviewing the provisions of the Convention was made at the Fifth Review Conference, and scientific and technological developments in the life sciences have continued to advance rapidly in the intervening period.

The Bradford University based Project on Strengthening the Biological Weapons Convention produced a detailed paper in September 2006 titled *Key Points for the Sixth Review Conference*[3] to assist States Parties in developing language for the Final Declaration. The main points of its chapter "Successful Outcomes for the Review Conference" are summarised here, along with points made about specific articles of particular relevance to control of the biotechnology revolution. The full document is available online at http://www.brad.ac.uk/acad/sbtwc/key6rev/contents.htm.

Eleven key successful outcomes for the Review Conference are outlined in the paper, covering:

1. The Final Declaration;
2. Universality;
3. National Implementation;
4. Education, Outreach and Codes of Conduct;
5. Article V Consultation and Cooperation Procedures;
6. Confidence-Building Measures;

[3] Graham S. Pearson, Nicholas A. Sims & Malcolm R. Dando (eds), *Strengthening the Biological Weapons Convention: Key Points for the Sixth Review Conference, University of Bradford, Department of Peace Studies*, September 2006. Accessible through: http://www.brad.ac.uk/acad/sbtwc.

7. Strengthening the Effectiveness and Improving the Implementation of the Convention;
8. Article VI Investigations;
9. Assistance
10. International Cooperation; and
11. Interim Support Structures.

*1. Final Declaration*

It is recommended that the Final Declaration of the Sixth Review Conference provides "a comprehensive article by article review of the Convention" in a cumulative manner – using the Final Declaration of the Fourth Review Conference as its basis, and building on this (p.24).

*2. Universality*

It is recommended that the Sixth Review Conference take action towards achieving universality of participation using an 'achievement timeline' and with the aim of increasing the number of States Parties to 180 by the Seventh Review Conference (2011).

*3. National Implementation*

It is recommended that national implementation measures cover "the full scope of the prohibitions contained in the Convention" and should be extended "to the control and monitoring of relevant dual-use materials and technologies" (p.29) and "to counter the continuing threat posed by biological and toxin weapons whether by States or by sub-State actors." (p.30). It is also recommended that, to increase participation in the implementation of national measures, assistance should be provided to assist States in developing and adopting appropriate measures. For this it is suggested that an 'achievement timeline' be set of two-thirds of States Parties having adopted national implementation legislation by the Seventh Review Conference (p.31).

*4. Education, Outreach and Codes of Conduct*

Here, it is recommended that:

> "an annual meeting of States Parties prepared for by a Meeting of Experts… [take place in] the intersessional period before the Seventh Review Conference to consider the topic: *Education and outreach for all those concerned with the life sciences*." (p.32).

*5. Article V Consultation and Cooperation Procedures*

It is recommended that the consultation and cooperation procedures under Article V be reviewed, particularly "in the light of the experience gained in the 1997 implementation of them and the developments in the international scene since then", and reaffirmed or amended as necessary (p.33).

*6. Confidence-Building Measures*

The Sixth Review Conference is unlikely to have time to deal fully with work to improve CBMs, which could include:

- Review of existing CBMs and their format;
- Proposals for new CBMs;
- Provision for electronic submission and circulation;
- Collation, translation and elaboration procedures; and
- Provision of assistance.

(p.36).

Instead, it is recommended that a Meeting of States Parties, preceded by a Meeting of Experts, be held in 2007 "to consider and decide how to improved the effectiveness of the CBM process" (p.36).

*7. Strengthening the Effectiveness and Improving the Implementation of the Convention*

For work on strengthening the effectiveness and improving the implementation of the Convention, an additional meeting to the Review Conference is recommended. This would be "an 'ad hoc' Meeting of Experts from States Parties", to be held in 2007, "to consider future action to strengthen the Convention" (p.37).

*8. Article VI Investigations*

Two main recommendations are made regarding Article VI investigations. First, that the procedure for making a complaint about breach of obligations (under Article VI.1) be elaborated. Suggested wording for this is:

> "*1. The State Party lodging a complaint should identify which obligation under the Convention it considers has been breached and in what manner the breach has occurred.*
> *2. The State Party lodging the complaint should compile a report containing possible evidence relating to the alleged breach of obligations and the evidence therein should be validated to the extent possible.*
> *3. The State Party lodging a complaint should implement the procedure as soon as possible after the alleged breach of the obligations under the Convention has taken place.*" (p.40)

Second, it is recommended that States Parties:

> "consider what steps are needed to ensure that the Secretary-General's mechanism for the investigation of cases of alleged use of biological and toxin weapons would indeed be effective and credible."

*9. Assistance*

There are recommendations made for both emergency and other assistance. For emergency assistance it is suggested that a Meeting of States Parties, preceded by a Meeting of Experts should be held "*To develop a procedure for the provisions of timely emergency assistance to States Parties on request.*" (p.41). This subject may be broadened to developing "a procedure for the provision of timely assistance to States Parties on request." (p.41). This would include other forms of assistance, for example for national implementation; preparation of CBM returns; and surveillance, detection, diagnosis and combating of infectious diseases (p.41).

*10. International Cooperation*

To enhance international cooperation the adoption of a new CBM for transparency of Article X cooperation (scientific cooperation for peaceful purposes) is suggested. This would form part of the work of and annual Meeting of States Parties, preceded by a Meeting of Experts, on facilitating international cooperation between States Parties.

*11. Interim Supportive Structures*

In order to develop interim supportive structures to operate before an Organisation for the Prohibition of Biological Weapons is established, it is recommended that a second part to the Article XII Review Conferences section be added to the Final Declaration of the Sixth Review Conference, authorising: "the President and General Committee to undertake continuing tasks after the end of the Conference in order to provide interim strengthening structures in support of the Convention." (p.44). Suggested structures include: a representative Intersessional Committee of Oversight or Annual Meeting of States Parties empowered to take decisions; and advisory panels and a standing secretariat to support it (p.44).

Along with these recommendations for successful outcomes, the paper provides detailed information on the cumulative development of the provisions of each Article through previous Final Declarations, and for each Article suggests possible wording for the Sixth Review Conference Final Declaration. Article I – Scope and Article IV – National Implementation have particular relevance for control of the biotechnology revolution.

*Article I - Scope*

Article I of the BTWC contains the prohibitions that:

> "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;"

The Final Declarations of Review Conferences 1 – 4 all reaffirmed the importance of this provision, and confirmed that it covers all scientific and technological developments. It is strongly recommended that this be continued in the Final Declaration of the Sixth Review Conference. Following the suggested cumulative process, the paper considers that three matters particularly require additional/altered wording. First, "that the scientific and technological developments that could be of concern apply to **animals and plants as well as human beings**." (p.66). Second, that it should be made clear in the wording "that developments throughout the **whole** of the life sciences could potentially be of concern" (p.66). And, third, that the fifth paragraph of the Fourth Review Conference's Final Declaration be extended so that it clearly covers "*prions, proteins and bioregulators and their synthetically produced analogues and components*." (p.67).

It is also suggested that the language of the Second Review Conference Final Declaration on the coverage of "*all natural or artificially created microbial or other biological agents or toxins*" be used in preference to that in the Fourth Review Conference Final Declaration, as it is less ambiguous on the coverage of synthetic biology (p.67). Finally, this section of the paper recommends that the Conference encourages the biomedical community to be "much more proactive in raising awareness of the dangers [of some experiments] and introducing effective mechanisms of self-monitoring." (p.67).

*Article IV – National Implementation*

In regard to Article IV, it has been made clear in previous Final Declarations, that this includes the need for education on the Convention's provisions in the medical, scientific and military communities. As part of the Inter-Review Conference Process a Meeting of States Parties was held on *the content promulgation and adoption of codes of conduct for scientists*. It produced a report which recognised the value of voluntarily adopted codes of conduct for scientists in supporting the objectives of the Convention. It is recommended that States Parties incorporate this issue in the Sixth Review Conference Final Declaration, including an additional paragraph in the Article IV section stating that the Conference notes the importance of "- *Adoption of codes of conduct for those engaged in relevant areas of science and technology*." (p.129) along with more detailed language regarding the codes – including: principles; coordination; involvement of those who will be affected; and promulgation (pp.129-131). Finally, this section of the paper recommends that a Meeting of States Parties, preceded by a Meeting of Experts, be held to consider "*Education and outreach for all those concerned with the life sciences*", (p.131).

# PART III – EVENTS AND RECENT PUBLICATIONS

## Arms Control

Sixth Review Conference of the States Parties to the Biological Weapons Convention – 20th November to 8th December 2006, Geneva. Information available through http://www.opbw.org.

Graham S. Pearson, Nicholas A. Sims & Malcolm R. Dando (eds), *Strengthening the Biological Weapons Convention: Key Points for the Sixth Review Conference, University of Bradford, Department of Peace Studies*, September 2006. Accessible through: http://www.brad.ac.uk/acad/sbtwc.

11th Session of the Conference of States Parties to the CWC, 5th-8th December 2006, The Hague. Information available at http://www.opcw.org/csp11/index.html.

Organisation for the Prohibition of Chemical Weapons, *Chemical Disarmament*, Vol.4(3), September 2006. http://www.opcw.org/docs/publication/cdq_sep2006.pdf.

## Health and Disease Control

International Plant Protection Convention Secretariat, *IPPC Dispute Settlement Manual*, August 2006. Available through http://www.ippc.int.

M. Hugh-Jones (ed.), "Biological disasters of animal origin – The role and preparedness of veterinary and public health services", in *OIE Scientific and Technical Review*, Vol. 25(1), April 2006. http://www.oie.int/eng/publicat/rt/A_RT25_1.htm.

**Environmental Protection**

3rd Meeting of Ad Hoc Open-Ended Working Group of Legal and Technical Experts on Liability and Redress in the Context of the Protocol, 19th-23rd February 2007, Montreal.

**Trade**

Food and Agriculture Organisation, *Final Report of the First Session of the Governing Body of the International Treaty on Plant Genetic Resources for Food and Agriculture*, 2006. ftp://ftp.fao.org/ag/cgrfa/gb1/gb1repe.pdf.

Food and Agriculture Organisation/ John Ruane & Andrea Sonnino, *The Role of Biotechnology in Exploring and Protecting Agricultural Genetic Resources*, Rome, 2006. ftp://ftp.fao.org/docrep/fao/009/a0399e/a0399e00.pdf.

World Intellectual Property Organisation, "Bioethics and patent law: the cases of Moore and the Hagahai people", *WIPO Magazine*, Issue 5, September 2006. http://www.wipo.int/wipo_magazine/en/2006/05/article_0008.html.

World Intellectual Property Organisation, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, 30th November – 8th December 2006, Geneva. Information available at http://www.wipo.int/meetings/en/details.jsp?meeting_id=11222.

World Trade Organisation Dispute Settlement Panel Report on "European Communities – Measures Affecting the Approval and Marketing of Biotech Products", 29th September 2006, http://www.wto.org/english/news_e/news06_e/291r_e.htm.

Palmer, Alice, (for GeneWatch UK, RSPB, Forum for Biotechnology and Food Security, and the GM Freeze), *The WTO GMO Dispute: Implications for Developing Countries and the Need for an Appeal*, November 2006. Access through http://www.genetwach.org.

**Drugs Control**

World Anti-Doping Association, *2007 Prohibited List*, 29th September 2006 (in force from 1st January 2007). http://www.wada-ama.org/en/prohibitedlist.ch2.

World Anti-Doping Association, "The World Anti-Doping Code – A Guide" in *Play True*, Issue 3, 2006. http://www.wada-ama.org/rtecontent/document/PlayTrue2006_TheCode_En.pdf.

**Social and Ethical Impacts of Human Genetics**

13th Session of the International Bioethics Committee – 20th-22nd November 2006, UNESCO Headquarters, Paris. Information available at http://portal.unesco.org/shs/en/ev.php-URL_ID=9929&URL_DO=DO_TOPIC&URL_SECTION=201.html.

United Nations Educational, Scientific and Cultural Organisation, *Social Justice in Healthcare: Bioethics and Human Rights*, 12th August 2006. http://portal.unesco.org/shs/en/ev.php-URL_ID=10074&URL_DO=DO_TOPIC&URL_SECTION=201.html.