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GENOMICS MONITOR – ISSUE 8 – CONTENTS

Preface	5
SECTION I: REGULATORY DEVELOPMENTS	7
1) Highlights	7
Quick Reference Table of the International Regulations	8
2) Arms Control	11
3) Health and Disease Control	11
61 st World Health Assembly – Implementation of the International Health Regulations (2005)	11
61 st World Health Assembly – Global Strategy and Plan of Action on Public Health Innovation and Intellectual Property	12
UN Secretary-General’s High-Level Taskforce on the Global Food Security Crisis	14
76 th Annual General Session of the International Committee of the Office International des Epizooties	16
3 rd Session of the Commission on Phytosanitary Measures	24
Codex Alimentarius Commission, 31 st Session	26
FAO, High-Level Conference on World Food Security: The Challenges of Climate Change and Bioenergy	27
4) Environmental Protection	29
Decisions of the 9 th Conference of the Parties to the Convention on Biodiversity	29
5) Trade	38
Work of the WTO’s Sanitary and Phytosanitary Committee	38
WTO – Work on the relationship between the TRIPS Agreement and the Convention on Biodiversity	38
WIPO – 2 nd Session of the Committee on Development and Intellectual Property	40
6) Drugs Control	40
World Anti-Doping Code	40
SECTION II – COOPERATION BETWEEN INTERNATIONAL ORGANISATIONS IN THE REGULATION OF BIOTECHNOLOGY II:	42

ACCESS TO GENETIC RESOURCES

Introduction	42
History of Genetic Resources as an International Issue	44
Current International Activity on Access to Genetic Resources	49
Cooperative Efforts in Relation to Access to Genetic Resources	56
Conclusion	60
References	62
Acronymns	66
SECTION III - EVENTS AND RECENT PUBLICATIONS	67

GENOMICS MONITOR – ISSUE 8

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 Issue 8

Issue 8 of the Genomics Monitor provides updated information on the status of the regulations applicable to the control of the biotechnology revolution (summaries of the regulations were provided in Issue 1) and reports on relevant interstate and international organisation meetings and initiatives. In this issue there is also analysis of cooperation between international organisations relating to access to genetic resources.

Importance of this Area

Current information sources on the international regulation of biotechnology are very limited. Six 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

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Structure of Issue 8

Issue 8 of the Genomics Monitor is in three sections: the first provides information on regulatory developments; the second provides analysis of cooperation between international organisations on access to genetic resources; and the third gives information about forthcoming events and recent publications. Figures given on numbers of states parties were accurate on 4th August 2008.

SECTION 1 - REGULATORY DEVELOPMENTS

1) Highlights

Changes to the numbers of states parties to the regulations are reported in each section (arms control; health and disease control; environmental protection; trade; drugs control; and social and ethical impacts). There are also reports, within the relevant sections, on:

- 61st World Health Assembly – Implementation of the International Health Regulations (2005)
- 61st World Health Assembly – Global Strategy and Plan of Action on Public Health Innovation and Intellectual Property
- UN Secretary-General’s High-Level Taskforce on the Global Food Security Crisis
- 76th Annual General Session of the International Committee of the Office International des Epizooties
- 3rd Session of the Commission on Phytosanitary Measures
- Codex Alimentarius Commission, 31st Session
- FAO, High-Level Conference on World Food Security: The Challenges of Climate Change and Bioenergy
- Decisions of the 9th Conference of the Parties to the Convention on Biodiversity
- Work of the WTO’s Sanitary and Phytosanitary Committee
- WTO – Work on the relationship between the TRIPS Agreement and the Convention on Biodiversity
- WIPO – 2nd Session of the Committee on Development and Intellectual Property
- World Anti-Doping Code

Links to the texts of the regulations and the associated international organisations can be found in Issue 1 of *Genomics Monitor* (<http://www.brad.ac.uk/acad/sbtwc/gateway/monitor/genomicsmonitorissue1.pdf>) or through the summary pages on the Genomics Gateway Website (<http://www.genomics-gateway.net>).

Quick Reference Table of the International Regulations Applicable to the Control of the Biotechnology Revolution

REGULATION	INTERNATIONAL ORGANISATION (WHERE APPLICABLE)	NUMBER OF STATES PARTIES (WHERE APPLICABLE)
<i>Arms Control</i>		
1925 Geneva Protocol		132
Biological and Toxin Weapons Convention		155
Chemical Weapons Convention	Organisation for the Prohibition of Chemical Weapons	184
Convention on the Prohibition of Military or Any Other Hostile Use of Environmental Modification Techniques		70
<i>Health and Disease Control</i>		
International Health Regulations	World Health Organisation	194
Terrestrial Animal Health Code	Office International des Epizooties	OIE has 172 member states
Aquatic Animal Health Code	Office International des Epizooties	OIE has 172 member states
International Plant Protection Convention	Food and Agriculture Organisation	169
Laboratory Biosafety Manual	World Health Organisation	WHO has 194 member states
Laboratory Biosecurity Guidance	World Health Organisation	WHO has 194 member states
Guidance on Regulations for the Safe Transport of Infectious Substances	World Health Organisation	WHO has 194 member states

Manual of Diagnostic Tests and Vaccines for Terrestrial Animals	Office International des Epizooties	OIE has 172 member states
Manual of Diagnostic Tests for Aquatic Animals	Office International des Epizooties	OIE has 172 member states
Principles for the Risk Analysis of Foods Derived from Modern Biotechnology	Codex Alimentarius Commission	CAC has 175 member states plus the European Community
Guideline on Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms	Codex Alimentarius Commission	CAC has 175 member states plus the European Community
Guideline on Food Safety Assessment of Foods Derived from Recombinant-DNA Plants	Codex Alimentarius Commission	CAC has 175 member states plus the European Community
<i>Environmental Protection</i>		
Convention on Biodiversity	Convention on Biodiversity Secretariat	191
Cartagena Protocol on Biosafety	Convention on Biodiversity Secretariat	147
<i>Trade</i>		
Sanitary and Phytosanitary Agreement	World Trade Organisation	153
Technical Barriers to Trade Agreement	World Trade Organisation	153
Trade Related Aspects of Intellectual Property Rights Agreement	World Trade Organisation	153
Patent Cooperation Treaty	World Intellectual Property Organisation	139
Patent Law Treaty	World Intellectual Property Organisation	18
Budapest Treaty on the Deposit of Microorganisms for the Purpose of Patent Procedure	World Intellectual Property Organisation	69
Convention on the Protection of New Varieties of Plants	International Union for the Protection of New Varieties of Plants	65
International Treaty on Plant Genetic Resources	Food and Agriculture Organisation	116

Bonn Guidelines on Access to Genetic Resources	Convention on Biodiversity Secretariat	
<i>Drugs Control</i>		
Single Convention on Narcotic Drugs	International Narcotics Control Board/ Commission on Narcotic Drugs	183
Convention on Psychotropic Substances	International Narcotics Control Board/ Commission on Narcotic Drugs	183
Convention Against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances	International Narcotics Control Board/ Commission on Narcotic Drugs	183
World Anti-Doping Code	World Anti-Doping Association	621 sporting organisations
International Convention Against Doping in Sport	United Nations Educational, Scientific and Cultural Organisation	92
<i>Social and Ethical Impacts of Human Genetics</i>		
Universal Declaration on the Human Genome and Human Rights	United Nations Educational, Scientific and Cultural Organisation	
International Declaration on Human Genetic Data	United Nations Educational, Scientific and Cultural Organisation	
Universal Declaration on Bioethics and Human Rights	United Nations Educational, Scientific and Cultural Organisation	
United Nations Declaration on Human Cloning	United Nations General Assembly	

SECTION I

2) ARMS CONTROL

Changes to number of states parties to the arms control regulations

There are now 184 states parties to the Chemical Weapons Convention.

3) HEALTH AND DISEASE CONTROL

61st World Health Assembly – Implementation of the International Health Regulations (2005)

The World Health Assembly adopted a decision on the scheduling of reporting requirements under the International Health Regulations (2005), this included instructions that:

- Member states and the Director-General should report annually on implementation to the World Health Assembly (pgh. 2.1);
- “the first review of the functioning of the Regulations shall be made by the Sixty-third World Health Assembly” (pgh. 2.2); and
- “the first review and evaluation of the functioning of Annex 2 shall be submitted to the Sixty-second World Health Assembly for its consideration” (pgh. 2.3)

There was also a request that the Director-General “provide support to member states with the most vulnerable health systems in strengthening core capacity requirements for surveillance and response at airports, ports and ground crossings (pgh. 4.2).

61st World Health Assembly – Global Strategy and Plan of Action on Public Health Innovation and Intellectual Property (Resolution 61.21)

(http://www.who.int/gb/ebwha/pdffiles/A61/A61_R21-en.pdf.)

The strategy and plan of action have been drawn up “in order to provide a medium-term framework based on the recommendations of the Commission on Intellectual Property, Innovation and Public Health, and to secure... an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries” (preamble)

Member states should:

- Support wide implementation of the strategy and plan (pgh. 2.2);
- Implement the recommended actions (pgh. 2.1); and
- “consider providing adequate resources” for this purpose (pgh. 2.2).

In addition other relevant intergovernmental organisations are asked “to give priority within their respective mandates and programmes to implementing the global strategy and plan of action” (pgh. 3). The Director-General is to coordinate with these organisations, including the World Intellectual Property Organisation, World Trade Organisation and United Nations Conference on Trade and Development (pgh. 4.5). She is also requested to take various actions to develop, support, promote and monitor the implementation of the strategy and plan (pgh. 4).

The strategy is contained in an annex to the Resolution; the plan of action forms an appendix to it. The strategy aims to give priority, in regard to innovation, to diseases that disproportionately affect developing countries (pgh. 1), and to address access to innovative products. It notes that:

“Advances in biomedical science have provided opportunities to develop new affordable, safe and effective health products and medical devices, particularly those that meet public health

needs. Urgent efforts should be made to make these advances more affordable, accessible and widely available in developing countries.” (pgh. 5)

Health products, as defined by the strategy, include “vaccines, diagnostics and medicines” (footnote 1).

The strategy recognises that intellectual property rights can be important incentives “for the development of new healthcare products” but that they are often not a sufficient incentive to address diseases disproportionately affecting developing countries (pgh. 7).

It reminds states of the point emphasised in the Doha Ministerial Declaration on the TRIPS Agreement and Public Health that the TRIPS Agreement “does not and should not prevent members from taking measures to protect public health” (pgh. 8) and that it contains flexibilities to enable states to do so (pgh. 12).

Successful implementation of the strategy will require, inter alia:

- Identification and assessment of gaps in public health research and development;
- Capacity-building and sustainable finance for research and development (pgh. 14.c & g);
- “management of intellectual property in a manner that maximises health-related innovation...” (pgh. 14.e);
- Monitoring and evaluation mechanisms (pgh. 14.h).

The World Health Organisation takes on a role in this area due to its constitutional remit of “the attainment by all peoples of the highest possible level of health”. It calls for a coherent international approach to intellectual property rights and public health (pgh. 21).

The innovations are to be:

- “(i) developed in an ethical manner
- (ii) available in sufficient quantities
- (iii) effective, safe and of good quality
- (iv) affordable and accessible
- (v) used in a rational way.” (pgh. 24)

The detailed points of the strategy are arranged around eight elements, which are also used to organise the plan of action. They are:

1. prioritising research and development needs;
2. promoting research and development;
3. building and improving innovative capacity;
4. transfer of technology;
5. application and management of intellectual property to contribute to innovation and promote public health;
6. improving delivery and access;
7. promoting sustainable finance mechanisms, and
8. establishing monitoring and reporting systems.

The plan of action contains points to each of the elements, detailing specific actions, stakeholders and timeframes. In several cases the stakeholders include other international organisations including specific mention of the World Intellectual Property Organisations, UN Conference on Trade and Development, Organisation for Economic Cooperation and Development, World Trade Organisation, UN Industrial Development Organisations, UN Environment Programme and the Convention on Biodiversity Secretariat. It includes points relating to health related traditional knowledge (pgh. 5.2).

United Nations Secretary-General’s High Level Task Force on the Global Food Security Crisis

This task force (see <http://www.un.org/issues/food/taskforce>) was established 28th April 2008. It includes as members, among others: the Food and

Agriculture Organisation; International Fund for Agricultural Development; UN Conference on Trade and Development; UN Development Programme, UN Environment Programme; World Bank; World Food Programme; and World Health Organisation. In July it produced a *Comprehensive Framework of Action* (<http://www.un.org/issues/food/taskforce/Documentation/FINAL%20CFA%20July%202008.pdf>).

This document notes that:

“The dramatic rise over the past twelve months in global food prices poses a threat to global food and nutrition security and creates a host of humanitarian, human rights, socio-economic, environmental, developmental, political and security-related challenges.” (pgh.1).

It calls for “an urgent, comprehensive, coherent and coordinated response” (pgh. 1) including “a renewed strategic stance on key issues, such as agricultural trade, biofuels, and management of food price rises” (pgh. 4). The work on biofuels is expected to incorporate:

- A common reference framework;
- Guidelines and safeguard measures;
- Re-assessment of targets, subsidies and tariffs; and
- Promotion of “research and development, knowledge exchanged and capacity-building” (Table 2.4, p.12).

And the framework notes that “The international response to biofuel development should also harmonize policy objectives across food security, climate change, environmental, energy and biofuel policies.”

76th Annual General Session of the International Committee of the Organisation International des Epizooties (OIE), 25-30 May 2008

Resolutions made by the 76th General Session which of relevance include:

- No. XXVI – Sharing of avian influenza viral material and information in support of global avian influenza prevention and control;
- No. XXVIII – Food security and animal health;
- No. XXIX – Amendments to the OIE Aquatic Animal Health Code;
- No. XXX – Amendments to the OIE Terrestrial Animal Health Code;
- No. XXXII – Implications of private standards in international trade of animals and animal products.

Resolution XXVI

This Resolution outlines several principles in relation to sharing of information on avian influenza virus, including:

- “It is paramount that any changes in the virological characteristics of avian influenza viruses resulting in increased risks to animal or human health are detected early.” (preamble);
- “Countries reporting outbreaks... are responsible for sharing material and data with the international scientific community in a timely manner to ensure that this is freely available to formulate global control and preparedness strategies.” (preamble);
- “Genetic information about current circulating field viruses is needed for the early development and preparation of human influenza vaccines and to facilitate accurate laboratory diagnosis” (preamble); and
- “All information about avian influenza viruses that can lead to the development of more effective prevention and control policies is a global public good and should be put into the public domain without delay” (preamble).

It then recommends:

- “OIE Members reporting outbreaks... agree to share animal avian influenza viral material and information about avian influenza viruses through OFFLU with the international scientific community.” (pgh. 1) [OFFLU is the OIE/FAO Network of Expertise on Avian Influenza – see <http://www.offlu.net>.]
- Sharing of relevant material and data between OIE Reference Laboratories and the international scientific community (pgh. 2); and
- “the actions taking by countries... be recognised in subsequent publications and other benefits arising from the use of biological material or data that they have submitted to OIE Reference Laboratories.” (pgh. 3).

Resolution XXVIII

In response to “The problems that many countries are experiencing with their food supply, in terms of quantity, quality and affordability” (preamble, pgh. 1) and noting “The strong link that exists between the... security of food production and control of animal diseases” (pgh. 1), the International Committee has recommended that OIE take action to support the capacity of veterinary services to apply quality standards from the Terrestrial Animal Health Code (pgh. 1) and in seeking resources in this regard (pgh. 2), and for general improvement in animal health investment (pgh. 3) and to produce research “on the current and likely future impact of animal diseases” for animal production (pgh. 4).

Resolution XXIX

Based on recommendations of the Aquatic Animal Health Standards Commission, the International Committee decided to update the Aquatic Animal Health Code, forming its 11th edition. The updates “include new and revised chapters on...: definitions, diseases listed by the OIE, obligations and

ethics in international trade, import risk analysis, recommendations for safe transport of aquatic animals and aquatic animal products” and some for specific aquatic animal diseases. There are also “three new appendices on welfare of farmed fish, control of aquatic animal health hazards and aquatic animal health surveillance”

(http://www.oie.int/eng/normes/en_acode.htm?e1d10).

Resolution XXX

Based on the recommendations of the Terrestrial Animal Health Standards Commission, with some amendments, the International Committee decided to update the Terrestrial Animal Health Code. The updated version forms the 17th edition of the Code. It includes:

Revised chapters on:

- General definitions;
- Notification criteria for listed diseases;
- Obligations and ethics in international trade;
- Import risk analysis;
- Veterinary services;
- Animal health measures during export/import;
- International transfer and laboratory containment of animal pathogens;
- and
- For several of the specific diseases.

Revised appendices on:

- Prescribed and alternative diagnostic tests for listed diseases;
- Categorisation of diseases and pathogenic agents by the International Embryo Transfer Society;
- Inactivation procedures for foot and mouth disease virus and avian influenza virus;
- Surveillance of certain listed diseases (including foot and mouth disease and avian influenza);

- Animal welfare; and
- Model veterinary certificate.

And new appendices, including on:

- Design and implementation of identification systems to achieve animal traceability;
- Somatic cell nuclear transfer in production of livestock and horses; and
- The role of veterinary services in food safety.

(http://www.oie.int/eng/normes/en_mcode.htm?e1d10.)

Resolution XXXII

The OIE remains concerned about the implications of the growing number of private commercial standards affecting international trade. The Committee therefore reaffirmed the central role of OIE standards as the official source of global standards on animal health and asked the Director-General to ensure that any private standards relating to animal health and welfare “are consistent with and do not conflict with those of the OIE.” (pgs. 3 & 4).

The Final Report of the 76th Session also contained several other points of relevance:

- The OIE’s Working Group on Animal Production Food Safety made note of work underway in the Codex Alimentarius Commission (since completed) on a Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals. It felt that OIE work relating to the health status of recombinant-DNA animals was relevant to this Guideline, but that this subject matter remains within the OIE’s jurisdiction (pgh.237).
- It was noted that the World Health Organisation has produced a revised version of its publication Terrorist Threats to Food (pgh.238).

This is available online at

<http://www.who.int/foodsafety/publications/foodsafety/general/en/terrorist.pdf>.

- The Working Group on Animal Production Food Safety also produced an updated work programme for 2008, which includes:
 - “Identification and tracing of animals and animal products that have resulted from biotechnological intervention” (pgh.239a);
 - and
 - “Food safety implications of the use in food-producing animals of vaccines derived from recombinant biotechnology” (pgh.239b).

It will next meet in November 2008 (pgh.239).

- The Aquatic Animal Health Standards Commission noted that “issue 27(1) of the OIE Scientific and Technical Review series...’Changing Trends in Managing Aquatic Animal Diseases’” had just been published, including information on “the use of biotechnology in vaccines and novel diagnostics” (pgh.361).
- The President of the Aquatic Animal Health Standards Commission also drew attention to OIE-Food and Agriculture Organisation cooperation on aquatic animal health, in particular the formation of the Regional Aquatic Biosecurity Framework Project for Africa (pgh.362).
- The OIE Ad Hoc Group on Biotechnology of the Biological Standards Commission was given the following work priorities:
 - Applications of biotechnology to molecular diagnostics;
 - RNA-based technologies; and
 - Use of genetically modified and recombinant-DNA vaccines and their implications for animal health and welfare (pgh.418).

The Group is in the process of developing Draft Guidelines for Veterinary Plasmid DNA Vaccines. It has also prepared a paper on “Potential Nanotechnology Applications in Animal Health” and submitted it to OIE’s publications department and has submitted for possible inclusion in the Terrestrial Manual a document “Nanotechnologies in Diagnosis and Vaccine Development” (pgh.418).

- The Biological Standards Commission “reviewed the current OIE standards for biosafety and biosecurity as published in the sixth edition of the Terrestrial Manual and concluded that they were appropriate and fit for purpose” (pgh.425).
- It also gave an opinion on codes of conduct relating to dual-use biology in which it recognised “the need to guard against bioterrorist-related activities, and the need for researchers to follow appropriate codes of conduct” but which stated that these “codes should not be overly restrictive for legitimate studies” (pgh.425).

Additionally, several international organisations which have cooperation agreements with OIE, were given the opportunity to make presentations to the 76th Session. These included:

The World Bank

Which noted its financial support to the OIE’s World Animal Health and Welfare Fund (pgh.84) and collaboration with OIE and the Food and Agriculture Organisation on the Global Animal Health Initiative, and its creation of a Global Programme for Avian and Human Influenza (GPAI) (pgh.85). This will provide World Bank funding for relevant activities, emphasising the importance of “technical and scientific support from the OIE, FAO and WHO... in framing the menu of activities eligible for funding”

(pgh.86). The World Bank continues to develop its focus on agriculture and wishes to continue collaboration with the OIE on animal health (pgh.89).

The Codex Alimentarius Commission

The Secretary of the Codex Alimentarius Commission (CAC) noted that OIE is an important partner for CAC on animal health, zoonoses, biotechnology, certification, traceability, food-borne pathogens, antimicrobial resistance and private standards (pgh.91). In order to maintain good collaboration between CAC and OIE the following points were considered particularly important: information exchange; mutual contribution to standard-setting processes particularly for consistency; improved coordination at national level of member states OIE/CAC contact points and of national ministries (pgh.94).

The World Trade Organisation

The representative of the World Trade Organisation (WTO) noted that of specific trade concerns raised by members at the Sanitary and Phytosanitary Committee in 2007, over half were related to animal health (pgh.97). She reported on the Committee's work on regionalisation and transparency (see p.18 in *Genomics Monitor Issue 7*).

The Food and Agriculture Organisation

The representative of the Food and Agriculture Organisation (FAO) reported on the FAO/OIE Global Framework for the Progressive Control of Transboundary Animal Diseases (GF-TADs) which had recently produced "a chart on complementarities and synergies between FAO and the OIE" and "A notice explaining the chart and the mandates, missions and expertise of each organisation" (pgh.103). Further information can be found at:

http://www.oie.int/eng/OIE/accords/GF_TADS_approved_version24May2004.pdf and the FAO's Animal Production and Health Division's Emergency Response webpage,

http://www.fao.org/ag/againfo/home/en/what/what_we_do.htm.

He made note of the various other inter-organisation cooperative initiatives involving FAO and OIE, such as the OIE/FAO Network of Expertise on Avian Influenza (OFFLU), Crisis Management Centre for Animal Health, and Global Early Warning System (pgh.104). He also stated that in FAO-OIE cooperative activities there remains a:

“need for more surveillance, detection, early response, improved biosecurity, global approach to diseases taking into account the epidemiological, socio-economic and institutional dimensions, as well as farming systems, trade and biodiversity.” (pgh.107).

The World Health Organisation

There was recognition of joint World Health Organisation (WHO) and OIE responsibility on addressing zoonotic diseases and foodborne diseases (pghs.334&335), along with FAO, and WHO wants to enhance this cooperative work. A note was also made on positive cooperation occurring between OIE, WHO, and FAO on highly pathogenic avian influenza, particularly in regard to information exchange (pgh.339). Another positive example given was the organisations’ work on antimicrobial resistance, including “initiating a new paradigm for joint provision of scientific advice in this area” (pgh.340). The World Health Organisation stated that it particularly wanted to replicate this positive example “of providing the best scientific advice in areas of joint responsibility and also apply it in the area of human health safety assessment of the use of genetically modified vaccines in animals” so that “both human and animal health are taken into account.” (pgh.341).

3rd Session of the Commission on Phytosanitary Measures, 7th-11th April 2008

Among the decisions made by the Commission on Phytosanitary Measures (CPM) were:

Amendments to ISPM [international standard for phytosanitary measures] No. 5 (Glossary of Phytosanitary Terms)

This included removal of the terms ‘biological pesticide’, ‘classical biological control’, and three others as they relate to biological control agents – ‘establishment’, ‘import permit’ and ‘introduction’ (point 9.2.1 and Appendix 3).

IPPC [International Plant Protection Convention] Training Material for Pest Risk Analysis

The current pest risk analysis training material (see p. in Genomics Monitor Issue 7) will be translated into Spanish (by the Interamerican Coordination Group in Plant Protection and Argentina) and French (by Canada and France) (point 9.9).

Outcome of the Open-Ended Working Group on a Possible International Plant Protection Convention Compliance Mechanism

This Working Group decided “that a compliance (enforcement) process was believed to be contrary to the objectives and philosophy of the CPM and FAO” (pgh.127) and instead elaborated an ‘implementation review and support system’ (IRSS) to facilitate and promote implementation in a non-binding manner (pgh.128). This system will assist in: monitoring and supporting implementation of the IPPC and ISPMs; and identifying “implementation problems before they become disputes” (pgh.129). The CPM decided that the IRSS would “be included in the IPPC procedural manual” and implemented “as soon as practically possible” (pgh.130.4).

Development of a CPM technical assistance strategy for phytosanitary capacity-building

The CPM decided to establish “an Open-ended Working Group on Building National Phytosanitary Capacity” (pgh. 41.2) which is tasked to draw up a concept paper and draft strategy for presentation to the CPM (pgh.141.2 i & ii) along with an operational plan for its implementation (iii).

Reports were submitted to the CPM by several observer organisations, including:

The World Trade Organisation (7.1)

Which outlined the Sanitary and Phytosanitary Committee’s work on transparency, regionalisation and private standards (see p.18 *Genomics Monitor Issue 7*).

The Convention on Biodiversity Secretariat

Which focused on CBD-IPPC collaboration on invasive alien species (pgh.7.3) and noted that:

“In the International Plant Protection Convention (IPPC), the CBD has found an invaluable partner whose knowledge and expertise has helped to strengthen our own programme of work on invasive alien species (IAS). Combining efforts and creating synergies is the only way through which the world can begin to limit the impacts of IAS and ultimately eradicate them.” (CPM2008/INF/22).

And the Office International des Epizooties

Which provided information on its activities in “regionalisation, capacity-building and dispute mediation” (pgh.7.5.1).

Codex Alimentarius Commission, 31st Session, 30th June-4th July 2008

Among decisions of relevance to the biotechnology field, the Codex Alimentarius Commission (CAC) “Agreed to dissolve the Ad hoc Task Force on Foods Derived from Biotechnology... as their work had been completed” (Executive Summary, p.2, point n).

An annex on Food Safety Assessment in Situations of Low-Level Presence of Recombinant-DNA Plant Material in Food (to the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant DNA-Plants) was adopted (pgh.60) along with an Annex on Food Safety Assessment of Foods Derived from Recombinant-DNA Plants Modified for Nutritional or Health Benefits. Also adopted was the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals.

These documents are not yet available through the Codex website (<http://www.codexalimentarius.net>) but the drafts on which they are based can be found in the October 2007 report of the 7th session of the Ad hoc Intergovernmental Taskforce on Foods Derived from Biotechnology (http://www.codexalimentarius.net/download/report/693/a131_34_e.pdf).

Presentations were made by several relevant international organisations, including:

The Office International des Epizooties

The Office International des Epizooties (OIE) observer noted collaboration between OIE and CAC going back to 2001, particularly in relation “to improving the coordination and harmonisation of standard setting activities” (pgh.191), noting that this “had resulted in an improved exchange of scientific and technical information and the use of cross references in several Codex

and OIE texts” (pgh.191). Further collaboration is expected to occur in relation to animal feeding and “guidance on the food safety of animals treated with recombinant-DNA vaccines” (pgh.191).

And the World Trade Organisation

The World Trade Organisation’s observer provided information on recent work of the Sanitary and Phytosanitary Committee and noted that it would be holding “a workshop on strengthening procedures of Codex, World Organisation for Animal Health [another term for the Office International des Epizooties] and International Plant Protection Convention (IPPC) in October 2009.” (pgh.196).

FAO High-Level Conference on World Food Security: The Challenges of Climate Change and Bioenergy

The High-Level Conference (HLC), organised by the FAO, was held 3rd-5th June 2008, and attended by representatives of over 180 countries, many non-governmental organisations and civil society groups, and several international intergovernmental organisations, including the UN Conference on Trade and Development, Intergovernmental Panel on Climate Change, UN Development Programme, UN Environment Programme, UN Industrial Development Organisation, World Bank, World Health Organisation, and World Trade Organisation. Various background documents produced by expert groups convened prior to the Conference are available through

http://www.fao.org/foodclimate/conference/doclist/en/?no_cache=1.

Discussion took place in four main parts:

- High food prices: causes, consequences and possible solutions;
- Climate change and food security;
- Transboundary pests and diseases; and
- Bioenergy and food security.

(<ftp://ftp.fao.org/docrep/fao/meeting/013/k2379e.pdf>)

The Conference produced a Declaration (http://www.fao.org/fileadmin/user_upload/foodclimate/HLCdocs/declaration-E.pdf), which stated that the attendees wished “to address challenges of higher food prices, climate change and bioenergy” in order to achieve world food security (preamble).

And included, inter alia, the following statements:

“We urge the international community... to decisively step up investment in science and technology for food and agriculture. Increased efforts in international cooperation should be directed to researching, developing, applying, transferring and disseminating improved technologies and policy approaches.” (pgh.7d)

“It is essential to address the challenges and opportunities posed by biofuels, in view of the world’s food security, energy and sustainable development needs. We are convinced that in-depth studies are necessary to ensure that production and use of biofuels is sustainable in accordance with the 3 pillars of sustainable development and takes into account the need to achieve and maintain global food security. We are further convinced of the desirability of exchanging experiences on biofuels technologies, norms and regulations. We call upon relevant intergovernmental organisations... within their mandates and areas of expertise... to foster a coherent, effective and results-oriented international dialogue on biofuels in the context of food security and sustainable development needs.” (pgh.7f).

Changes to the number of states parties to the health and disease control regulations

There are now 194 states parties to the International Health Regulations. The International Plant Protection Convention now has 169 states parties.

4) ENVIRONMENTAL PROTECTION

Decisions of the 9th Conference of the Parties to the Convention on Biodiversity, 19th-30th May 2008

Agricultural biodiversity: biofuels and biodiversity (IX/2)

This decision (<http://www.cbd.int/decisions/?m=COP-09&id=11645&lg=0>) recognises that biofuels production and use can be of both potential benefit and harm to biodiversity and emphasised the need for: a sustainable development approach; capacity-building; technology transfer and cooperation; new and additional finance; and “adequate policy frameworks” (preamble).

Member states agreed that: “biofuel production and use should be sustainable in relation to biodiversity”, and that they should:

- “(a) Promote the sustainable production and use of biofuels...;
- (b) Promote the positive and minimize the negative impacts on biodiversity that would affect socio-economic conditions and food and energy security...;
- (c) Develop and apply sound policy frameworks... taking into account their full life cycle... making use of relevant tools and guidance under the Convention as appropriate...”

The decision also asks for: additional research and monitoring of the environmental impacts of biofuels production and use (pgh.5); improved technological cooperation (pgh.6); sharing of experiences and participation “in

efforts, carried out by various bodies other than the Convention on Biodiversity, who are addressing matters relevant to the sustainable production and use of biofuels” (pgh.8); “the Executive Secretary to convene regional workshops on the sustainable production and use of biofuels” (pgh.12); and for the Subsidiary Body on Scientific, Technical and Technological Advice to look at “ways and means to promote the positive and minimize the negative impacts of the production and use of biofuels on biodiversity” (pgh.13).

Access and Benefit-Sharing (IX/12)

In this decision (<http://www.cbd.int/decisions/?m=COP-09&id=11655&lg=0>) the COP noted that paragraph 44(o) of the Johannesburg Plan of Implementation (of the World Summit on Sustainable Development) called for action to:

“negotiate within the framework of the Convention on Biodiversity, bearing in mind the Bonn Guidelines, an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources” (preamble)

And acknowledged: “the potential role of the Clearing House Mechanism... as a tool to facilitated that dissemination and exchange of information on access to genetic resources and benefit-sharing” (preamble).

It also noted other international work on access and benefit-sharing, with particularly mention of the International Treaty on Plant Genetic Resources and the work of the Commission on Genetic Resources for Food and Agriculture (preamble).

The CBD’s Ad Hoc Group on Access and Benefit-Sharing provided text on the ‘international regime’, which is reproduced in Annex I of the decision, and provides the “basis for further elaboration and negotiation” (pgh.1) by the

Group. This work should be completed before the 10th COP, taking the form of “an instrument/instruments to effectively implement the provisions in Article 15 and Article 8(j) of the Convention and its three objectives” (pgh.3).

The Group is scheduled to meet three times before the 10th COP; these will be its 7th, 8th and 9th meetings, and are instructed respectively to involve:

- “Negotiation of operational text on the objective, scope, compliance, fair and equitable benefit-sharing, access;”
- “Negotiation of operational text on nature, traditional knowledge associated with genetic resources, capacity-building, compliance, fair and equitable benefit-sharing, access;” and
- “Consolidation of all operational text” (pgh.7).

At the 8th meeting the group is also instructed to begin: “identifying the components of the international regime that should be addressed through legally binding measures, non-legally binding measures or a mix of the two and to draft these provisions accordingly” (pgh.8).

To assist the Group’s work, three groups of technical and legal experts are established on: compliance; concepts, terms, working definitions and sectoral approaches; and traditional knowledge associated with genetic resources (pgh.11). In addition the CBD’s Executive Secretary is to commission studies on:

- “(a) Recent developments in methods to identify genetic resources directly based on DNA sequences;
- (b) To identify the different possible ways of tracking and monitoring genetic resources through the use of persistent global unique identifiers, including the practicality, feasibility, costs and benefits of the different options;
- (c) How an international regime on access and benefit-sharing could be in harmony and be mutually supportive of the mandates of and coexist alongside other international

instruments and forums that govern the use of genetic resources, such as the FAO International Treaty on Plant Genetic Resources for Food and Agriculture;

(d) Development of a comparative study of the real and transactional costs involved in the process of access to justice across jurisdictions;

(e) How can compliance be ensured in conformity with Indigenous Peoples and local communities customary law, national law, across jurisdictions, and international law, including human rights and trade?" (pgh.11)

Currently the text for the international regime is structured under the headings:

I. Objective

II. Scope

III. Main components

A. Fair and equitable benefit-sharing

B. Access to genetic resources

C. Compliance

D. Traditional knowledge associated with genetic resources

E. Capacity

IV. Nature

Article 8(j) and Related Provisions (IX/13)

In this decision (<http://www.cbd.int/decisions/?m=COP-09&id=11656&lg=0>) the COP wants "further progress in the integration of the objectives of Article 8(j)... into thematic programmes and other... cross-sectional issues" pgh (.1). (Article 8(j) relates to the 'knowledge, innovations and practices of indigenous and local communities'.) And asks for a progress report on implementation from the Executive Secretary before the 6th Meeting of the Ad Hoc Group on Article 8(j) and for states and other relevant groups to provide "submissions on the desirability and the potential elements of a strategy for conservation

and sustainable use... of biodiversity by indigenous and local communities” (pgh.10).

The 10th COP will include “an in-depth review of the tasks in the programme of work on Article 8(j)” (pgh.11).

The decision also includes sections on:

The composite report on the status and trends regard the knowledge, innovations and practices of indigenous and local communities, relevant to the conservation and sustainable use of biodiversity, which noted completion of phase 2 of this report.

Considerations for guidelines for documenting traditional knowledge, which included requests that:

- States and international organisations “support and assist indigenous and local communities to retain control and ownership of their traditional knowledge, innovations and practices” (pgh.1); and
- The Executive Secretary to collaborate with the UN Forum on Indigenous Issues, UN Educational, Scientific and Cultural Organisation, and World Intellectual Property Organisation “to address both the potential benefits and threats of documentation” (pgh.2)

Plan of action for the retention of traditional knowledge, which encourages reporting of experiences through the Clearing House Mechanism and Traditional Knowledge Information Portal (see <http://www.cbd.int/tk/>), and includes an annex of examples of positive retention measures.

Participatory mechanisms for indigenous and local communities in the Convention, which “Notes with appreciation the revitalization of the Article 8(j) homepage... and the creation of the Traditional Knowledge Information Portal” (.6) and requests “further regional and sub-regional workshops on community-friendly communication tools.” (pgh.7a).

Development of elements of sui generis systems for the protection of traditional knowledge, innovations and practices, which asks for sharing of experiences through the Clearing House Mechanism and Traditional Knowledge Information Portal (pgh.4), and refers to note UNEP/CBD/WG8J/5/6, which provides elements to be considered by states (pgh.1). This can be found at: <http://www.cbd.int/doc/meetings/tk/wg8j-05/official/wg8j-05-06-en.pdf>.

And Elements of a code of ethical conduct, which is in a revised draft stage and reproduced in an annex to the decision. Interested states and other relevant groups should “submit written comments... at least six months prior to the sixth meeting of the Ad Hoc Group on Article 8(j)” (pgh.2). It is intended that the code be further developed for “consideration and possible adoption” by the 10th COP (pgh.5).

Technology Transfer and Cooperation (IX/14)

In this decision (<http://www.cbd.int/decisions/?m=COP-09&id=11657&lg=0>) the COP emphasised the need for “immediate implementation” of its Strategy for the Practical Implementation of the Programme of Work on Technology Transfer and Scientific and Technical Cooperation, which is annexed to the decision (pgh.3). The Executive Secretary provided a note on “possibilities of developing a Biodiversity Technology Initiative” which “would facilitate enhanced interaction with Parties with identified capacity/technology building needs and international organisations, Parties, or other relevant organisations, which could assist” (pgh.5). The COP requested that options be identified by the Executive Secretary for: “activities to be included”; “structure, functioning and governance”; and “criteria for selecting the host institution” (pgh.6). Which should go to the 3rd meeting of the Ad Hoc Open-Ended Working Group on Review of Implementation of the Convention and subsequently to the 10th COP (pgh.7).

The COP noted “the cooperation of the United Nations Conference on Trade and Development and the World Intellectual Property Organisation” in a “Technical study on the role of intellectual property rights in technology transfer in the context of the Convention” (pgh.8 & pgh.10). (This can be found at: <http://www.cbd.int/doc/meetings/cop/cop-09/information/cop-09-inf-07-en.pdf>.) The COP asked, in regard to this topic, that:

“relevant international organizations and initiatives, research institutions at all levels, and non-governmental organizations, to undertake further research on the role of intellectual property rights in technology transfer in the context of the Convention, such as:

- (a) More in-depth analysis of new open-source-based modes of innovation, as well as other additional options to intellectual property rights;
- (b) More empirical studies on the extent of use of patent data information in research and development in different sectors;
- (c) Further empirical analysis on the scope and extent of patent clustering on technologies and other associated biological materials that are necessary inputs to desired technology development processes and on how prospective technology users in developing countries cope with patent clustering;
- (d) Further examination by relevant international organizations of the overall trends in the application of the flexibilities provided by the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPs);” (pgh.13)

It further noted that the Clearing House Mechanism has a role “as a key mechanism in technology transfer and technological and scientific cooperation, including provision of information on patent registry systems” (pgh.12) and remarked on:

“the importance of establishing or strengthening cooperation with relevant processes in other conventions and international organisations, with a view to ensure consistency and mutual supportiveness, maximize possible synergy, and avoid duplication of work” (pgh.14)

Where the Strategy address funding mechanisms, there is a note of disappointment that:

“After a decade of continuous recognition of the continual need for the effective transfer of technologies of relevance for conservation and sustainable use of biodiversity....: Implementing the objectives of the Convention has not been the aim of many existing technology transfer activities and mechanisms; There is a lack of synergy among existing funding mechanisms...; The long-standing needs of many countries... have not been well addressed.” (pgh.32).

Liability and Redress (IX/23)

In this decision (<http://www.cbd.int/decisions/?m=COP-09&id=11666&lg=0>) it was recommended that the Synthesis Report provided by the Executive Secretary* be made available to states through the CBD’s Clearing House Mechanism, to use “if they decided to develop national legislative regimes and policy and administrative measures” (pgh.2). The Conference of the Parties (COP) will consider whether further work on liability and redress is needed at its 10th meeting (pgh.4).

* Synthesis Report on Technical Information Relating to Damage to Biological Diversity and Approaches to Valuation and Restoration of Damage to Biological Diversity, as well as Information on National/Domestic Measures and Experiences, UNEP/CBD/COP/9/20/Add1, <http://www.cbd.int/doc/meetings/cop/cop-9/official/cop-9-20-add1-en.doc>.

Cooperation among multilateral environmental agreements and other organisations (IX/27)

This decision (<http://www.cbd.int/decisions/?m=COP-09&id=11670&lg=0>) emphasised the importance of cooperation between international organisations, particularly those in the ‘Liaison Group of Biodiversity-Related Conventions’ (for more information see <http://www.cbd.int/cooperation/related-conventions/blg.shtml>). This cooperation provides “options for enhancing synergies, avoiding duplication of efforts and improving the coherent implementation of the biodiversity-related conventions” (pgh.3). The decision particularly encourages cooperation between scientific bodies related to these conventions (pgh.5) and, in this regard, mentions “the establishment of the Consortium of Scientific Partners on Biodiversity”, consisting of the Convention on Biodiversity (CBD) Secretariat and “eight leading scientific institutions”, which, through training and education activities, should “promote the effective implementation” of the Convention and Cartagena Protocol (pgh.6) (for more information on the Consortium see <http://www.cbd.int/cooperation/scientific.shtml>).

Also specifically mentioned are:

- CBD collaboration with the World Health Organisation in the ‘Cooperation on Health and Biodiversity (COHAB) Initiative’ (pgh.9); and
- Renewal of its “pending applications for observer status in relevant bodies of the World Trade Organisation” and continued cooperation with it (pgh.11).

Parties and other relevant stakeholders are requested to make use of the TEMETEA modules (pgh.14), see p.55 of *Genomics Monitor Issue 7*.

5) TRADE

Work of the World Trade Organisation's Sanitary and Phytosanitary Committee

The Committee's decisions on transparency and on regionalisation have been confirmed as no objections were raised by states (see p.18 of *Genomics Monitor Issue 7* for details).

At its June meeting the Committee began work on "drafting procedures for mediation" using the Committee's Chair. The option had been available in the Committee's working procedures as a way of avoiding disputes, but this new work is intended to clarify how the option can be used. Proposals were made by the US and Argentina, who will work on combining them for the Committee's October meeting

(http://www.wto.org/english/news_e/news08_e/sps_24june08_e.htm.)

WTO – Work on the relationship between the TRIPS Agreement and the Convention on Biodiversity

In a report to the General Council and the Trade Negotiating Committee (http://www.wto.org/english/tratop_e/trips_e/giextension_cbd_dgreport_9jun08_e.pdf) the Director-General noted that, in regard to work on the relationship between the Convention on Biodiversity (CBD) and the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement:

"There is important common ground on key underlying objectives, notably the importance of the TRIPS Agreement and the CBD being implemented in a mutually supportive way, the avoidance of erroneous patents for inventions that involve use of genetic resources and related traditional knowledge and securing compliance with national access and benefit sharing regimes." (pgh.1)

But that:

“Work continues to be characterized by different approaches to meeting these objectives, including whether the TRIPS Agreement needs to be amended and whether it was agreed at Doha that this issue is part of the negotiations and of the Single Undertaking.” (pgh.1)

For reference the relevant part of the Doha Declaration states:

“We instruct the Council for TRIPS, in pursuing its work programme, including under the review of Article 27.3(b), the review of the implementation of the TRIPS Agreement under Article 71.1 and the work foreseen pursuant to paragraph 12 of this declaration, to examine, inter alia, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore...”

http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm.

The Director-General reported that “a large group of developing country Members... have proposed an amendment of the TRIPS Agreement to introduce a mandatory disclosure requirement in patent applications” in relation to “origin of biological resources and/or associated traditional knowledge in patent applications” (pgh.2). However, other Members oppose “negotiations on this matter” arguing that the issues can be better dealt with through other forums and mechanisms (pgh.3). There are particular suggestions, for example, relating to work that may be done in the World Intellectual Property Organisation (pgh.4).

WIPO – 2nd Session of the Commission on Development and Intellectual Property, 7th-11th July 2008

The Commission on Development and Intellectual Property (CDIP) continued its discussion of activities under the 45 recommendations adopted in October 2007 (see <http://www.wipo.int/ip-development/en/agenda/recommendations.html>). In addition to those recommendations previously discussed by the Commission it began examining recommendations 20, 22, and 23 of Cluster B, proposed activities for which will be sent to the member states prior to the CDIP's 3rd session. It was also agreed that the 3rd session would discuss mechanisms for coordination with other WIPO bodies (Chair's Summary, http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_2/cdip_2_summary.pdf). Other documents related to the meeting are available through http://www.wipo.int/meetings/en/details.jsp?meeting_id=15487.

Changes in the number of states parties to the trade regulations

The World Trade Organisation now has 153 member states. There are now 69 states parties to the Budapest Treaty on the Deposit of Microorganisms for the Purpose of Patent Procedure.

6) DRUGS CONTROL

World Anti-Doping Code

In addition to the revision of the World Anti-Doping Code (the revised version comes into force 1st January 2009), revisions have been made to the International Standard for Testing and the International Standard for Therapeutic Use Exemption. These revisions will also enter into force 1st January 2009. The revised versions can be found at: <http://www.wada-ama.org/en/dynamic.ch2?pageCategory.id=371> and <http://www.wada-ama.org/en/dynamic.ch2?pageCategory.id=373>.

Changes to the number of parties to the drugs control regulations

The World Anti-Doping Code now has 621 signatory organisations; the International Convention Against Doping in Sport has 92 states parties.

SECTION II – COOPERATION BETWEEN INTERNATIONAL ORGANISATIONS IN THE REGULATION OF BIOTECHNOLOGY II: ACCESS TO GENETIC RESOURCES

Introduction

This is the second part of a series looking at the issue of cooperation between international organisations in the regulation of biotechnology. The first part, which appeared in Issue 7, looked at the opportunities for and constraints on cooperation between international organisations. This part looks at how cooperation between international organisations has developed for one particular issue – access to genetic resources. It looks at the history of international work on genetic resources, what the current situation is, and what forms of cooperation are involved. The issue of access to genetic resources is particularly relevant to regulation of biotechnology because genetic resources frequently form the base of biotechnology research and development, products and processes – particularly in the areas of agriculture and pharmaceuticals.

The issue of access to genetic resources has been on the international agenda for several decades. Its early focus was on access to plant germplasm for agricultural research purposes. States are highly interdependent in relation to germplasm which is needed to improve and renew agricultural crops. It is thus vital to food security. The issue of access to genetic resources has broadened: to incorporate issues of sustainability and conservation of biodiversity; to extend to forestry, fisheries, and livestock genetic resources; to cover fair and equitable benefit-sharing; to examine its relationship with intellectual property rights; and more recently to cover the issue of access to viral genetic resources for public health research.

There has been a similar expansion of the number of international organisations involved in the issue of access to genetic resources. Early work started in the Food and Agriculture Organisation and the Consultative Group on International Agricultural Research, and has since expanded to involve,

inter alia, the United Nations Environment Programme and Convention on Biodiversity Secretariat, Union for the Protection of New Varieties of Plants, World Intellectual Property Organisation, World Trade Organisation, and World Health Organisation. (A list of acronyms for the organisations and regulations is provided at the end of this section.)

Genetic resources are defined in the Convention on Biodiversity as: “genetic material of actual or potential value”, with genetic material being defined as: “any material of plant, animal, microbial or other origin containing functional units of heredity.” (Article 2).

The World Intellectual Property Organisation (WIPO) provides a good summary of the current international situation regarding access to genetic resources:

“ Genetic resources can provide an important input for research and the development of new products, in an increasingly broad range of technological and industrial sectors. The terms and conditions of access to genetic resources, the exercise of prior informed consent by the providers of genetic resources, and the resulting arrangements made for the sharing of benefits from their use and development, are critical issues.

Existing international law and a number of regional, national and sub-national laws and regulations set the framework for exercising prior informed consent and determining the terms and conditions of access as well as benefit-sharing. Key elements of international law include the Convention on Biological Diversity (CBD) and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR) of the Food and Agricultural Organization (FAO). The CBD, adopted in 1992, provides an international framework for access and benefit-sharing for genetic resources. The ITPGR,

adopted in 2001, covers plant genetic resources for food and agriculture (PGRFA) and will establish a multilateral system of access and benefit-sharing for certain PGRFA. In conformity with the access and benefit-sharing provisions of these international instruments, national regimes have been developed to regulate access to genetic resources.” (WIPO, 2004).

History of Genetic Resources as an International Issue

Genetic resources form a vital shared global resource with key importance to agriculture, food security, and the maintenance of biodiversity, and forming the basis of many other essential products and processes. It is not surprising, therefore, that the issue of access to genetic resources entered the international arena at an early stage of post-Second World War cooperative efforts. Access to plant genetic resources for collection and agricultural research and development emerged on the agenda of the Food and Agriculture Organisation (FAO) within a few years of its establishment. Scientists, plant breeders and governments wanted assistance in accessing resources through collections and exchange. In the 1950s the FAO created some *World Catalogues of Genetic Stocks*, a seed exchange mechanism, *World List of Plant Breeders* and a *Plant Introduction Newsletter* (Pistorius, 1997, pp.12-14).

The issue of *conservation* of genetic resources became more prominent in the 1960s. The Convention on the Protection of New Varieties of Plants was adopted in 1961 dealing with the subject of plant breeders' rights. Its associated international organisation is the Union for the Protection of New Varieties of Plants (UPOV) – its mission statement is “To provide and promote an effective system of plant variety protection, with the aim of encouraging the development of new varieties of plants, for the benefit of society.” (UPOV, no date given). UPOV does not specifically deal with the issues of access and benefit-sharing in relation to genetic resources, but has gained increasing

relevance to the area in subsequent decades as the issue of the impact of intellectual property rights became more prominent.

In the late 1960s the FAO established a Crop Ecology Unit and a Genetic Resources Information Centre, and in 1967 organised a Technical Conference on Exploration, Utilization, and Conservation of Plant Genetic Resources (Pistorius, 1997, p.21). A further Technical Conference on Plant Genetic Resources was held by FAO in 1973. By this time the genetic resources issue had begun to take on a more political dimension, particularly in terms of North-South politics (as most research and development was taking place in developed countries, while most of the resources being accessed were from developing countries). This brought the issue to the attention of non-governmental organisations concerned with development issues, and to the public (Pistorius, 1997, p.69).

The Consultative Group on International Agricultural Research

A series of high-level meetings concerned with transforming global agriculture to ensure continued improvement in food security for developing countries led to a request to the World Bank for the establishment of a Consultative Group on International Agricultural Research (CGIAR). This was created in 1971, providing support to four existing international agricultural research centres, and was cosponsored by the FAO and United Nations Development Programme. It has a mixed membership of states, international organisations, development organisations and charitable foundations, and currently covers 15 research centres (CGIAR, no date given[1]). Its mission has expanded to include sustainability and biodiversity issues, and its current mission statement is:

“To achieve sustainable food security and reduce poverty in developing countries through scientific research and research-related activities in the fields of agriculture, forestry, fisheries, policy and the environment.”

(CGIAR, no date given[2])

Its centres are key collectors of plant germplasm, currently estimated to hold “over 650,000 samples of crop, forage and agroforestry genetic resources in the public domain” (CGIAR, no date given[3]). CGIAR is involved in a variety of cooperative initiatives on genetic resources, and in 2006 its centres were placed under the FAO’s International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR), and now use its Standard Material Transfer Agreement for all transfers of plant genetic resources for food and agriculture (PGRFA) (CGIAR, no date given[3]).

By the end of the 1970s the idea of developing an international agreement on genetic resources had been raised in the FAO. Its drafting was formally requested by the 1981 FAO Conference, and in 1983 the Conference approved the International Undertaking on Plant Genetic Resources for Food and Agriculture (IUPGR) along with the establishment of a Commission on Plant Genetic Resources (Pistorius, 1997, pp.79-82).

A key development in the 1980s was the shift of attention to conservation of genetic resources as an environmental issue as well as an agricultural one. This was promoted by the development of the concept of sustainable development, and a general increase in awareness of the international character of many environmental issues. The issue of genetic resources was included in work towards the drafting of a biodiversity convention and the preparatory work for the United Nations Conference on Environment and Development (held in 1992). The FAO put forward a draft biodiversity convention, but the issue was moved to the forum of the United Nations Environment Programme (Pistorius, 1997, pp.96-97).

The Convention on Biological Diversity that was subsequently adopted in 1992, has as one of its three main objectives:

“the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.”
(Article 1)

This is then further elaborated in Article 15 – Access to Genetic Resources, which, *inter alia*, recognises states’ sovereign rights over their natural resources, granting them authority “to determine access”; instructs states to “facilitate access to genetic resources for environmentally sound uses”; and says that access should “be on mutually agreed terms” and “subject to prior informed consent”; and that states should take measures to facilitate “sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources” with the provider country.

It has since been felt necessary to elaborate further on the issue of access and benefit-sharing under the Convention. Work on this has mainly taken place under the Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing (established in 2000). In 2002 the Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising out of their Utilisation were adopted by the Conference of the Parties. These are seen as a stage in the development of an international regime on access and benefit-sharing, not as the end point. The Ad Hoc Group has continued its work, and has been asked to finalise a proposed international regime by 2010.

Agenda 21, an international document that was produced by the 1992 UN Conference on Environment and Development, requested that the IUPGR be revised in harmony with the Convention on Biodiversity. FAO began work on this in 1993, and in 2001 adopted the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR), which is legally-binding, and entered into force in 2004. A core aspect of the new Treaty is its Multilateral System for Access and Benefit-Sharing, which is designed to facilitate access

to key plant genetic resources designated as being important to food security and interdependence (currently covering 64 food and forage crops). The system became operational in 2007.

In the early 1990s, states were becoming increasingly concerned about how intellectual property rights (IPRs) would impact access and benefit-sharing mechanisms, and particularly about whether IPRs would have the effect of restricting access, and, through failure to recognise the source of a genetic resource, not allow benefits to be fairly shared.

The international approach to IPRs changed significantly in 1995 with the adoption of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) as part of the founding agreements of the World Trade Organisation. A particularly significant article in relation to access to genetic resources is Article 27 on Patentable Subject Matter. Clause 27.3(b) reads:

“Members may also exclude from patentability:
...(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.”

Work on Article 27.3(b) is still ongoing within the WTO. The clause is controversial in relation to genetic resources as it means that IPRs should be given to new plant varieties. Its coverage of extracted genetic material is unclear, and states have varying national policies on patentability. In the 2001 Doha Declaration, states requested the WTO examine further the relationship between TRIPS and the CBD, particularly in relationship to genetic resources. This work is also ongoing.

In the late 1990s, the World Intellectual Property Organisation also began work on the issue of the interaction between intellectual property rights and access to genetic resources. This happens mainly through its Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC). WIPO has been consulted by other international organisations for information on this area, and recognises the importance of cooperation between these organisations.

International work on genetic resources has further expanded recently. The Food and Agriculture Organisation is moving forward its work on animal genetic resources, and more recently the issue of access to genetic resources has come up in the public health context under the World Health Organisation.

Current International Activity on Access to Genetic Resources

The CBD's Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing

In 2000 the CBD Conference of the Parties (COP) established the Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing. It was mandated to “develop guidelines and other approaches to assist Parties with the implementation of the access and benefit-sharing provisions of the Convention”. In 2002 following the adoption of the Bonn Guidelines, the Working Group was asked to deal with any outstanding issues and following an instruction by the World Summit on Sustainable Development in 2002, the 7th COP extended the group’s mandate to “elaborate and negotiate the nature, scope and elements of an international regime on access and benefit-sharing within the framework of the Convention on Biodiversity” (Decision VII/19) with its work to be completed by 2010. The latest COP has reaffirmed this (see p. 29-31 of this Issue of Genomics Monitor).

The CBD’s COP has made numerous decisions relating to access to genetic resources which have included requests for liaison with other relevant international organisations, especially the World Trade Organisation (WTO),

and for the avoidance of duplication of work of other organisations. There was a specific reference in Decision VII/19, for example, that invited UNEP, FAO, WTO, WIPO, and UPOV “to cooperate with the Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing in elaborating the international regime.” (CBD Secretariat, 2004, .5)

The CBD also has a database on access and benefit sharing measures (<http://www.cbd.int/abs/measures.shtml>); a set of case studies on access and benefit sharing (<http://www.cbd.int/abs/cs.shtml>); and a roster of experts on access and benefit-sharing (<http://www.cbd.int/abs/roster.shtml>).

The WIPO’s Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore

The World Intellectual Property Organisation considers that it “provides a forum for international policy debate and development of legal mechanisms and practical tools concerning... the intellectual property (IP) aspects of access to and benefit-sharing in genetic resources.”

(<http://www.wipo.int/tk/en>).

Its work began in 1998/99 with stakeholder consultations on “IP needs and expectations of the holders of TK [traditional knowledge]”. It later established an Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), which first met in 2001.

A key feature of WIPO’s work on genetic resources “has been careful coordination with and responsiveness to the work of” the CBD, FAO, and UNEP, “in particular the Conference of the Parties of the CBD and the FAO’s Commission on Genetic Resources for Food and Agriculture have provided important guidance to the IGC in this work”

(<http://www.wipo.int/tk/en/genetic/>).

Its work “has covered three main areas:

- Defensive protection of genetic resources through measures which prevent the grant of patents over genetic resources that do not fulfill the requirements of novelty and non-obviousness...
- IP aspects of access to genetic resources and equitable benefit-sharing arrangements that govern use of genetic resources...
- Disclosure requirements in patent applications that relate to genetic resources and associated TK used in a claimed invention..."

Among other activities the IGC has:

- Produced a *Technical Study on Disclosure Requirements in Patent Systems Related to Genetic Resources and Traditional Knowledge* (WIPO, 2004[1]), partly in response to a request from the CBD's 6th COP;
- Created a database of IP licensing provisions relating to access to genetic resources; and
- Published *Draft Intellectual Property Guidelines for Access and Equitable Benefit-Sharing* (WIPO, 2004[2]).

Review of Article 27.3(b) of the Agreement on Trade Related Aspects of Intellectual Property Rights and Work on the Relationship Between TRIPS and the CBD

Work on Article 27.3(b) has been ongoing since 1999. Discussion has included:

- "proposals on disclosing the source of biological material";
- how the provisions should be applied;
- what 'effective protection' for plant varieties means;
- "how to handle moral and ethical issues",
- "how to deal with the commercial use of traditional knowledge and genetic material"; and
- how to ensure TRIPS and the CBD support each other.

(WTO, no date given).

The Doha Declaration of 2001 included instruction to the TRIPS Council to “examine, inter alia, the relationship between the TRIPS Agreement and the Convention on Biological Diversity”. Current ideas include:

- Disclosure as a TRIPS obligation – this is disclosure of country of origin, any traditional knowledge used, plus evidence of prior informed consent and evidence of fair and equitable benefit sharing.
- Disclosure through WIPO and its Patent Cooperation Treaty – to enable national law to ask for disclosure of origin.
- Disclosure outside patent law – with all applications to disclose source/origin, but consequences of not doing so outside of patent law.
- Use of national legislation and contractual arrangements based on it.

(WTO, no date given).

In 2006 the WTO Secretariat produced a summary report on deliberations on the TRIPS-CBD relationship (WTO, 2006). This noted that the two main issues were:

“whether or not there is a conflict between the TRIPS Agreement and the CBD” and “whether something needs to be done, at least on the TRIPS side, to ensure that the two instruments are applied in a non-conflicting and mutually supportive way, and if so, what.”

And that member states’ opinions could be roughly grouped into four categories of:

- No conflict and can be implemented nationally in a mutually supportive way.
- No conflict, but “further study is required to determine whether any international action in relation to the patent system is called for”.

- “no inherent conflict... but... a case for international action in relation to the patent system in order to ensure or enhance, in their implementation, the mutual supportiveness of both Agreements.”
- “there is inherent conflict... and the TRIPS Agreement needs to be amended to remove such conflict.”

The document gives more details on the arguments presented to back up each opinion.

Within the arguments on there being conflict there are three further strands of opinion:

- That “allowing patents to be granted in respect of genetic material is in itself inconsistent with the CBD”;
- “That problems... arise more particularly where members do not follow closely enough the criteria for patentability laid down in the TRIPS Agreement” (that the material is in its natural state and so isn’t eligible for patent; that the material has been isolated but not modified and so isn’t eligible for patent; or that it is not novel/inventive as it is based on traditional knowledge, and so isn’t eligible for patent.)
- “that the grant of overly broad patents could impede access to and use of genetic resources.”

Arguments in opposition to these views are also presented.

Animal Genetic Resources

The FAO organised an International Technical Conference on Animal Genetic Resources in September 2007, which adopted a *Declaration on Animal Genetic Resources and Global Plan of Action on Animal Genetic Resources*, details of which can be found in Section I of Genomics Monitor Issue 5. The Conference request that the Plan of Action be presented to relevant international organisations, including the FAO Conference, ITPGR’s

Governing Body, the Commission on Sustainable Development, and the CBD's Conference of the Parties and Subsidiary Body on Scientific, Technical and Technological Advice.

Avian Influenza

In 2007 an issue relating to access to genetic resources emerged in the World Health Organisation (WHO). Indonesia temporarily stopped supplying samples of avian influenza virus to a WHO collaborating centre[†]. Indonesia stated that this was due to concerns that vaccines or other medical products that would be produced from research on the virus would not be accessible to it. This can be seen as a case of a restriction on access to genetic resources, due to concerns that benefits would not be shared equitably. As an urgent global public health issue, it was important that WHO find some resolution to this, and it rapidly began work on the issue.

This work has included, in November 2007, an Intergovernmental Meeting on Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits. An Interim Statement[‡] produced by the meeting acknowledged that:

“there has been a breakdown in trust in this essential system of the international collaboration and collective action” relating to “sharing of viruses and specimens, the development and production of preventive and curative measures such as vaccines and anti-virals”, and “that the current system does not deliver the desired level of fairness, transparency and equity;”

(WHO, 23rd November 2007, Preamble).

[†] “By definition, a WHO collaborating centre is an institution designated by the Director-General of WHO to form part of an inter-institutional collaborative network set up by WHO in support of its programme at the country, intercountry, regional, interregional and global levels, as appropriate.” http://www.who.int/collaboratingcentres/cc_historical/en/index1.html.

[‡] It is interim until the World Health Assembly makes a decision on a “detailed framework for virus sharing and benefit sharing”. (WHO, 23rd November 2007).

It was agreed that action would be taken “to develop fair, transparent and equitable international mechanisms on virus sharing and benefit sharing.” (WHO, 23rd November 2007).

And two measures were established:

- Traceability mechanism – “a technical and feasible system... within WHO to track all shared H5N1 and other potentially pandemic human viruses and the parts thereof”; and
- Advisory mechanism – “to monitor, provide guidance to strengthen the functioning of the system and undertake necessary assessment of the trust-based system needed to protect public health”.

(WHO, 23rd November 2007).

It was also agreed that “viruses and samples are to be shared within the WHO system, consistent with national laws and regulations, while the detailed framework for virus sharing and benefit-sharing continues to be developed.” (WHO, 23rd November 2007).

An Open-Ended Working Group of the Intergovernmental Meeting was established and it was agreed that the Meeting would be reconvened to consider the group’s work.

UNESCO Declarations

Through its bioethics programme, UNESCO (the United Nations Educational, Scientific and Cultural Organisation), has produced three declarations relating to human genetics, each of which has included a clause relating to access and benefit sharing. These are:

- Universal Declaration on the Human Genome and Human Rights, Article 12:

“(a) Benefits from advances in biology, genetics and medicine, concerning the human genome, shall be made available to all, with due regard for the dignity and human rights of each individual.” (UNESCO, 1997)

- International Declaration on Human Genetic Data, Article 19 – Sharing of Benefits:

“(a) In accordance with domestic law or policy and international agreements, benefits resulting from the use of human genetic data, human proteomic data or biological samples collected for medical or scientific research should be shared with the society as a whole and the international community.” (UNESCO, 2003)

- Universal Declaration on Bioethics and Human Rights, Article 2 – Aims:

“The aims of this Declaration are:...

(f) to promote equitable access to medical, scientific and technological developments as well as the greatest possible flow and the rapid sharing of knowledge concerning those developments and the sharing of benefits, with particular attention to the needs of developing countries.” (UNESCO, 2005)

Cooperative Efforts in Relation to Access to Genetic Resources

A few prominent examples of cooperation activities between international organisations on the issue of access to genetic resources are outlined here:

Union for the Protection of New Varieties of Plants and the Convention on Biodiversity Secretariat

The CBD and UPOV have corresponded since 2003 on the issue of access and benefit-sharing, and particularly “the process, nature, scope, elements and modalities of an international regime on access to genetic resources and benefit-sharing” (UPOV, April 2008). This has taken the form of gaining information on the position of UPOV on work being done by the Ad Hoc Open-Ended Working Group.

A letter of October 2005 (extracting from a 2003 letter) outlined UPOV’s position:

“access to genetic resources is a key requirement for sustainable and substantial progress in plant breeding. The concept of the ‘breeder’s exemption’ in the UPOV Convention, whereby acts done for the purpose of breeding other varieties are not subject to any restriction, reflects the view of UPOV that the worldwide community of breeders needs access to all forms of breeding material to sustain greatest progress in plant breeding and, thereby, to maximize the use of genetic resources for the benefit of society. In addition, the UPOV Convention has inherent benefit-sharing principles in the form of the breeder’s exemption and other exceptions to the breeder’s right and UPOV is concerned about any other measures for benefit-sharing which could introduce unnecessary barriers to progress in breeding and the utilization of genetic resources. UPOV urges the Ad Hoc Open-ended Working Group on Access and Benefit-Sharing to recognize these principles in its work and to ensure that any measures it develops are supportive of these principles and, therefore, of the UPOV Convention.”

(UPOV, October 2005)

UPOV, while stating that its Convention does not cover access and benefit-sharing, has urged the CBD to ensure that the proposed international regime is mutually supportive with the Convention. It has made clear that adding

additional clauses relating to disclosure of origin or prior informed consent to the UPOV requirements is not possible because no additional 'conditions for protection' are allowed, but notes that it does encourage information on origin to be supplied where possible (UPOV, October 2005). UPOV has also noted that since it has defined in the Convention the terms 'breeder', 'breeders' right' and 'variety' if the international regime gave any other definition to these terms it "would cause confusion" (UPOV, October 2005).

World Intellectual Property Organisation and the Convention on Biodiversity Secretariat

There have also been information sharing efforts between the Convention on Biodiversity's Conference of the Parties and WIPO. On request WIPO provided a background document to the 2005 COP to the CBD on *Examination of Issues Regarding the Interrelation of Access to Genetic Resources and Disclosure Requirements in Intellectual Property Rights Applications*. This provided information on existing mechanisms including:

- International Treaty on Plant Genetic Resources,
- Convention on Biodiversity,
- Bonn Guidelines,
- Council for TRIPS,
- Draft Substantive Patent Law Treaty;
- Patent Cooperation Treaty;
- Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore; and
- Regional and national measures.

It also covered the technical and legal background, and options for model provisions, triggers for disclosure requirements, incentive measures for applicants, implications for WIPO treaties, and international certification as requested by the CBD-COP (WIPO, 2005). WIPO and UNEP also produced a joint *Study on the role of Intellectual Property Rights in the Sharing of Benefits*

Arising from the Use of Biological Resources and Associated Traditional Knowledge in 2004. This noted that the IGC has “illustrated the benefits of interaction and feedback between the parallel processes concerning policy dialogue, pooling information and building capacity.” (WIPO, 2004[3]).

World Intellectual Property Organisation and the World Health Organisation

As part of its work on gaining access to avian influenza virus for public health research WHO requested information from WIPO on patent issues. WIPO produced a paper on *Patent Issues Related to Influenza Viruses and Their Genes*, which noted that:

“Existing patent systems present opportunities and constraints in the field of influenza. A balanced and effective patent system should by definition provide positive incentives and technological diffusion structures that sustainably promote new research and development in relation to the flu virus and vaccines against it.”

(WIPO, 19th October 2007)

The issue of benefit-sharing was deliberately not addressed.

It also produced a document *Patent Landscape for the H5 Virus*, which noted that there is need “for clear and accessible overviews of patent trends and their implications”, but that there are difficulties in doing so. This includes that there is no organisation which has an overview of global patenting activity. WIPO has information on applications which use the Patent Cooperation Treaty system, but there is no obligation for applicants to use this system, even when applying for patents in more than one state. The document is stated to be incomplete and a work in progress. It has identified 36 patent families[§] relating to avian influenza virus sequences and gene products

[§] A group of patents granted under/outlined in an application.

(WIPO, November 2007). These documents informed the WHO Director-General's report to the Intergovernmental Meeting on Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits (WHO, 7th November 2007).

World Intellectual Property Organisation Intellectual Property and the Life Sciences Programme

WIPO has engaged with WHO, UNESCO, the CBD Secretariat, FAO, UNEP and the WTO in its Intellectual Property and the Life Sciences Programme. For example, a recent WIPO Symposium on Public Policy Patent Landscaping in the Life Sciences was organised in cooperation with FAO (WIPO, April 2008).

Conclusion

The issue of access to genetic resources has several dimensions (agricultural, environmental, intellectual property protection, human rights) which bring it into the remit of a variety of international organisations including the Food and Agriculture Organisation, World Intellectual Property Organisation, Convention on Biodiversity Secretariat, United Nations Environment Programme, World Trade Organisation and World Health Organisation. These organisations have undertaken some cooperative efforts on access to genetic resources. Most extensive appear to be those of the World Intellectual Property Organisation and its Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore.

The analysis of opportunities and constraints for inter-organisation cooperation in Section II of Genomics Monitor Issue 7, noted that member states have key influence over whether and to what extent cooperation takes place. Some constraints do appear to have been placed on inter-organisation cooperation on access to genetic resources, with, for example, repeated withholding of observer status on the TRIPS Council for the Convention on

Biodiversity Secretariat. However, for the area of access to genetic resources there does seem to be a good level awareness of the interconnections among the various international organisations and regulatory processes, and efforts are being made to resolve (real or perceived) tensions and contradictions.

The issue of intellectual property rights and access to genetic resources is complex and is likely to take several more years to resolve. The disagreements partly rest on how states are interpreting and implementing regulations and the international organisations can help promote coherent implementation by cooperating and providing information to their member states.

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Acronyms:

AGR – Animal Genetic Resources

CBD – Convention on Biodiversity

CGIAR – Consultative Group on International Agricultural Research

CPGR – Commission on Plant Genetic Resources

CGRFA – Commission on Genetic Resources for Food and Agriculture

COP – Conference of the Parties (to the Convention on Biodiversity)

FAO – Food and Agriculture Organisation

IGC – Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (of the World Intellectual Property Organisation)

IP – intellectual property

IPRs – intellectual property rights

ITPGR – International Treaty on Plant Genetic Resources for Food and Agriculture

IUPGR – International Undertaking on Plant Genetic Resources for Food and Agriculture

PGRFA – Plant genetic resource for food and agriculture

TRIPS – Trade Related Aspects of Intellectual Property Rights

UNEP – United Nations Environment Programme

UNESCO – United Nations Educational, Scientific and Cultural Organisation

UPOV – Union for the Protection of New Varieties of Plants

WHO – World Health Organisation

WIPO – World Intellectual Property Organisation

WTO – World Trade Organisation

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