

# GENOMICS MONITOR

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## GENOMICS MONITOR – ISSUE 9 – CONTENTS

Preface	1
<b>SECTION I: REGULATORY DEVELOPMENTS</b>	<b>3</b>
<b>1) Highlights</b>	<b>3</b>
Quick Reference Table of the International Regulations	4
<b>2) Arms Control</b>	<b>7</b>
Biological Weapons Convention – Intersessional Process 2007-2010: Final Report of the 2008 Meeting of Experts	7
Biological Weapons Convention – Intersessional Process 2007-2010: Informal Advance Report of the 2008 Meeting of States Parties	8
Changes to the Number of States Parties to the Arms Control Regulations	12
<b>3) Health and Disease Control</b>	<b>13</b>
17th/2008 Edition of Terrestrial Animal Health Code	13
11th/2008 Edition of the Aquatic Animal Health Code	15
Codex Alimentarius – Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals	16
2008 (amended version) of Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants	19
Changes to the Number of States Parties to the Health Regulations	20
<b>4) Environmental Protection</b>	<b>21</b>
International Regime on Access and Benefit-Sharing – Report of the Meeting of the Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches	21
Changes to the Number of States Parties to the Environment Regulations	25
<b>5) Trade</b>	<b>26</b>
Workshop on Good Practice in Sanitary and Phytosanitary Related Technical Cooperation	26
Meeting of the TRIPS (Trade Related Aspects of Intellectual Property Rights Agreement) Council	27
Optional Supplementary International Search under the Patent Cooperation Treaty	29

UPOV Council 42nd Session – Report on Decisions	29
Launch of Capacity-Building Project – Legal and Technical Assistance to Developing Countries on Implementing the International Treaty on Plant Genetic Resources for Food and Agriculture with Particular Reference to the Multilateral System of Access and Benefit-Sharing	30
Changes to the Number of States Parties to the Trade Regulations	30
<b>6) Drugs Control</b>	<b>31</b>
Changes to the Number of States Parties to the Drugs Regulations	31
<b>SECTION II – Interactions Between Indigenous Peoples Rights and International Regulation of Biotechnology</b>	<b>32</b>
Introduction	32
Definition	33
Indigenous Peoples Rights	33
Indigenous Rights with Particular Relevance to the International Regulation of Biotechnology	36
Implications of these Rights in Relation to Biotechnology	38
Interaction of these Rights with the International Regulation of Biotechnology	38
Summary/Conclusions	55
References	58
<b>SECTION III - EVENTS AND RECENT PUBLICATIONS</b>	<b>60</b>

# GENOMICS MONITOR – ISSUE 9

## **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 9**

Issue 9 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 interactions between indigenous rights and the international regulation of biotechnology.

## **Importance of this Area**

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

across regulatory areas. It will provide a central authoritative source for anyone interested in this area.

### **Acknowledgements**

The development and production of the Monitor has been made possible through the support of the Strengthening the Biological Weapons Convention Project based in the Department of Peace Studies, University of Bradford and the Institute for Science, Ethics and Innovation at the University of Manchester. The Institute of Science, Ethics and Innovation aims to examine the ways in which science is used in the 21<sup>st</sup> Century, to evaluate possible or desirable changes, and to consider the forms of regulation and control of the process that are appropriate or required ([www.manchester.ac.uk/isei](http://www.manchester.ac.uk/isei)).

### **Structure of Issue 9**

Issue 9 of the Genomics Monitor is in three sections: the first provides information on regulatory developments; the second provides analysis of interactions between indigenous rights and international regulation of biotechnology; and the third gives information about forthcoming events and recent publications. Figures given on numbers of states parties were accurate on 26<sup>th</sup> February 2009.

## 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:

- Biological Weapons Convention – Intersessional Process 2007-2010: Final Report of the 2008 Meeting of Experts
- Biological Weapons Convention – Intersessional Process 2007-2010: Informal Advance Report of the 2008 Meeting of States Parties
- 17th/2008 Edition of Terrestrial Animal Health Code
- 11th/2008 Edition of the Aquatic Animal Health Code
- Codex Alimentarius – Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals
- 2008 (amended version) of Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants
- International Regime on Access and Benefit-Sharing – Report of the Meeting of the Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches
- Workshop on Good Practice in Sanitary and Phytosanitary Related Technical Cooperation
- Meeting of the TRIPS (Trade Related Aspects of Intellectual Property Rights Agreement) Council
- Optional Supplementary International Search under the Patent Cooperation Treaty
- UPOV Council 42nd Session – Report on Decisions
- Launch of Capacity-Building Project – Legal and Technical Assistance to Developing Countries on Implementing the International Treaty on Plant Genetic Resources for Food and Agriculture with Particular Reference to the Multilateral System of Access and Benefit-Sharing

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**

<b>REGULATION</b>	<b>INTERNATIONAL ORGANISATION (WHERE APPLICABLE)</b>	<b>NUMBER OF STATES PARTIES (WHERE APPLICABLE)</b>
<i>Arms Control</i>		
1925 Geneva Protocol		132
Biological and Toxin Weapons Convention		163
Chemical Weapons Convention	Organisation for the Prohibition of Chemical Weapons	186
Convention on the Prohibition of Military or Any Other Hostile Use of Environmental Modification Techniques		73
<i>Health and Disease Control</i>		
International Health Regulations	World Health Organisation	193
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	170
Laboratory Biosafety Manual	World Health Organisation	WHO has 193 member states
Laboratory Biosecurity Guidance	World Health Organisation	WHO has 193 member states

Guidance on Regulations for the Safe Transport of Infectious Substances	World Health Organisation	WHO has 193 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 179 member states plus the European Community
Guideline on Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms	Codex Alimentarius Commission	CAC has 179 member states plus the European Community
Guideline on Food Safety Assessment of Foods Derived from Recombinant-DNA Plants	Codex Alimentarius Commission	CAC has 178 member states plus the European Community
Guideline on Food Safety Assessment of Foods Derived from Recombinant-DNA Animals	Codex Alimentarius Commission	CAC has 178 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	153
<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	19
Budapest Treaty on the Deposit of Microorganisms	World Intellectual Property Organisation	72

for the Purpose of Patent Procedure		
Convention on the Protection of New Varieties of Plants	International Union for the Protection of New Varieties of Plants	67
International Treaty on Plant Genetic Resources	Food and Agriculture Organisation	119
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	634 sporting organisations
International Convention Against Doping in Sport	United Nations Educational, Scientific and Cultural Organisation	108
<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	

## **2) ARMS CONTROL**

### **Biological Weapons Convention – Intersessional Process 2007-2010: Final Report of the 2008 Meeting of Experts**

The 2008 Meeting of Experts took place from 18<sup>th</sup>-22<sup>nd</sup> August in Geneva. It was a one week meeting in preparation for the 2008 Meeting of States Parties, and considered the topics of:

“(iii) National, regional and international measures to improve biosafety and biosecurity, including laboratory safety and security of pathogens and toxins;  
(iv) Oversight, education, awareness raising and adoption and/or development of codes of conduct with the aim of preventing misuse in the context of advances in bio-science and bio-technology research with the potential of use for purposes prohibited by the Convention.”

There were participants from 96 states parties, 4 signatory states, and 3 other states, the United Nations Office for Disarmament Affairs, United Nations Institute for Disarmament Research, United Nations Environment Programme, the Security Council’s 1540 Committee, the European Commission, International Council for Genetic Engineering and Biotechnology, International Committee of the Red Cross, Organisation for Economic Cooperation and Development, United Nations Educational, Scientific and Cultural Organisation, World Health Organisation and the World Animal Health Organisation (OIE). Several non-governmental organisations, industry associations, scientific, academic and other groups attended the open sessions.

Annex I to the Report contains a table of summaries of Considerations, Lessons, Perspectives, Recommendations, Conclusions and Proposals Drawn from the Presentations, Statements, Working Papers and Interventions on the Topics Under Discussion. The Report can be found at

<http://daccessdds.un.org/doc/UNDOC/GEN/G08/630/84/PDF/G0863084.pdf?OpenElement>.

### **Biological Weapons Convention – Intersessional Process 2007-2010: Informal Advance Report of the 2008 Meeting of States Parties**

The 2008 Meeting of States Parties (considering the same topics as the Meeting of Experts – see above) was held 1<sup>st</sup>-5<sup>th</sup> December in Geneva. It was attended by 97 states parties, five signatory, and one non-signatory state. Also attending as observers were the United Nations Office of Disarmament Affairs, United Nations Institute of Disarmament Research, the European Commission, International Committee of the Red Cross, Interpol, the World Health Organisation, and the World Animal Health Organisation, plus 17 non-governmental organisations and research institutes.

In the Informal Advance Report (available at [http://www.unog.ch/80256EDD006B8954/\(httpAssets\)/C70514F42F7BF072C1257516005B1E7A/\\$file/BWC+MSP+2008+Advance+Report.pdf](http://www.unog.ch/80256EDD006B8954/(httpAssets)/C70514F42F7BF072C1257516005B1E7A/$file/BWC+MSP+2008+Advance+Report.pdf)) states parties noted the need for: “carefully assessing risks” and “balancing security concerns against the need to avoid hampering the peaceful development of biological science and technology” (pgh.19).

Under discussions on the topic of ‘national, regional and international measures to improve biosafety and biosecurity, including laboratory safety and security of pathogens and toxins’, the terms biosafety and biosecurity were given the following definitions within the context of the Convention:

“*biosafety* refers to principles, technologies, practices and measures implemented to prevent the accidental release of, or unintentional exposure to, biological agents and toxins, and *biosecurity* refers to the protection, control and accountability measures implemented to prevent the loss, theft, misuse, diversion or intentional release of biological agents and toxins and related resources as well as unauthorized access to, retention or transfer of such material.” (pgh.20)

The distinction made in this definition is similar to that made by the World Health Organisation in its Laboratory Biosafety Manual:

“Laboratory biosafety’ is the term used to describe the containment principles, technologies and practices that are implemented to prevent unintentional exposure to pathogens and toxins, or their accidental release. ‘Laboratory biosecurity’ refers to institutional and personal security measures designed to prevent the loss, theft, misuse, diversion or intentional release of pathogens and toxins.” (p.47)

The states parties “agreed on the value of:”

- Definition and implementation of biosafety and biosecurity concepts by national authorities, with the suggestion of “taking advantage of relevant guidance and standards such as those produced by the FAO, OIE and WHO”;
- Nominating a lead agency for biosafety and biosecurity measures;
- “specifying mandates for participating departments or agencies”;
- “ensuring effective enforcement and regular review of relevant measures”;
- Using various tools for oversight and implementation of biosafety and biosecurity in relation to facilities, organisations and individuals, such as certification, licensing, training, checks on qualifications, and “national lists of relevant agents, equipment and other resources”;
- “Building networks between scientific communities and academic institutions and increasing interactions with professional associations”;
- “International cooperation on biosafety and biosecurity” particularly in relation to capacity-building; and
- Facilitation of networking activities by the Implementation Support Unit.

(pgh.21 points i-vii)

Any measures adopted ought to: be “practical, sustainable, enforceable and readily understood”; “avoid unduly restricting the pursuit of biological sciences

for peaceful purposes”; be “adapted for local needs” and “appropriate for the agents being handled and the work being undertaken” (pgh.21.v).

Some of these points were expanded on. For example in relation to international cooperation:

“States Parties noted that pursuing biosafety and biosecurity measures could also contribute to the fulfilment of their other respective international obligations and agreements, such as the revised International Health Regulations of the World Health Organisation, and relevant codes of the World Organisation for Animal Health (OIE).” (pgh.22)

And in relation to capacity-building:

“States Parties recognise the value of cooperation and assistance to build biosafety and biosecurity capacity, particularly in States Parties in need of assistance in the fields of disease surveillance, detection, diagnosis and combating of infectious diseases and related research.” (pgh.23)

Under the second topic - oversight, education, awareness raising and adoption and/or development of codes of conduct with the aim of preventing misuse – in relation to oversight some similar points were made on the value of national frameworks of oversight measures, and on the need for such measures to be proportionate, practical and “not unduly restrict permitted biological activities” (pgh.25). Further, States Parties “agreed on the importance of involving national stakeholders in all stages of the design and implementation of oversight frameworks” and “noted the value of harmonizing...national, regional and international oversight mechanisms” (pgh.25).

In relation to awareness raising:

“States Parties recognized the importance of ensuring that those working in the biological sciences are aware of their obligations under the Convention and relevant national legislation and guidelines, have a clear understanding of

the content, purpose and foreseeable social, environmental, health and security consequences of their activities, and are encouraged to take an active role in addressing the threats posed by the potential misuse of biological agents and toxins as weapons, including for bioterrorism.” (pgh.26)

They also noted that formal educational requirements (possible mandatory) “could assist raising awareness” (pgh.26). It was felt that education/awareness programmes could usefully:

- Include explanation of “the risks associated with the potential misuse of the biological sciences and biotechnology”; “the moral and ethical obligations incumbent on those using the biological sciences”; “guidance on the types of activities which could be contrary to the aims of the Convention”;
- Be “supported by accessible teaching materials, train-the-trainer programmes, seminars, workshops, publications, and audio-visual materials”;
- Address “leading scientists and those with responsibility for oversight of research or for evaluation of projects or publications at a senior level, as well as future generations of scientists, with the aim of building a culture of responsibility”; and
- Be “integrated into existing efforts at the international, regional and national levels.” (pgh.27, points i-vi).

In relation to codes of conduct, it was seen that they could complement other (e.g. regulatory) frameworks “and help guide science so that it is not misused” and that national stakeholders should be encouraged to “voluntarily develop, adopt and promulgate codes of conduct” (pgh.28).

States Parties have been “encouraged to inform the Seventh Review Conference of, inter alia, any actions, measures or other steps that they may have taken on the basis of discussions at the 2008 Meeting of Experts and the outcome of the 2008 Meeting of the States Parties” (pgh.31).

An Annex to the Report – Synthesis of Considerations, Lessons, Perspectives, Recommendations, Conclusions and Proposals Drawn from the Presentations, Statements, Working Papers and Interventions on the Topics Under Discussion at the Meeting of Experts – contains some additional suggestions, including that: biosafety and biosecurity measures should “address resources relevant to humans, animals and plants” (pgh.2.iv); and that States Parties should “Ensure that adequate preparedness and response capacity exists in case of failures” (pgh.3.vii), adopt measures to protect whistleblowers (pgh.9.vi), and “Regularly review scientific and technological developments relevant to the Convention and consider creating an international science advisory panel to independently analyze such developments.” (pgh.9.viii).

The 2009 Meeting of Experts is scheduled for 24<sup>th</sup>-28<sup>th</sup> August, and the 2009 Meeting of States Parties is scheduled for 7<sup>th</sup>-11<sup>th</sup> December. These meetings will consider point (v) of the 2007-2010 Intersessional Process – *With a view to enhancing international cooperation, assistance and exchange in biological sciences and technology for peaceful purposes, promoting capacity building in the fields of disease surveillance, detection, diagnosis, and containment of infectious diseases: (1) for States Parties in need of assistance, identifying requirements and requests for capacity enhancement; and (2) from States Parties in a position to do so, and international organizations, opportunities for providing assistance related to these fields.*

### **Changes to number of states parties to the arms control regulations**

There are now 163 states parties to the Biological Weapons Convention and 186 states parties to the Chemical Weapons Convention.

### 3) HEALTH AND DISEASE CONTROL

#### 17<sup>th</sup>/2008 Edition of Terrestrial Animal Health Code

The 2008 version of the Terrestrial Animal Health Code (TAHC) contains amendments, revisions and new information as agreed by OIE (World Organisation for Animal Health) member states in May 2008. It is split into two volumes, the first containing more general guidance, the second containing disease-specific recommendations. The Foreword to the TAHC states that the changes include:

*“revised information on the following subjects: general definitions, notification criteria for listing diseases, obligations and ethics in international trade, import risk analysis, evaluation of Veterinary Services, zoning and compartmentalisation, animal health measures applicable before and at departure, border posts and quarantine stations in the importing country, international transfer and laboratory containment of animal pathogens”* and for several of the disease specific chapters;

*“revised information on prescribed and alternative diagnostic tests for OIE listed diseases, on categorisation of diseases and pathogenic agents by the International Embryo Transfer Society, on inactivation procedures for FMD virus and AI virus, on surveillance for BSE, FMD, CSF, AI and bluetongue, on animal welfare, on factors to consider in conducting BSE risk assessments and on model veterinary health certificates”*; and

*“six new appendices covering the application of compartmentalisation, surveillance for AHS and ND, the design and implementation of identification systems to achieve animal traceability, the production of livestock and horses using somatic cell nuclear transfer (SCNT) and the role of the Veterinary Services in food safety”*

([http://www.oie.int/eng/normes/mcode/en\\_preface.htm](http://www.oie.int/eng/normes/mcode/en_preface.htm)).

The appendices do not appear in the TAHC’s table of contents, and these topics appear instead to have been incorporated into chapters of the Code. For example ‘Design and implementation of identification systems to achieve animal traceability’ forms Chapter 4.2, and ‘Somatic cell nuclear transfer in

production of livestock and horses' is Chapter 4.12. This chapter provides "a starting point for identifying, characterising and providing a basis for discussion on the animal health risks associated with SCNT cloning technology" (4.12.1). Its initial focus is on "the scientific basis for the risk assessment aspects, prevention measures and guidance", which currently include:

- "identification of animal health risks and recommendations for management of those risks in embryos, recipients, animal clones and progeny of clones;
- risk and prevention measures related with SCNT cloning technology;
- some welfare issues related to animal health."

(4.12.3)

It specifically notes that the chapter does not address the following issues, which "may be addressed at a later stage by the OIE" or "may be addressed by other bodies or instruments":

- "safety and nutritional aspects of food derived from ART, for example transgenics (addressed by Codex);
- risks related to the environmental release of animal clones;
- risks related to transgenic animals that have not involved SCNT or other cloning technology;
- non-reproductive animal biotechnologies;
- risks related to animals produced for xenotransplantation or organ donors;
- technologies related to stem cells;
- risks related to aquatic animal health, including fish clones;
- risks related to other terrestrial animals, such as wild mammals and non-mammals, including avian species and insects."

The rest of the chapter outlines general principles for risk analysis, and then specific guidance on managing animal health risks associated with embryos and animal health risks related to the recipients.

## 11<sup>th</sup>/2008 Edition of the Aquatic Animal Health Code

The 11<sup>th</sup> Edition of the Aquatic Animal Health Code (AAHC) incorporates changes agreed by the OIE member states in May 2008.

*“These include new and revised chapters on the following subjects: 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”* as well as to some of the disease specific chapters, and also *“three new appendices on welfare of farmed fish, control of aquatic animal health hazards in aquatic animal feed and aquatic animal health surveillance”*

([http://www.oie.int/eng/normes/fcode/en\\_preface.htm#sous-chapitre-0](http://www.oie.int/eng/normes/fcode/en_preface.htm#sous-chapitre-0)).

### International Plant Protection Convention – Draft Report of the Open-Ended Working Group on Building National Phytosanitary Capacity

At the December 2008 meeting of the Open-Ended Working Group on Building National Phytosanitary Capacity, several discussion papers were presented and their main points are summarised in the Report. The meeting produced a draft concept paper, draft strategy document and an indicative operational plan (reproduced in Annexes 4, 5, and 6 of the Report respectively), and agreed a definition of ‘phytosanitary capacity’ – “The ability of individuals, organizations and systems of a country to perform functions effectively and sustainably in order to protect plants and plant products from pests and to facilitate trade, in accordance with the IPPC.” (pgh.101).

The Concept Paper (Annex 4) further expands on the definition. For example it explains that:

“The functions which need to be performed are technical, legal, administrative, and managerial. Capacity includes the ability to develop and apply knowledge, skills and tools appropriate to these functions.”; and

“The ability to support biosecurity also contributes to achieving other national or international goals under other initiatives which deal with protecting biodiversity, food security and poverty reduction.”

The Draft Strategy (Annex 5) contains six strategic areas which it was felt the IPPC should work on. Some of these areas have two parts:

- 1a. assessment of country phytosanitary needs
- 1b. development of national phytosanitary action plans
2. advise/assist countries in establishing systems for standards implementation
3. facilitate improved coordination/communication
- 4a. implement appropriate structures in IPPC Secretariat
- 4b. mobilise resources
5. advocacy
6. sustainability of the CB [capacity-building] strategy

The Annex contains a table which for each strategic area lists activities and how they should be undertaken. There is also a column labelled 'who', but at present this is blank.

The Indicative Operational Plan (Annex 6) contains a table linked to the six strategic areas, providing information for each area on 'activity', 'who', 'timeframe', 'resources', and 'assumptions'. The assumptions column is blank.

### **Codex Alimentarius – Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals**

This new Codex Guideline supplements the Guidelines for Foods Produced Using Recombinant-DNA Microorganisms and Foods Derived from Recombinant-DNA Plant, and it uses the risk analysis base of the Codex Principles for the Risk Analysis of Foods Derived from Modern Biotechnology. Summaries of these three documents can be found on pages 20-22 of *Genomics Monitor Issue 1* ([www.brad.ac.uk/acad/sbtwc/gateway/monitor/genomicsmonitorissue1.pdf](http://www.brad.ac.uk/acad/sbtwc/gateway/monitor/genomicsmonitorissue1.pdf)).

The Guideline specifically states that, although they might be connected issues, it does not address animal welfare; ethical, moral and socioeconomic

aspects; environmental risks; the safety of recombinant-DNA animals used as feed; or the safety of animals fed with feed derived from recombinant-DNA animals, plants and microorganisms (pgh.2).

The approach to food safety assessment recommended in the Guideline assesses the new animal (line) relative to a “conventional counterpart having a history of safe use”, covering “intended and unintended effects” in order to “identify new or altered hazards relative to the conventional counterpart” (pgh.4). The assessment is to include consideration of:

- “A) the nature of the recombinant-DNA construct and its expression product(s), if any;
- B) the health status of the recombinant-DNA animal; and
- C) the composition of foods produced from recombinant-DNA animals, including key nutrients” (pgh.7).

The Guideline uses the following definition of a recombinant-DNA animal:

“an animal in which the genetic material has been changed through *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles.” (pgh.9)

And defines the conventional counterpart as:

“an animal breed with a known history of safe use as food from which the recombinant-DNA animal line was derived, as well as the breeding partners used in generating the animals ultimately used as food, and/or food derived from such animals.” (pgh.9).

A particular requirement of the food safety assessment is that it pick up any “unexpected, adverse effect on human health” (pgh.15). The Guideline sets up a “stepwise process” including:

- “A) General description of the recombinant-DNA animal;
- B) Description of the recipient animal prior to the modification and its use as food or for food production;

- C) Description of the donor organism or other source(s) of the introduced recombinant-DNA;
- D) Description of the genetic modification(s) including the construct(s) used to introduce the recombinant-DNA;
- E) Description of the methods used to produce the initial recombinant-DNA animal and the processes to produce the recombinant-DNA animal ultimately used as food or for food production;
- F) Characterization of the genetic modification(s) in the recombinant-DNA animal ultimately used as food or for food production;
- G) Safety assessment:
  - a) Health status of the recombinant-DNA animal;
  - b) Expressed substances (non-nucleic acid substances);
  - c) Compositional analyses of key components;
  - d) Food storage and processing; and
  - e) Intended nutritional modification;
- H) Other considerations.” (pgh.19)

The overall aim of conducting the food safety assessment “is to provide assurance, in the light of the best available scientific knowledge, that the food does not cause harm when prepared, used and/or eaten according to its intended use.” (pgh.22) It will include, in regard to expressed substances, assessment of potential toxicity, bioactivity, or allergenicity (pp.7-8). It should also include consideration of “potential altered accumulation or distribution of substances or microorganisms significant to human health” and the appropriateness of using antibiotic resistance marker genes (p.9). In particular it advises that “The transfer of genes from commonly allergenic foods should be avoided unless it is documented that the transferred gene does not code for an allergen.” (pgh.53) and that “Antibiotic resistance genes used in food production that encode resistance to clinically used antibiotics should not be present in foods.” (pgh.67). There is also an annex on Assessment of Possible Allergenicity. It is recommended that food safety

assessments “be reviewed in the light of new scientific information that calls into question the conclusions of the original safety assessment”.

### **2008 (amended version) of Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants**

Two main amendments have been adopted to the Recombinant-DNA Plant Guideline: a new annex (Annex 3) on Food Safety Assessment in Situations of Low-Level Presence of Recombinant-DNA Plant Material in Food; and a new annex (Annex 2) on Food Safety Assessment of Foods Derived from Recombinant-DNA Plants Modified for Nutritional or Health Benefits.

Annex 3 applies to situations where recombinant-DNA plant material which has passed a Codex food safety assessment in one country is present in low-levels in food imported to other countries which have not yet completed the food safety assessment. This can occur because of different rates of authorisation, and is likely to occur in two main ways. The first may occur during the processing stages for grains, beans and oil seeds, and in these cases the recombinant-DNA material “would be present only at a low level in any individual serving of food.” (pgh.4). The second relates to fruit and vegetables, and in these cases “exposure would be rare but could be to an undiluted form of the unauthorized recombinant-DNA plant material.” (pgh.4).

In either case the exposure level is lower than that which would be assessed in the Codex food safety assessment and therefore “only certain elements of the Codex Plant Guideline will be relevant” and these are indicated in the annex (pgh.5). Where provisions have been amended for the purposes of the annex these are reproduced in full, otherwise the relevant paragraphs in the main text are listed.

The annex specifically does not: address risk management; “preclude national authorities” from undertaking the full food safety assessment; or affect obligations to meet import requirements (pgh.6). Nor does it apply where the

importing country has already conducted the food safety assessment and decided against authorisation (footnote 24).

Annex 2 details additional considerations that need to be taken into account in safety assessment of foods modified for nutritional or health benefits. It specifically does not extend into assessment of the benefits. Provisions of both the Plant Guideline and the Codex General Principles for the Addition of Essential Nutrients to Foods are also generally applicable to these foods.

A recombinant-DNA plant modified for nutritional or health benefits is defined as one which:

“exhibits a particular trait in portion(s) of the plant intended for food use” and that this trait “is a result of i) introduction of a new nutrient(s) or related substance(s), or ii) alteration of either the quantity or bioavailability of a nutrient(s) or related substance(s), iii) removal or reduction of undesirable substance(s) (e.g. allergens or toxicants), or iv) alteration of the interaction(s) of nutritional or health relevance of these substances.” (pgh.2)

A nutrient is defined as:

“any substance normally consumed as a constituent of food:  
(a) which provides energy; or  
(b) which is needed for growth and development and maintenance of health life; or  
(c) a deficit of which will cause characteristic biochemical or physiological changes to occur.” (pgh.3)

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

There are now 170 states parties to the International Plant Protection Convention. The Codex Alimentarius Commission now has 179 member states plus the European Community.

#### **4) ENVIRONMENTAL PROTECTION**

##### **International Regime on Access and Benefit-Sharing – Report of the Meeting of the Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches**

This Working Group was established by Decision IX/12 of the 9<sup>th</sup> Conference of the Parties to the Convention on Biodiversity, which instructed it to:

“address the following questions:

- (a) What are the different ways of understanding biological resources, genetic resources, derivatives and products and what are the implications of each understanding for the development of the main components of the international regime on access and benefit-sharing, including in relation to sectoral and sub-sectoral activities in relation to commercialised and noncommercialised research?
- (b) Identify different forms of utilization of genetic resources in relation to sectoral and subsectoral activities in the context of Article 15, paragraph 7 of the Convention;
- (c) Identify and describe sector specific characteristics of access and benefit-sharing arrangements and to identify the differences, if any, between approaches in sectors;
- (d) What are the range of options and approaches for taking these different characteristics into account and that may bring coherence to access and benefit-sharing related practices in different sectors?”

Its meeting, held in December 2008, was attended by 21 experts nominated by member states and the European Community, and 13 expert observers from organisations, including from the Commission on Genetic Resources for Food and Agriculture and the secretariat of the International Treaty on Plant Genetic Resources.

*An annex to the Report – Outcome of the Meeting of the Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral*

*Approaches* – provides details on the discussions that took place (<https://www.cbd.int/doc/meetings/abs/absqtle-01/official/absqtle-01-abswg-07-02-en.pdf>). Under point a. the experts discussed biological resources, genetic resources, derivatives and products in turn. In most cases finding that further clarification is needed on these terms. A non-exhaustive list was established of activities in which genetic resources are used, their use in such cases indicating actual or potential value. (Genetic resources are defined in the Convention as “genetic material of actual or potential value”.) These activities were listed under the broad headings of:

1. Genetic modification;
2. Biosynthesis;
3. Breeding and selection;
4. Propagation and cultivation of the genetic resource in the form received;
5. Conservation;
6. Characterization and evaluation;
7. Production of compounds naturally occurring in genetic material.

(pgh.13)

In relation to biological resources, the Group recognised “that biological resources used as commodities are subject to a separate set of international norms and rules and there was general agreement that commodities should be outside the scope of the international regime for purposes of prior informed consent” while acknowledging that “the scope of the regime was outside the mandate of the group.” (pgh.10.)

The terms biological resources and genetic resources are both defined in the Convention. The terms derivatives and products are not. A list of 11 ways of understanding the term derivatives was elaborated by the Group. They agreed that these could generally be grouped into:

- “Derivatives understood as the results of an organism’s metabolism
- Derivatives understood as any result of human activity utilizing a genetic resource

- Derivatives understood as information on genetic resources.” (pgh.20.)

The scope of the regime in relation to naturally occurring derivatives that can be accessed “without also accessing the genetic resource at the same time” was questioned (pgh.21).

The Group noted that “all products are derivatives but not all derivatives are products” and provided a set of potential indicators that allow judgement of when a derivative is a product, which include: “(i) commercialization and availability on the open market/for sale to the public; (ii) seeking marketing or other approvals such as product registration; (iii) submission of applications for intellectual property protection; and (iv) the identification of a specific use for a derivative.” (pgh.23).

For discussion of points b. and c. the experts divided into four groups looking at: “1. Non-commercial research, including *ex situ* collections

2. Food and agriculture
3. Pharmaceuticals and biotech
4. *Ex situ* conservation.” (pgh.38)

The sub-groups each considered the topics of:

- “Genetic resources used by their sectors
- How these genetic resources are used by the sector based on the list of typical uses identified earlier during the meeting
- What are the mechanisms for benefit-sharing used in each sector
- Whether any standards for benefit-sharing had been developed for the sector
- Specific characteristics of the sectors” (pgh.39).

The sub-groups reported back to the main group and these reports are summarised later in the annex. This includes: paragraph 43 summarising genetic resources for each sector and how they are used; paragraph 44 containing listings of benefit-sharing mechanisms by sector; and paragraph 45 containing listings of specific characteristics of each sector.

After the subgroups had reported the experts discussed “differences between sectoral ABS approaches” based on the subgroup characterisations (in paragraphs 46-55). In particular, it was noted that “the agricultural sector is unique due to a number of factors, including the following:

- (a) Under the multilateral system of the International Treaty for Plant Genetic Resources for Food and Agriculture, prior informed consent is not required to access breeding material;
- (b) Plant breeding needs access to a wide pool of genetic resources and then creates a product which is also a genetic resource;
- (c) Countries have become strongly interdependent for their food production;
- (d) The sector continuously uses its own genetic resources for the generation of new products and needs access to a wide range of different genetic resources for the development of new products.” (pgh.49).

General differences identified between sectors included:

- “some sectors had taken a more active approach... and had developed very detailed mechanisms and approaches” (pgh.48)
- “the way in which they sourced genetic resources, with some sourcing mainly from ex situ collections and others mainly through intermediaries” (pgh.51)
- “ABS arrangements range from highly standardized forms of transaction to customized arrangements... Use is also made of phased agreements...” (pgh.53)
- “Each sector has specific references to prior informed consent, access and benefit-sharing” (pgh.54)
- “Groups of users respond to different interests” (pgh.54)
- “Differences in techniques or activities depending on the sector” (pgh.54)

- “Within some commercial sectors there are very significant differences regarding the size, technological capacity, research and development strategies and target markets of companies.” (pgh.55).

Overall “The experts therefore considered that a ‘one size fits all’ approach would not be suitable under the international regime” (pgh.53).

Under point d. the experts looked at options and approaches and particularly the issue of bringing coherence to the regime, noting that this could have some negative as well as positive aspects, for example possible loss of flexibility. It was also felt that: “The international regime could provide for minimal access and benefit-sharing requirements that apply across sectors if no specific system is in place.” (pgh.57.g.)

Examples are listed in the annex of national and international voluntary codes of conduct and best practice that the subgroups highlighted (pgh.59).

### **Changes to the number of states parties to the environmental protection regulations**

There are now 150 states parties to the Cartagena Protocol on Biosafety.

## 5) TRADE

### **Workshop on Good Practice in Sanitary and Phytosanitary Related Technical Cooperation**

This workshop was held in Geneva in October 2008 with the cooperation of the Standards and Trade Development Facility and the Organisation for Economic Cooperation and Development. Its aims were:

- “(i) to review experiences related to good practice in SPS-related technical assistance projects in three pilot regions and identify elements of good practice that could be replicated in future assistance;
- (ii) to discuss what is required from donors, development agencies and beneficiaries in order to disseminate and implement the identified good practices more widely; and
- (iii) to discuss how to maximize the impact of SPS-related technical assistance on trade performance.”

[http://www.wto.org/english/tratop\\_e/sps\\_e/wkshop\\_oct08\\_e/wkshop\\_oct08\\_e.htm](http://www.wto.org/english/tratop_e/sps_e/wkshop_oct08_e/wkshop_oct08_e.htm)).

The work of the meeting and the report it produced were based on surveys and interviews on good practice undertaken by STDF and OECD. The meeting’s report (Summary Report of the Good Practice Workshop, <http://docsonline.wto.org/DDFDocuments/t/G/SPS/R52.doc>) gave suggestions for follow up work to focus on:

- “the development of a framework to assess impacts quickly and relatively easily;
- the development and use of impact indicators;
- case studies on how a value-chain approach has enhanced trade performance for particular commodities or to consider the cumulative effects of technical assistance in the SPS area over time; and

- ongoing cooperation with the EIF to ensure that SPS issues are integrated into national development plans and budgetary processes” (pgh.6) [EIF is not defined]

The research findings highlighted the following areas of good practice for SPS-related technical assistance:

“thorough preparation and sound project design; careful assessment and prioritization of needs and the use of more consistent and rigorous tools for this purpose; adequate consideration of absorptive capacity; transparency and communication; flexibility; involvement of the private sector; attention to sequencing; coordination and efforts to ensure linkages with related activities; a value chain approach, results-based management” (pgh.10)

But also noted that there are continuing problems, including “fragmented, supply-driven assistance, insufficient attention to ownership or absorptive capacity, a cursory approach to assessing and prioritizing needs, inadequate coordination, limited focus on and involvement of the private sector, not enough focus on developing local capacity to build capacity, and limited complementary investments in infrastructure.” (pgh.17) along with poor integration “into broader development assistance” (pgh.25).

### **Meeting of the TRIPS (Trade Related Aspects of Intellectual Property Rights Agreement) Council**

The TRIPS Council meeting, held in October 2008, discussed a range of topics including: biodiversity, pharmaceutical patents, technology transfer, technical assistance, and intellectual property and public health.

In relation to ongoing negotiations on TRIPS and the Convention on Biodiversity (TRIPS/CBD) it was noted that some member states want to link these negotiations (particularly the disclosure aspect) with negotiations on the issue of extending the multilateral register for geographical indications for

wines and spirits to other geographical indications ([http://www.wto.org/english/news\\_e/news08\\_e/trips\\_28oct08\\_e.htm](http://www.wto.org/english/news_e/news08_e/trips_28oct08_e.htm)). There was disagreement both on whether the issues should be linked in negotiations, and on whether the negotiations with TRIPS Council have reached an appropriate stage to be included in the Doha Round Negotiations. The Secretariat of the Convention on Biodiversity continues to be refused observer status in the TRIPS Council due to member state disagreement on this matter ([http://www.wto.org/english/news\\_e/news08\\_e/trips\\_28oct08\\_e.htm](http://www.wto.org/english/news_e/news08_e/trips_28oct08_e.htm)).

In regard to the issue of TRIPS and public health, implementation of the 2003 Decision on TRIPS and Public Health was reviewed. It was noted that the amendment to the TRIPS Agreement that makes the 2003 Decision permanent, had only been accepted by a limited number of member states “leaving just over a year for the number of accepting members to reach the required two thirds” ([http://www.wto.org/english/news\\_e/news08\\_e/trips\\_28oct08\\_e.htm](http://www.wto.org/english/news_e/news08_e/trips_28oct08_e.htm)). The amendment will not come into force until two thirds of members have accepted it. Forty-five member states have accepted the amendment and “Switzerland and the EU said their legislation is in place, so eligible importing countries can seek supplies under the new rules from them as well.” ([http://www.wto.org/english/news\\_e/news08\\_e/trips\\_28oct08\\_e.htm](http://www.wto.org/english/news_e/news08_e/trips_28oct08_e.htm)). The amendment allows exporting member states to manufacture patented pharmaceutical products under compulsory licence at the request of an eligible importing member state (generally a least-developed country) that requires the products for public health reasons, but lacks the capacity to undertake production domestically. The text of the amendment is available at [http://www.wto.org/english/tratop\\_e/trips\\_e/wtl641\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm).

In discussions on technical cooperation and technology transfer, member states “stressed that providing incentives is not enough to ensure technology transfer. The receiving countries’ investment and intellectual property framework and their ability to absorb the technology is also important” ([http://www.wto.org/english/news\\_e/news08\\_e/trips\\_28oct08\\_e.htm](http://www.wto.org/english/news_e/news08_e/trips_28oct08_e.htm)). There

was disagreement about whether consideration of technical cooperation with the TRIPS Council should “take into account the cluster of 14 proposals on the subject of World Intellectual Property Organisation’s Committee on Development and Intellectual Property” or whether these should only be applied to WIPO activities  
([http://www.wto.org/english/news\\_e/news08\\_e/trips\\_28oct08\\_e.htm](http://www.wto.org/english/news_e/news08_e/trips_28oct08_e.htm)).

### **Optional Supplementary International Search under the Patent Cooperation Treaty**

As of the 1<sup>st</sup> January 2009 there is an optional supplementary international search service available to applicants using the Patent Cooperation Treaty (PCT) system. It is offered due to the possibility that because some international search authorities may lack skill in some languages, not all prior art might be identified in the main international search. The WIPO explains that “it is not expected that SIS [supplementary international search] will be requested routinely, but rather as a strategic decision by the applicant, taken after consideration of the results of the main international search.”  
([http://www.wipo.int/pct/en/newslett/2008/12/article\\_0002.html](http://www.wipo.int/pct/en/newslett/2008/12/article_0002.html)). SIS is currently offered by three international search authorities details of which are provided in a table in the article referenced above and in an annex to the PCT Applicant’s Guide  
([http://www.wipo.int/guide/en/gdvol1/annexes/annexsis/ax\\_sisa\\_ru.pdf](http://www.wipo.int/guide/en/gdvol1/annexes/annexsis/ax_sisa_ru.pdf)).

There is also a powerpoint presentation available at  
<http://www.wipo.int/pct/en/texts/ppt/sis.ppt>. However, requests for SIS should be made to the International Bureau not to directly to the international search authorities.

### **UPOV Council 42<sup>nd</sup> Session – Report on Decisions**

This report is available at  
[http://www.upov.int/export/sites/upov/en/documents/c/42/c\\_42\\_20.pdf](http://www.upov.int/export/sites/upov/en/documents/c/42/c_42_20.pdf). Inter alia, the meeting noted a decision of the 76<sup>th</sup> Session of the UPOV Consultative Committee, that:

“(a) approved an arrangement between UPOV and WIPO, concerning the UPOV plant variety database whereby WIPO would undertake the collation of data for the UPOV-ROM [term not explained] and provide the necessary assistance to deliver a program of improvements and UPOV would agree that data in the UPOV-ROM Plant Variety Database could be included in the WIPO Patentscope® Search Service...; (b) approved the development of an ‘Assistance’ webpage on the UPOV website to provide information on relevant forms of assistance in the development of plant variety protection” (point 18). (this webpage is not yet online.)

**Launch of Capacity-Building Project – Legal and Technical Assistance to Developing Countries on Implementing the International Treaty on Plant Genetic Resources for Food and Agriculture with Particular Reference to the Multilateral System of Access and Benefit-Sharing**

This project, launched in November 2008, is designed to help countries to “develop improved national laws and regulations as well as administrative and information technology arrangements for the operation of the Multilateral System” and to “improve knowledge among national stakeholders of issues underlying the implementation of the Treaty and... Multilateral System.” ([ftp://ftp.fao.org/ag/agp/planttreaty/noti/NCP\\_GB3\\_JIPI\\_e.pdf](ftp://ftp.fao.org/ag/agp/planttreaty/noti/NCP_GB3_JIPI_e.pdf)). It will do this through provision of technical assistance.

**Changes in the number of states parties to the trade regulations**

The Patent Law Treaty now has 19 states parties, the Budapest Treaty on the Deposit of Microorganisms for the Purpose of Patent Procedure now has 72 states parties, the Convention for the Protection of New Varieties of Plants now has 67 states parties, and the International Treaty on Plant Genetic Resources now has 119 states parties.

## **6) DRUGS CONTROL**

### **Changes to the number of parties to the drugs control regulations**

The World Anti-Doping Code now has 634 sporting organisation members and the International Convention Against Doping in Sport has 108 states parties.

## **SECTION II: INTERACTIONS BETWEEN INDIGENOUS PEOPLES RIGHTS AND THE INTERNATIONAL REGULATION OF BIOTECHNOLOGY**

### **Introduction**

This section of the Genomics Monitor considers interactions between indigenous peoples' rights and the international regulation of biotechnology. Indigenous rights have received increasing recognition by the international community over the past two decades, this has included, in 2007, the adoption of a Declaration on the Rights of Indigenous Peoples. Some of the rights that have been recognised have direct relevance to two particular areas of biotechnology regulation: rules on genetic resources and rules on intellectual property rights. The relevant principles are outlined here, followed by discussion of how indigenous issues are being taken up in the development / interpretation of the biotechnology regulations.

In some cases, international rules are broadly compatible with the protection of indigenous rights, in other cases some adaptation or agreement on interpretation and implementation in the context of these rights will be necessary (and may already be underway). However, many long-standing international laws and declarations protect the rights of states (e.g. sovereign rights) and the rights of individuals (particularly, human rights) and points of conflict between these rights and the collective rights assigned to indigenous groups can be anticipated. To illustrate the UN Development Group *Guidelines on Indigenous Peoples' Issues* (2008) state that "the implementation of collective human rights should not adversely affect the implementation of individual rights" – this means that there may be a conflict between the indigenous right to own and control genetic resources and traditional knowledge and the individual right, as stated in Article 27.2 of the *Universal Declaration on Human Rights* (UNGA, 1948): "to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author."

## Definition

There is no internationally agreed definition of 'indigenous peoples', however Article 1 of the *Indigenous and Tribal Peoples Convention* describes them as, inter alia:

“Peoples in independent countries who are regarded as indigenous on account of their descent from the populations which inhabited the country, or a geographical region to which the country belongs, at the time of conquest or colonisation or the establishment of present state boundaries and who, irrespective of their legal status, retain some or all of their own social, economic, cultural and political institutions.” (ILO, 1989)

## Indigenous Peoples Rights

It is the view of several UN bodies including the General Assembly, Human Rights Council and International Labour Organisation, that – due to indigenous peoples' historical experiences of oppression and exploitation, and current situations of marginalisation and inequity – their survival, development and flourishing require that their collective rights be recognised and protected. For this reason several separate international declarations/conventions have been created on indigenous peoples' rights. In its *Guidelines on Indigenous Peoples' Issues*, the UN Development Group provides examples of the above arguments:

“In many parts of the world, indigenous peoples suffer from a history of discrimination and exclusion that has left them on the margins of the larger societies in which they exist. For this reason, they face great difficulties in maintaining and developing their own models of development and well-being and are consequently disproportionately affected by poverty and exclusion.”

(UN Development Group, 2008, p.6)

“indigenous peoples as collectivities, have distinct and unique cultures and world views, and their current needs and aspirations for the future may differ from those of the mainstream population. Their equal worth and dignity can only be assured through the recognition and protection of not only their individual rights, but also their collective rights as distinct groups. It is when these rights are asserted collectively that they can be realized in a meaningful way.”

(UN Development Group, 2008, p.6)

Two key international sources elaborating indigenous rights are the International Labour Organisation’s *Indigenous and Tribal Peoples Convention* (ITPC) of 1989 and the *United Nations Declaration on the Rights of Indigenous Peoples* (UNDRIP) of 2007. The ITPC is legally-binding on contracting states, however it has, so far, only 19 contracting states. UNDRIP is an aspirational declaration.

The international documents indicate that two main types of rights are assigned to indigenous peoples:

**Individual rights** – indigenous peoples have the same human rights as everyone else:

“Indigenous and tribal peoples shall enjoy the full measure of human rights and fundamental freedoms without hindrance or discrimination.” (Article 3.1 of ITPC, ILO, 1989).

**Collective rights** – additionally, indigenous peoples have been assigned several collective rights, including rights over land, resources, knowledge, institutions, and of self-determination:

“right to self-determination”;

“right to autonomy or self-government in matters relating to their internal and local affairs”;

“right to maintain and strengthen their distinct... institutions”;

“right to practice and revitalize their cultural traditions and customs”;

“right to the use and control of their ceremonial objects”;

“right to the repatriation of their human remains”

(Articles 3, 4, 5, 11, and 12 of UNDRIP, UNGA, 2007)

“rights of ownership and possession of the peoples concerned over the lands which they traditionally occupy”

(Article 7 of ITPC, ILO, 1989).

Alongside the ITPC and UNDRIP there are several other international declarations and conventions of relevance to indigenous peoples rights as well as various mechanisms that promote inclusion of indigenous issues in relevant international organisations. These include:

- Convention on the Rights of the Child
- Convention on Biological Diversity
- International Convention on the Elimination of all Forms of Racial Discrimination
- International Covenant on Civil and Political Rights
- International Covenant on Economic, Social and Cultural Rights
- Universal Declaration on Cultural Diversity
- Convention on the Protection and Promotion of the Diversity of Cultural Expressions
- Convention for the Safeguarding of the Intangible Cultural Heritage
- Convention Concerning the Protection of the World Cultural and Natural Heritage

(List adapted from UN Development Group, 2008, p.10)

And the:

- Special Rapporteur on the situation of human rights and fundamental freedoms of indigenous people (see <http://www2.ohchr.org/english/issues/indigenous/rapporteur>)
- Expert Mechanism on the Rights of Indigenous Peoples (a subsidiary body to the Human Rights Council) (see <http://www2.ohchr.org/english/issues/indigenous/ExpertMechanism/ind ex.htm>)
- UN Permanent Forum on Indigenous Issues - UNPFII (see [http://www.un.org/esa/socdev/unpfii/en/about\\_us.html](http://www.un.org/esa/socdev/unpfii/en/about_us.html))
- Interagency Support Group on Indigenous Issues (see <http://www.un.org/esa/socdev/unpfii/en/iasg.html>)
- International Governmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) of the World Intellectual Property Organisation (see <http://www.wipo.int/tk/en/igc/>)
- Ad Hoc Working Group on Article 8(j) of the Convention on Biodiversity (see <http://www.cbd.int/convention/wg8j.shtml>)
- Ad Hoc Working Group on Access and Benefit-Sharing of the Convention on Biodiversity (see <http://www.cbd.int/convention/wgabs.shtml>)

### **Indigenous Rights with Particular Relevance to the International Regulation of Biotechnology**

Most relevant to the relationship between indigenous rights and the international regulation of biotechnology are collective rights granted over (natural) resources and traditional knowledge. For example the following statements are made in UNDRIP:

“Indigenous peoples have the right to their traditional medicines and to maintain their health practices.” (Article 24.1, UNGA, 2007)

“Indigenous peoples have the right to maintain and strengthen their distinctive spiritual relationship with their traditionally owned or otherwise occupied and used... resources.” (Article 25, UNGA, 2007)

“2. Indigenous peoples have the right to own, use, develop and control the... resources that they possess...

3. States shall give legal recognition and protection to these... resources.” (Article 26, UNGA, 2007)

“Indigenous peoples have the right to redress, by means that can included restitution or, when this is not possible, just, fair and equitable compensation for the... resources which they have traditionally owned or otherwise... used, and which have been confiscated, taken..., used or damaged without their free, prior and informed consent.” (Article 28.1, UNGA, 2007)

“1. Indigenous peoples have the right to maintain, control, protect and develop their cultural heritage, traditional knowledge and traditional cultural expressions, as well as the manifestations of their sciences, technologies and cultures, including human and genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs, sports and traditional games and visual and performing arts. They also have the right to maintain, control, protect and develop their intellectual property over such cultural heritage, traditional knowledge, and traditional cultural expressions.

2. ... States shall take effective measures to recognize and protect the exercise of these rights.” (Article 30, UNGA, 2007)

And the following clause appears in the ITPC:

“The rights of the peoples concerned to the natural resources pertaining to their lands shall be specially safeguarded.

These rights include the right of these peoples to participate in the use, management and conservation of these resources.”

(Article 15.1, ILO, 1989)

### **Implications of these Rights in Relation to Biotechnology**

Biotechnology makes use of living organisms, biological materials and other genetic resources. Many of the areas in which indigenous groups are located/over which they have been granted rights, are centres of genetic diversity. The natural biological resources (and associated knowledge) in these areas are frequently of interest to, in particular, the pharmaceutical and agricultural industries and research institutions, for use in the development of biotechnology-based medicines and plants. The stated indigenous rights can be expected to influence access to and use of these resources in biotechnology industries and institutions (both public and private), because they place the resources under the control of the indigenous groups. Among other things, the rights require: free, prior and informed consent; fair, just and equitable compensation or benefit-sharing; and continued control over/participation in the development and use of products based on the resources and/or knowledge.

### **Interaction of these Rights with the International Regulation of Biotechnology**

There are two main, strongly interconnected, areas of international biotechnology regulation that interact with these rights:

- Conservation, sustainable use, access and benefit-sharing relating to genetic resources, traditional knowledge and traditional cultural expressions; and
- Intellectual property rights.

## *Genetic Resources and Traditional Knowledge*

### The Convention on Biodiversity – Article 8(j) and the International Regime on Access and Benefit-Sharing

One of the three main objectives of the Convention on Biodiversity (CBD) is:

“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.” (Article 1, CBD, 1992)

The CBD does not apply to all genetic resources, traditional knowledge, innovations and practices – its scope is limited to those which can be considered relevant to the conservation and sustainable use of biodiversity. The CBD does not define ‘indigenous and local communities’ or ‘traditional knowledge, innovations and practices’. The CBD Secretariat does, however, describe traditional knowledge on its website as:

“the knowledge, innovations and practices of indigenous and local communities around the world. Developed from experience gained over the centuries and adapted to the local culture and environment... transmitted orally from generation to generation... it tends to be collectively owned... mainly of a practical nature, particularly in such fields as agriculture, fisheries, health, horticulture, forestry and environmental management in general.” (CBD Sec., 2007).

Article 15 of the CBD covers the topic of access to genetic resources. It first states that:

“Recognizing the sovereign rights of states over their natural resources, the authority to determine access to genetic

resources rests with national governments and is subject to national legislation.” (.1, CBD, 1992)

This appears to conflict with, and therefore might need to be limited by, the rights of indigenous peoples to “maintain, control, protect and develop their... genetic resources” (Article 30.1 of UNDRIP, UNGA, 2007).

The access is to be on mutually agreed terms and subject to prior informed consent – but prior informed consent specifically of the Contracting Party i.e. the state. It is also the state, and not sub-state or transboundary groups, that is to participate in scientific research on the genetic resource and in fair and equitable benefit-sharing.

Article 8(j) of the CBD (1992) covers traditional knowledge, innovations and practices, it reads:

“Each Contracting Party shall, as far as possible and as appropriate:  
...respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities... relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices;”

To assist in the implementation of Article 8(j) the CBD’s Conference of the Parties (COP) established a working group, in which “indigenous and local communities play a full role” (CBD Sec., 2007). This group is known as the Ad Hoc Working Group on Article 8(j). The Secretariat, in relation to its support of the Working Group, collaborates with the UN Permanent Forum on Indigenous Issues, Food and Agriculture Organisation, World Intellectual

Property Organisation, World Trade Organisation, and UN Conference on Trade and Development, on relevant issues (CBD Sec., 2007).

The Group's current work includes:

- “the development of elements of sui generis systems;
  - developing indicators for the retention of traditional knowledge and methods and measures to address the underlying causes of the loss of such knowledge;
  - the development of an ethical code of conduct to ensure respect for the cultural and intellectual heritage of indigenous and local communities relevant to the conservation and sustainable use of biological diversity;
- and
- contribute to the negotiation of an international regime on access and benefit sharing, research on the impact of climate change into highly vulnerable indigenous and local communities, among others.”

(CBD Sec., 2007)

The work of the Group can be followed on the CBD website at <http://www.cbd.int/convention/wg8j.shtml>. It closely follows and exchanges information with the work of the CBD's Working Group on Access and Benefit-Sharing.

The Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing was established in 2000. It developed the *Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization* (approved by the Conference of the Parties in 2002). Since 2004 the group has been developing an international regime for access and benefit-sharing. This work is ongoing and details can be found at <http://www.cbd.int/abs/regime.shtml>.

The Bonn Guidelines (CBD Sec., 2002) make several references to indigenous and local communities in relation to genetic resources and traditional knowledge. Its objectives include:

“To contribute to the development by Parties of mechanisms and access and benefit-sharing regimes that recognize the protection of traditional knowledge, innovations and practices of indigenous and local communities.” (Article I.E.j)

Countries involved in granted access to or receiving genetic resources, users and providers, are requested, inter alia, to:

- “Seek to ensure that the commercialization and any other use of genetic resources should not prevent traditional use of genetic resources”
- “Respect customs, traditions, values and customary practices of indigenous and local communities”
- “Only supply genetic resources and/or traditional knowledge when they are entitled to do so”; and consider
- “Measures to encourage the disclosure of the country of origin of the genetic resources and of the origin of traditional knowledge, innovations and practices of indigenous and local communities in applications for intellectual property rights”

(Article II.C.16)

It is not explicitly stated in the Guidelines who is entitled to supply genetic resources/traditional knowledge, but the authority to agree access and make benefit-sharing arrangements remains with the Contracting Parties (states).

The Guidelines provide principles for systems of prior informed consent, which:

“should include:

- a) Legal certainty and clarity;
- b) Access to genetic resources should be facilitated at minimum cost;

- c) Restrictions on access to genetic resources should be transparent, based on legal grounds, and not run counter to the objectives of the Convention;
- d) Consent of the relevant competent national authority(ies) in the provider country. The consent of relevant stakeholders, such as indigenous and local communities, as appropriate to the circumstances and subject to domestic law, should also be obtained.”

(Article C.III.26)

The Guidelines do not assign rights directly to indigenous and local communities – it is still the state that has authority to make decisions, give consent, etc. Consultation is required, and consent suggested, but control is not given to the indigenous and local communities. Point c) above seems to indicate that once indigenous rights are incorporated into national law, those rights might count as ‘legal grounds’ for restrictions on access.

The Working Group on Access and Benefit-Sharing is expected to finish elaborating and negotiating an international regime in time for the CBD’s 10<sup>th</sup> Conference of the Parties in 2010. An Annex to the *Report of the Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing on the Work of its 6<sup>th</sup> Meeting* (January 2008) contains a draft of the International Regime, setting out options for its objectives, scope, main components, and nature. This Report is available at: <http://www.cbd.int/doc/meetings/cop/cop-09/official/cop-09-06-en.doc>.

It is not yet clear whether the regime will include a legally-binding instrument or how indigenous rights over genetic resources and traditional knowledge will be framed. States are, however, unlikely to agree to additional legal limitations on sovereign rights over their natural resources.

Relevant Work of the Food and Agriculture Organisation and the Commission for Genetic Resources in Food and Agriculture

The Food and Agriculture Organisation (FAO) aims to achieve ‘food security for all’ and maintenance and development of diverse plant genetic resources are essential for food security. The FAO has worked on issues relating to plant genetic resources since the 1950s (its history in this area is briefly outlined in pages 44-46 of *Genomics Monitor Issue 8*). In 2001 the FAO adopted the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR). The Treaty’s scope is limited to “plant genetic resources for food and agriculture”, which it defines as “any genetic material of actual or potential value for food and agriculture” (Articles 3 & 2, FAO, 2001).

Indigenous and local communities are mentioned in Article 9 of the Treaty:

“1. The Contracting Parties recognize the enormous contribution that the local and indigenous communities and farmers of all regions of the world, particularly those in the centres of origin and crop diversity, have made and will continue to make for the conservation and development of plant genetic resources which constitute the basis of food and agricultural production throughout the world.” (FAO, 2001)

However, the rights recognised are those, specifically, of farmers. Farmers rights’ are listed as including:

“a. protection of traditional knowledge relevant to plant genetic resources for food and agriculture;  
b. the right to equitably participate in sharing benefits arising from the utilization of plant genetic resources for food and agriculture; and  
c. the right to participate in making decisions, at the national level, on matters related to the conservation and sustainable use of plant genetic resources for food and agriculture.”  
(Article 9.2 of ITPGR, FAO, 2001)

The article further states that farmers have rights “to save, use, exchange and sell farmed-saved seed/propagating material” (Article 9.3 of ITPGR, FAO, 2001).

The responsibility for ensuring farmers’ rights is assigned to national governments.

ITPGR thus legally obliges states to ensure farmers’ rights over plant genetic resources for food and agriculture are recognised and protected. This is not extended to indigenous and local communities’ rights, nor does the CBD provide any legal requirement of this kind. It may, however, form part of the International Regime for Access and Benefit-Sharing.

While states sovereign rights over their plant genetic resources are recognised by ITPGR, contracting states agree that they will exercise these rights through the Treaty’s Multilateral System of Access and Benefit-Sharing (for more information see [http://www.planttreaty.org/mls\\_en.htm](http://www.planttreaty.org/mls_en.htm)). Benefits from resources accessed through the Multilateral System are specifically to “flow primarily... to farmers” (Article 13.3 of ITPGR, FAO, 2001).

Much of FAO’s work on genetic resources is undertaken by the Commission on Genetic Resources for Food and Agriculture (CGRFA – <http://www.fao.org/ag/cgrfa>). As well as plant genetic resources, FAO and CGRFA are also working on animal genetic resources and FAO member states adopted *the Interlaken Declaration on Animal Genetic Resources* and a *Global Plan of Action for Animal Genetic Resources* in September 2007 (see <ftp://ftp.fao.org/docrep/fao/010/a1404e/a1404e00.pdf> and pages 27 - 30 of *Genomics Monitor Issue 5*).

The *Interlaken Declaration* (which is not legally-binding) recognises:

- “that states have sovereign rights over their animal genetic resources for food and agriculture”;
- “the interdependence of countries, regions and peoples regarding these resources”;

- “the enormous contribution that the local and indigenous communities and farmers, pastoralists and animal breeders of all regions of the world have made, and will continue to make for the sustainable use, development and conservation of animal genetic resources for food and agriculture”; and that
- “it is their ownership and management of the genetic resources of their livestock that has enabled them to make important contributions in the past. It is this ownership and management that should be ensured for future societal benefits.”

(pp.1-2, FAO/CGRFA, 2007)

Outlines commitment to:

- “facilitating access to these resources and the fair and equitable sharing of the benefits arising from their use.” (p.1, FAO/CGRFA, 2007)

And, affirms:

- “the desirability... of respecting, preserving and maintaining traditional knowledge relevant to animal breeding and production.” (p.2, FAO/CGRFA, 2007)

Among the main aims of the Global Plan of Action are:

- “promote a fair and equitable sharing of the benefits arising from the use of animal genetic resources for food and agriculture”;
- “recognise the role of traditional knowledge, innovations and practices relevant to the conservation of animal genetic resources and their sustainable use.”; and
- “meet the needs of pastoralists and farmers, individually and collectively... to have non-discriminatory access to genetic materials, information, technologies, financial resources, research results, marketing systems, and natural resources, so that they may continue to manage and improve animal genetic resources and benefit from economic development”

(p.10, FAO/CGRFA, 2007)

If the FAO were to move to develop an international treaty on animal genetic resources, it is likely that it would take a similar form to the ITPGR and protect farmers' and animal breeders' rights rather than, specifically indigenous rights.

### *Intellectual Property Rights*

Indigenous (and other) groups have raised concerns about intellectual property rights (IPRs), particularly patents, being claimed by biotechnology research institutions and industries on natural (particularly genetic) resources and associated traditional knowledge that belong to their group, often without notification, informed consent, recognition, or benefit-sharing. Part of this concern is based on notions of sacredness, interconnection of all living things, traditional forms/concepts of ownership (particularly collective ownership), and fears – based on past experiences – of exploitation.

Patent rights granted to inventors allow them to:

“prevent third parties not having the owner’s consent from the acts of: making, using, offering for sale, selling, or importing for these purposes” the product or product obtained from the process (Article 28 of TRIPS, WTO, 1994).

Patents are granted to inventors on the basis of a product or process being: new/novel; involving an inventive step/non-obvious; and capable of industrial application (see pgh 27.1 and note 5 of the TRIPS Agreement). Not all national patent systems allow patenting of genetic material, but some internationally significant ones do – notably that of the US. The interpretation of the international agreement that sets minimum IPR standards (TRIPS) on this point is still being discussed by states.

In addition to concerns that their resources should not be owned / used by others without their consent, indigenous groups have expressed concerns that such ownership could exclude them from exploiting the resource or accessing

resulting products and research. Many current intellectual property systems have little capacity to recognise contributions or check on traditional knowledge in prior art searches, for example.

### Work in the World Trade Organisation under the Doha Development Agenda

A key international agreement relating to intellectual property rights is the Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS) of the World Trade Organisation (WTO). Issues relating to traditional knowledge and traditional cultural expressions have been raised within the WTO. In particular, the 2001 *Doha Ministerial Declaration* instructed the TRIPS Council (the WTO body which administers the Agreement) to “examine, inter alia, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore” (pgh 19, WTO, 2001).

Discussions in the TRIPS Council have so far focused predominantly on traditional knowledge. There remain significant divisions between member states on: whether there is a need for international action on traditional knowledge; whether it should be dealt with by the WTO; at what point the WTO ought to get involved in the international action on traditional knowledge; and what form any action by WTO should take.

In the document *The Protection of Traditional Knowledge and Folklore – Summary of Issues Raised and Points Made*, the TRIPS Council lists the arguments made by its members for and against international action on protection of traditional knowledge. These include:

“concern about the granting of patents or other IPRs covering traditional knowledge to persons other than those indigenous peoples or communities who have originated and legitimately control the traditional knowledge” and “concern that traditional knowledge is being used without the authorization” of those groups “and without proper sharing of the benefits”

(pgh.8, WTO/TRIPS Council, 2006)

Which need to be addressed internationally because:

- It is in the common (economic) interest to protect such a valuable resource;
- Issues of equity in recognition and benefit-sharing should be dealt with by the international community;
- It is part of a range of international action that will help protect indigenous communities and promote their development;
- It would be helpful for the TRIPS Agreement to be consistent with other international rules on genetic resources and traditional knowledge;
- “legal protection of traditional knowledge would improve confidence in the international intellectual property system”; and
- The concerns raised frequently relate to transboundary uses of traditional knowledge.

(pgh.9, WTO/TRIPS Council, 2006)

The counterarguments include:

- There are already laws that could be used to protect traditional knowledge, and this would have a more rapid effect;
- National regimes may well be capable of dealing with the issues;
- Further research is needed on the efficacy of national systems; and
- National systems are anyway a necessary part of international regimes.

(pgh.10, WTO/TRIPS Council, 2006)

Another key point of contention has been whether WTO is a suitable forum – particularly at the current stage – for debates on these issues. Some states believe that the TRIPS Council should be addressing the area now (in a way supportive of other fora) and other states argue that the Council should wait until work in the other fora, particularly that within the World Intellectual Property Organisation (WIPO) “has sufficiently clarified conceptual issues and possible options” (pgh.13, WTO/TRIPS Council, 2006). WIPO is argued to

have “more expertise and capacity” and experience in the area (pgh.13, WTO/TRIPS Council, 2006).

Additionally, some states argue that traditional knowledge ought not be discussed in the WTO at all as it “does not involve trade” (pgh.13, WTO/TRIPS Council, 2006). This is a weak argument since the concerns about protection of traditional knowledge relate to its use in products and processes that are likely to be traded internationally.

The document also notes that there are particular concerns and suggested responses in relation to the difficulty of traditional knowledge being found in prior art searches. This relates to both the way in which prior art is defined, and the lack of documentation available to patent examiners on traditional knowledge (pgh.20, WTO/TRIPS Council, 2006). Suggested responses (though this is not yet accepted by all member states as a problem) include: “development of databases” of traditional knowledge that could be searched during patent examinations (pgh.25, WTO/TRIPS Council, 2006); and use of disclosure of traditional knowledge in applications which would raise awareness among both holders and examiners of potential problems (pgh.27, WTO/TRIPS Council, 2006).

Disclosure has also been suggested as part of measures to ensure consent and benefit-sharing with a possible requirement for applicants not only to indicate origin of traditional knowledge, but also that “they have obtained any necessary prior informed consent” and “entered into appropriate benefit-sharing arrangements” (pgh.28, WTO/TRIPS Council, 2006).

Arguably, there is some scope within the TRIPS Agreement for states to provide national requirements relating to genetic resources and traditional knowledge within their IP systems:

“Article 8. Principles

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public

health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development.” (WTO, 1994)

The WTO still appears to be some way from reaching consensus on whether and how to approach issues of intellectual property and traditional knowledge. It is unlikely, in the short-term, that there will be any adaptation of the legal texts on which the international intellectual property system is based in response to indigenous rights. This is not to say that these rights are/will not be recognised within or alongside current intellectual property systems – international awareness of the issues has increased substantially over the past decade, and several international fora are actively debating and/or working on related issues, often collaboratively.

Work of the World Intellectual Property Organisation and its Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore

The relationship between intellectual property and genetic resources and traditional knowledge has been raised within the World Intellectual Property Organisation which is responsible for administering several international intellectual property agreements, including the Patent Cooperation Treaty. WIPO established an Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) in 2000 to serve as “an international forum for debate and dialogue concerning the interplay between intellectual property (IP), and traditional knowledge (TK), genetic resources, and traditional cultural expressions (TCEs)/(folklore)” (WIPO, no date given 3). Details of its work can be found through <http://www.wipo.int/tk/en/igc>.

The IGC’s work on genetic resources and intellectual property has covered three main areas:

- “**Defensive** protection of genetic resources through measures which prevent the grant of patents over genetic resources that do not fulfil the requirements of novelty and non-obviousness.”

In this area, WIPO has created “improved search tools and classification systems for patent examiners when they examine patent applications which claim genetic resources” (WIPO, no date given 2);

- “**IP aspects** of access to genetic resources and equitable **benefit-sharing** arrangements that govern use of genetic resources.”

As part of which, it is creating “an online, searchable database of biodiversity-related Access and Benefit-Sharing Agreements, with a particular emphasis on the intellectual property aspects” (WIPO, no date given 2) (This database can be found at <http://www.wipo.int/tk/en/databases/contracts/index.html>.); and

- “**Disclosure requirements** in patent applications that relate to genetic resources and associated TK used in a claimed invention.”

This includes a *Technical Study on Disclosure Requirements in Patent Systems Related to Genetic Resources and Traditional Knowledge* ([http://www.wipo.int/export/sites/www/tk/en/publications/technical\\_study.pdf](http://www.wipo.int/export/sites/www/tk/en/publications/technical_study.pdf)) and *Examination of Issues Relating to the Interrelation of Access to Genetic Resources and Disclosure Requirements in Intellectual Property Rights Applications* ([http://www.wipo.int/edocs/mdocs/tk/en/wipo\\_ip\\_gr\\_05/wipo\\_ip\\_gr\\_05\\_01.pdf](http://www.wipo.int/edocs/mdocs/tk/en/wipo_ip_gr_05/wipo_ip_gr_05_01.pdf)). (Both these documents were developed in response to requests for information from the Convention on Biodiversity’s Conference of the Parties).

The IGC has also drafted *Revised Draft Provisions for the Protection of Traditional Knowledge* and *Revised Draft Provisions for the Protection of Traditional Cultural Expressions* (both are available at

[http://www.wipo.int/tk/en/consultations/draft\\_provisions/draft\\_provisions.html](http://www.wipo.int/tk/en/consultations/draft_provisions/draft_provisions.html)).

Neither document has legal force. WIPO's disclaimer states:

“The drafts have not been adopted or endorsed by the IGC, but may be developed further if the IGC so chooses. While the draft objectives and principles have no formal status, they illustrate some of the perspectives and approaches that are guiding work in this area and could suggest possible frameworks for the protection of TCEs and TK against misappropriation and misuse.”

(WIPO, no date given 1)

For TK the relevant principles include:

“Protection of traditional knowledge should aim to: ...

Repress unfair and inequitable uses

(viii) repress the misappropriation of traditional knowledge and other unfair commercial and non-commercial activities, recognizing the need to adapt approaches... to national and local needs.

...Ensure prior informed consent and exchanges based on mutually agreed terms

...Promote equitable benefit-sharing

...Preclude the grant of improper IP rights to unauthorized parties

(xiv) curtail the grant or exercise of improper intellectual property rights over traditional knowledge and associated genetic resources, by requiring in part, as a consideration for the granting of patent rights, the patent applicants for inventions involving traditional knowledge and associated genetic resources disclose the source and country of origin of those resources, as well as evidence of prior informed consent and [that] benefit-sharing conditions have been complied with...”

“Article 1 – Protection Against Misappropriation

...2. Any acquisition, appropriation or utilization of traditional knowledge by unfair or illicit means constitutes an act of misappropriation. Misappropriation may also include deriving commercial benefit from the acquisition, appropriation or utilization of traditional knowledge when the person using that knowledge knows, or is negligent in failing to know, that it was acquired or appropriated by unfair means; and other commercial activities contrary to honest practices that gain inequitable benefit from traditional knowledge.”

(WIPO, no date given 1)

It then mentions that “legal means should be provided to prevent”:

Acquisition by/through/without –

- *“theft, bribery, coercion, fraud, trespass, breach or inducement of breach of contract, breach or inducement of breach of confidence or confidentiality, breach of fiduciary obligations or other relations of trust, deception, misrepresentation, the provision of misleading information when obtaining prior informed consent or other unfair or dishonest means”* (Article 1.3.i)
- *“violation of legal measures that require prior informed consent”* (Article 1.3.ii)
- *“false claims or assertions of ownership or control over traditional knowledge, including acquiring, claiming or asserting intellectual property rights over traditional knowledge-related subject matter when these intellectual property rights are not validly held in the light of that traditional knowledge.”* (Article 1.3.iii)
- *“just and appropriate compensation to the recognised holders of the knowledge”* (Article 1.3.iv)

(WIPO, no date given 1)

Article 2 of the substantive provisions suggests the types of legal protection which may be used including specific traditional knowledge laws, intellectual property laws, contract law, civil liability law, indigenous rights' laws, environmental laws, etc. and notes that, while such may be made available, it is not necessarily the use of exclusive property rights that need be involved. Article 6 covers fair and equitable benefit-sharing and Article 7 prior informed consent.

So far, WIPO has not developed any legally-binding provisions on intellectual property, genetic resources and traditional knowledge and folklore, but it has made and continues to make efforts to improve the recognition/disclosure of sources of genetic resources and traditional knowledge within patent applications, and to set out what actions should be considered inappropriate or misuse. The work of the IGC is supportive of indigenous rights over natural (genetic) resources and traditional knowledge.

### **Summary/Conclusions**

The international organisations responsible for regulations in the areas of access to and benefit-sharing from genetic resources, and of intellectual property rights, all demonstrate awareness, and have at least begun discussing, and in some cases taking action on, issues relating to indigenous rights. The CBD has recognised contributions and rights of indigenous and local communities from the time of its creation, and has undertaken further work on issues of access and benefit sharing, genetic resources, and traditional knowledge. However, there is so far, no legal recognition under the Convention of indigenous rights over natural resources – these rights are clearly assigned to states, and not sub-state or transboundary groups. The CBD continues to work on elaboration of an international regime on access and benefit-sharing which will most likely incorporate indigenous and local communities' rights in some form.

The FAO has over fifty years experience of work relating to plant genetic resources. Its International Treaty on Plant Genetic Resources recognises

contributions to the development of these resources by indigenous and local communities, but the rights it recognises are those of farmers. There is no reason to think that this is detrimental to indigenous rights, since it will include indigenous farmers' rights. The FAO is also working on animal genetic resources, again recognising the contributions of indigenous and local communities, alongside states' sovereign rights over natural resources.

Discussion on the intellectual property aspects of genetic resources and traditional knowledge and folklore is furthest advanced in the World Intellectual Property Organisation through its Intergovernmental Committee on IP and Genetic Resources, Traditional Knowledge and Folklore. The Committee is not currently working to create any legally-binding provisions on these issues, but has drafted substantial guidance/principles that may be used by states in considering the relationship between the IP systems and the recognition of indigenous rights over traditional knowledge and genetic resources. The Committee continues to provide a key international forum for discussion on these issues. Debate within the WTO TRIPS Council on the relationship between TRIPS, the CBD, and traditional knowledge has not progressed to this stage. There remain strong divisions between states on the issues, including on whether traditional knowledge should even be considered within the WTO. This lack of consensus need not, necessarily, preclude states from taking national action to recognise traditional knowledge within intellectual property systems, but they may be reluctant to do so before international agreement is reached (for example, because of potential costs of adapting to comply with any subsequent international standards).

Many of the concerns relating to genetic resources and traditional knowledge, their access, use and ownership are not limited to indigenous groups, and while international documents relating to indigenous rights may be useful in promoting rights over genetic resources and traditional knowledge, they are not the only motivation for such efforts.

Rights frequently come into conflict when it comes to their application, this is true even when balancing one individual right against another. Since issues

relating genetic resources, traditional knowledge and intellectual property involve state rights, individual rights, and collective rights, it is inevitable that there will be some areas of incompatibility and aspects that remain difficult to resolve. The increased international awareness of indigenous rights is a positive sign, as is the discussion of their interaction with existing international rules that are taking place in several international organisations. It is, however, unrealistic to expect that they can always be directly incorporated into these existing rules, as negotiating states will continue to balance competing rights claims.

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## SECTION III – EVENTS AND RECENT PUBLICATIONS

### ARMS CONTROL

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