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Aims of the Monitor

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

Aims of Issue 10

Issue 10 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 information provided about development provisions and activities within 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) was established to bring together, in one central location, information on all the international regulations in this area, with links provided to the official texts. A more thorough study of developments in this area is now provided through the Monitor, to inform all those working in this area of current issues and debates and of the status of the regulations. Its value lies in the range of information it provides on the regulations, its emphasis on the interconnections between the regulations, and highlighting of debates that cut across regulatory areas. It will provide a central authoritative source for anyone interested in this area.

Acknowledgements

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Structure of Issue 10

Issue 10 of the Genomics Monitor is in three sections: the first provides information on regulatory developments; the second provides information on development and the 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 29th September 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:

- World Health Assembly Resolution 62.10 Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits
- World Health Assembly Resolution 62.16 Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property
- 62nd World Health Assembly Background Document A62/40 Collaboration within the United Nations System and with other Intergovernmental Organisations
- OIE International Conference on Animal Identification and Traceability – Recommendations
- New OIE Publication – International Trade: Rights and Obligations of OIE Members
- International Plant Protection Convention – Report of the Commission for Phytosanitary Measures, 4th Session
- Food and Agriculture Organisation Document for debate prior to World Summit of Heads of State and Government on Food Security
- Report of the 32nd Session of the Codex Alimentarius Commission
- Statements and Initiatives of International Organisations Relating to Pandemic Influenza H1N1 2009
- Final Report of the Seventh Meeting of the Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing
- Report of the First Meeting of the Ad Hoc Technical Expert Group on Risk Assessment and Risk Management under the Cartagena Protocol on Biosafety
- World Intellectual Property Organisation – Simplification of the International Patent Classification System
- World Intellectual Property Organisation – Launch of Access to Research for Development and Innovation
- World Intellectual Property Organisation – Third Session of the Commission on Development and Intellectual Property

- International Treaty for Plant Genetic Resources in Food and Agriculture – Third Session of the Governing Body

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

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

REGULATION	**INTERNATIONAL ORGANISATION (WHERE APPLICABLE)**	**NUMBER OF STATES PARTIES (WHERE APPLICABLE)**
Arms Control		
1925 Geneva Protocol		132
Biological and Toxin Weapons Convention		163
Chemical Weapons Convention	Organisation for the Prohibition of Chemical Weapons	188
Convention on the Prohibition of Military or Any Other Hostile Use of Environmental Modification Techniques		73
Health and Disease Control		
International Health Regulations	World Health Organisation	193
Terrestrial Animal Health Code	Office International des Epizooties	OIE has 174 member states
Aquatic Animal Health Code	Office International des Epizooties	OIE has 174 member states
International Plant Protection Convention	Food and Agriculture Organisation	173
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 174 member states
Manual of Diagnostic Tests for	Office International des	OIE has 174 member

Aquatic Animals	Epizooties	states
Principles for the Risk Analysis of Foods Derived from Modern Biotechnology	Codex Alimentarius Commission	CAC has 182 member states plus the European Community
Guideline on Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms	Codex Alimentarius Commission	CAC has 182 member states plus the European Community
Guideline on Food Safety Assessment of Foods Derived from Recombinant-DNA Plants	Codex Alimentarius Commission	CAC has 182 member states plus the European Community
Guideline on Food Safety Assessment of Foods Derived from Recombinant-DNA Animals	Codex Alimentarius Commission	CAC has 182 member states plus the European Community
Environmental Protection		
Convention on Biodiversity	Convention on Biodiversity Secretariat	191
Cartagena Protocol on Biosafety	Convention on Biodiversity Secretariat	156
Trade		
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	141
Patent Law Treaty	World Intellectual Property Organisation	20
Budapest Treaty on the Deposit of Microorganisms for the Purpose of Patent Procedure	World Intellectual Property Organisation	72
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	120
Bonn Guidelines on Access to Genetic Resources	Convention on Biodiversity Secretariat	
Drugs Control		
Single Convention on Narcotic Drugs	International Narcotics Control Board/ Commission on Narcotic Drugs	184
Convention on Psychotropic Substances	International Narcotics Control Board/	183

	Commission on Narcotic Drugs	
Convention Against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances	International Narcotics Control Board/ Commission on Narcotic Drugs	184
World Anti-Doping Code	World Anti-Doping Association	Over 630 sporting organisations
International Convention Against Doping in Sport	United Nations Educational, Scientific and Cultural Organisation	124
Social and Ethical Impacts of Human Genetics		
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

Changes to number of states parties to the arms control regulations

There are now 188 states parties to the Chemical Weapons Convention.

3) HEALTH AND DISEASE CONTROL

World Health Assembly Resolution 62.10 Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and other Benefits, 22.05.09, (http://apps.who.int/gb/ebwha/pdf_files/A62/A62_R10-en.pdf)

The Resolution asks that the World Health Organisation's Director-General "take forward the agreed parts of the Pandemic Influenza Preparedness Framework" and "facilitate a transparent process to finalize the remaining elements, including the Standard Material Transfer Agreement (SMTA) and its annex". It is based on the World Health Assembly's consideration of documents A62/5 and A62/5Add.1.

Background document A62/5 (http://apps.who.int/gb/ebwha/pdf_files/A62/A62_5-en.pdf) gives details of various strands of World Health Organisation (WHO) activities relating to the topic of pandemic influenza preparedness. Information was provided under the following sub-headings:

- Traceability Mechanism

In response to a request of the November 2007 intergovernmental meeting on pandemic influenza preparedness, the WHO Secretariat has created an 'interim influenza virus traceability system', which has generally been well received but due to its rapid development has some technical deficiencies (point 6). The Secretariat has since initiated work to improve the system (point 9). The interim mechanism includes:

> "information on all influenza A (H5N1) viruses and clinical specimens shared by member states with WHO's Global Influenza Surveillance Network since 24 November 2007, and tracking of all influenza A(H5N1) viruses that have been selected and developed under WHO's aegis into candidate vaccine viruses using reverse genetics…[and] on analysis results and progeny materials, if any, that have been generated." (point 6).

- Advisory Group

The WHO Director-General has established an eighteen member Advisory Group "comprising internationally recognised policy-makers, public health experts and technical experts in the field of influenza" (point 10). Its role is to advise "on

strengthening the trust-based system needed to protect public health and undertake necessary monitoring and assessment of the system." (point 11).

- International Stockpile of H5N1 Influenza Vaccines

Information is provided on the 'optimal configuration' for the stockpile developed by the Director-General. She recommended a short-term stockpile at an estimated cost of $70 million (point 13).

- Strengthening Surveillance at the Animal-Human Interface

This notes continued collaboration with (among others) the FAO and OIE and the need for development of a "framework to enable a response to diseases at the human-animal interface" (point 15).

Document A62/5 Add.1 (http://apps.who.int/gb/ebwha/pdf_files/A62/A62_5Add1-en.pdf) presents in an annex the outcome document of the Advisory Group that has been developing a Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits. The framework includes: principles; objective; scope; definitions and use of terms; pandemic influenza preparedness system for sharing of H5N1 and other influenza viruses with human pandemic potential; pandemic influenza preparedness benefit sharing system; and governance and review. The document also includes drafts of: a standard material transfer agreement; terms of reference for the advisory group; terms of reference for WHO collaborating centres for influenza; and guiding principles for the development of terms of reference for WHO network laboratories for human pandemic influenza viruses.

World Health Assembly Resolution 62.16 Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, 22.05.09
(http://apps.who.int/gb/ebwha/pdf_files/A62/A62_R16-en.pdf)

This resolution adopted a final version of the Plan of Action, adding additional stakeholders and proposed timeframes. It also asks the WHO Director-General "to significantly increase support towards greater efficiency and effectiveness in the implementation of the global strategy and plan of action and prioritize concrete actions in the area of capacity-building and access;" (.5) and to review the strategy and plan in 2014, for consideration by the 68th World Health Assembly the following year (.6)

Document A62/12 – *Public health, innovation and intellectual property: global strategy and plan of action* – on which the above decision was based (http://apps.who.int/gb/ebwha/pdf_files/A62/A62_12-en.pdf) noted the importance of cooperation with other international organisations, which has included:

> "Activities in the areas of intellectual property and trade are coordinated with other relevant international intergovernmental organisations, including UNCTAD, WIPO and WTO, and aim at capacity-building, information sharing, and technical and policy support to Member States. This ongoing work is guided by the global strategy and relevant Health Assembly resolutions. A report of the Secretariat's work was also presented to WTO's Council for Trade-Related Aspects of Intellectual Property Rights. High level meetings between the Director-Generals of UNCTAD, WHO, WIPO and WTO have been held to discuss the global strategy and potential interagency collaboration to facilitate its implementation." (.8)

Addendum 1 to decision A62/16 – *Public health innovation and intellectual property: Proposed timeframes and estimated funding needs* (http://apps.who.int/gb/ebwha/pdf_files/A62/A62_16Add1-en.pdf), contains tables on Cost by Element for funding needs and on Research and Development, Innovation and Technology Transfer. The total cost by element is just over US$ 2 billion, and total cost for research, development, innovation and technology transfer US$ 147 billion. This gives a total estimate of additional funding needs from 2009-2015 of US$ 21 billion a year. WHO notes that the following should result if this funding is made available:

> "[by] 2015 a total of about 530000 research and development workers will have been trained, and there will be new and improved research infrastructure, 10 public access compound libraries, some 35 new health products (vaccines, diagnostics and medicines), extensive national research underway on diseases or conditions of importance in each country, strengthened regulatory capacity, political will supportive of innovation and access, and an improved

environment for global sharing of information and technology transfer." (.6)

WHO provides information on how this figure relates to current health R&D funding (of approximately $160 billion p.a.) and estimates that there would be a resulting increase in the proportion of R&D "directed at diseases which disproportionately affect developing countries" from 3% to 12% of the total (.8).

Addendum 2 covers Proposed Progress Indicators (http://apps.who.int/gb/ebwha/pdf_files/A62/A62_16Add2-en.pdf). Thirty-two indicators are suggested under eight elements:

1. Prioritizing research and development needs
2. Promoting research and development
3. Building and improving innovative capacity
4. Transfer of technology
5. Application and management of intellectual property to contribute to innovation and promote public health
6. Improving delivery and access
7. Promoting sustainable financing mechanisms
8. Establishing monitoring and reporting systems

And Addendum 3 suggests additional stakeholders for particular actions in the plan (http://apps.who.int/gb/ebwha/pdf_files/A62/A62_16Add3-en.pdf).

62nd World Health Assembly, Background Document A62/40 *Collaboration within the United Nations System and with other intergovernmental organisations* – Report by the Secretariat, 07.05.09
(http://apps.who.int/gb/ebwha/pdf_files/A62/A62_40-en.pdf)

In this document, WHO emphasises the importance of its interactions with the UN system. Within UN system reform efforts this particularly focuses on: "the promotion of health as a contributor to national development processes; and the increased coherence and effectiveness of the United Nations System's contribution to national development processes." (pgh.1)

OIE International Conference on Animal Identification and Traceability, Buenos Aires, 23-25 March 2009 – Recommendations, (http://www.oie.int/eng/traceability-2009/documents/recommendations/ENG-%20Recommendations.pdf)

Recommendations of the OIE (Office International des Epizooties) International Conference include that member states should, in regard to international animal identification and traceability standards of the Codex Alimentarius Commission and OIE:

- Ensure awareness and promote implementation by "all parties in the food production chain" (p.2)
- "Establish a clear regulatory framework for animal identification and traceability." (p.2)
- "address concerns that animal identification and traceability programmes may be used for the purpose of collecting or raising tax revenues." (p.3)
- "support the development of educational and scientific research programmes relevant to animal identification and traceability." (p.3) and
- "encourage the private sector to respect the official standards… and not to promote private standards that could conflict with the official standards nor to impose unjustified requirements." (p.3)

And that the OIE, with the motivation of improving systems of animal identification and traceability which contribute to animal health, disease surveillance and animal production food safety:

- Continue its work recommending appropriate programmes
- "provide appropriate capacity building" (p.3)
- "influence those responsible for making decisions on applied scientific research to develop new programmes addressing identification and traceability priorities relevant to all animal species, that are affordable , reliable and as robust as practical, including the use of new technologies." (p.4) and
- "promote the development of OIE Collaborative Centres on animal identification and traceability that could build and manage a global database on different national approaches and provide advice to developing countries in the implementation of programmes." (p.4)

New OIE publication, *International Trade: Rights and Obligations of OIE Members*, March 2009,
(http://www.oie.int/eng/normes/A_Right%20and%20obligations_March2009.pdf)

This publication outlines procedures and standards of both the OIE and the World Trade Organisation (WTO) and consists of two main parts: the first explains OIE's "informal mediation procedure for resolving trade disputes between Members" (reproduced in Annex 1 of the publication), which it notes is independent of WTO mechanisms; and the second "presents the rights and obligations of Members with reference to the conduct of international trade." Noting that "Members should base their import measures on the OIE standards. This approach provides for safe trade, the avoidance of unjustified trade barriers and a strong presumption of compliance with the WTO Agreement on the Application of Sanitary and Phytosanitary Measures." (p.1)

International Plant Protection Convention, *Report of the Commission for Phytosanitary Measures 4th Session*, May 2009,
(http://www.ippc.int/id/213049?language=en)

At the 4th session of the Commission for Phytosanitary Measures (CPM), representatives from the WTO Sanitary and Phytosanitary Committee, Convention on Biodiversity, and OIE reported on activities relevant to the International Plant Protection Convention (IPPC). The IPPC Secretariat gave a report on its cooperation with other international organisations and regional plant protection organisations.

The CPM also adopted Amendments to the Glossary of Phytosanitary Terms (ISPM No.5) along with an Appendix – Terminology of the Convention on Biological Diversity (CBD) in relation to the Glossary of Phytosanitary Terms. Appendix 3 to the Report presents the Appendix to ISPM No.5 – Terminology of the Convention on Biological Diversity in Relation to the Glossary of Phytosanitary Terms. It has a note up front that it "is for reference purposes only and is not a prescriptive part of the standard". The introduction explains that the original plan had been to add terms from the CBD directly to the glossary, but this was considered inappropriate because "the terms and definitions available from the Convention on Biological Diversity are based on concepts different from those of the IPPC, so that similar terms are given

distinctly different meanings". Instead the Appendix has been created to list relevant terms and explain "how they differ from IPPC terminology" (point 1).

The terms are listed in a table with two columns: CBD definition; and Explanation in IPPC context. Additional explanatory footnotes are provided. The terms include: 'alien species'; 'introduction'; 'invasive alien species'; 'establishment'; 'intentional introduction'; and 'risk analysis' (point 3). The table is followed by a statement and list of other concepts not specifically defined by the CBD but which "do not seem to be considered in the same light by the IPPC and the CBD, or are not distinguished by the IPPC". These include:

- "border controls
- quarantine measures
- burden of proof
- natural range or distribution
- precautionary approach
- provisional measures
- control
- statutory measures
- regulatory measures
- social impact
- economic impact." (point 4).

FAO document for debate prior to World Summit of Heads of State and Government on Food Security (16-18 November 2009, Rome)

In a press release of 31.07.09 the FAO's Director-General invites "governments around the world to participate in negotiations to agree a declaration for adoption" by the Summit (see http://www.fao.org/news/story/en/item/29219/icode/). A document – *Secretariat contribution to defining the objectives and possible decisions of the World Summit on Food Security* – has been sent to relevant ministers in FAO member states (http://www.fao.org/fileadmin/user_upload/newsroom/docs/Secretariat_Contribution_for_Summit%20.pdf). Key points in this document include:

- That the 1996 World Food Summit target of halving the number of hungry people by 2015 (to 420 million) "is unlikely to be reached" and that decisions

made at previous summits “were not followed by actions commensurate with achieving the goals set” (.2);

- The unacceptability of over 1 billion people not having “sufficient food to meet their daily basic nutritional needs” (.3);
- “The present situation has come about because, instead of tackling the structural factors of hunger, in recent decades the world has neglected agriculture in development policies. The time has come to act responsibly and address the root and multifaceted causes of food insecurity by adopting lasting political, economic, financial and technical solutions so that all people in the world can enjoy the ‘Right to Food’, which is the most fundamental of all human rights.” (.5); and
- An aim of “total eradication of hunger from the world by 2025” (.1).

The document moves on to cover the subject of World Food Security Governance. This needs to be improved, made more coherent and more efficient, and involve international coordination and cooperation among international organisations and agencies, and should cover the full food chain. More specifically there is a call for the Committee on World Food Security (CFS):

> “to be renewed and strengthened as a system of governance… to serve as the global forum for debate and convergence on the causes and consequences of food insecurity and the ways to address them. It should lay the principles for the formulation of appropriate policies and strategies and the means to monitor progress” (.10)

The preceding paragraph in the document, presents three reasons why the CFS has not so far been able to adequately fulfil its role:

> “(i) it has neither the political power nor all the scientific elements needed to tackle the short-, medium- and long-term problems of hunger in a satisfactory manner; (ii) it has no effective mechanism to follow up food security issues at national, regional and international level; and (iii) it lacks financial resources to exercise its mandate.” (.9)

It is proposed that a High-Level Panel of Experts support the CFS "to act as a scientific and technical platform for policy decisions and recommendations by supplying objective and impartial analyses." (.12) The CFS would also include an Early Reaction System for food crises and should be able to "intervene in the control of transboundary insect, animal and plant pests and diseases that threaten world food security." (.17).

Statements are also made in relation to negotiations and actions within the international trading system, for example:

> "We reiterate that a rules-based international agricultural trading system that is open, non-distorted, non-discriminatory, equitable and fair can promote agricultural and rural development and contribute to world food security. That is why we are hoping for a successful conclusion to the Doha round of trade negotiations." (.26)

> "We urge governments to refrain from using TBT type measures to block imports, particularly from developing countries, and to adhere fully to the provisions of the TBT Agreement set by the WTO. We also emphasize the need to provide developing countries with the information, training and resources needed to comply with standards and regulations governing their exports." (.31)

And concerns about the rapid expansion of biofuel production and consumption are noted:

> "We underline that biofuels should be produced and used in an environmentally sustainable manner, with consideration being given to the need to secure global food security. In addition, biofuels should, in compliance with the competition rules for international trade, be able to contribute to energy provision in countries with sufficient land and water, especially in rural areas. Considerable benefits should reach rural farmers and poor populations. We reiterate the need to develop research into better options, exchange experiences and knowledge on biofuel technologies, norms and

> regulations, and to consequently adopt the most appropriate practices on that basis." (.39)

There is also recognition of the need for capacity building for successful control of pests and diseases:

> "It is… a top priority to build capacity of national veterinary and plant health services through producer training and the development of institutions and infrastructure, as well as border control. It is also necessary to enhance the ability to respond to any movements of animal and plant pests and diseases by increasing preparedness, maintaining expertise, adopting rapid diagnostic tools and improving forecasting models." (.48)

The document also covers the topic of Climate Change.

***Report of the 32nd Session of the Codex Alimentarius Commission*, 29 June - 4 July 2009,** (http://www.codexalimentarius.net/download/report/728/al32REPe.pdf)

Agenda Item 13 dealt with 'Relations between the Codex Alimentarius Commission and other international organisations'. The observer from OIE gave a summary report of OIE activities relevant to Codex, and noted that cooperation between the two organisations "was essential given the impact of animal health at the production level on safety along the food chain." (.229). The observer expressed concern about the proliferation of private standards which "may not be based on science or risk analysis" (.230) and reported on OIE/FAO/WHO work "towards the timely establishment of a legal base for the development of join OIE-Codex standards" (.230).

There was also a report from the World Trade Organisation, relating mainly to activities of its Sanitary and Phytosanitary Committee. The Codex Commission's conclusions under an agenda item on the role of private standards (item 13.c) included that "the right forum to address the legal implications of private standards was the WTO SPS Committee" (.268) and "that a study should be conducted to analyse the role, cost and benefits of private standards in a more critical manner especially with respect to the impact on developing countries." (.270).

Statements and Initiatives of International Organisations Relating to Pandemic Influenza H1N1 2009

OIE, Editorial by the Director-General, "OIE's role in the pandemic influenza H1N1 2009", 21.07.09, (http://www.oie.int/eng/edito/en_lastedito.htm)

A key point made in this Editorial is that despite frequent references to 'swine flu', "there is no evidence that" swine or other animals are involved in the spread of pandemic influenza H1N1 2009. Unfortunately widespread use of the term 'swine flu' led to some countries placing import bans on pigs and pig products or culling pigs "without any benefit" to animal or human health.

While trade restrictions and culls are unnecessary, the OIE has asked "for enhanced surveillance among swine populations and enhanced on-farm biosecurity measures - including the protection of pigs from exposure to potentially affected people" and for states to report to OIE any incidence of the virus in animals.

Joint WTO/OIE/WHO/FAO statement on A/H1N1 influenza, 03.05.09, (http://www.oie.int/eng/press/en_090503.htm)

The joint statement included the following information:

> "In light of the spread of influenza A/H1N1, and the rising concerns about the possibility of this virus being found in pigs and the safety of pork and pork products, we stress that pork and pork products, handled in accordance with good hygienic practices recommended by the WHO, FAO, Codex Alimentarius Commission and the OIE, will not be a source of infection.
>
> To date there is no evidence that the virus is transmitted by food. There is currently therefore no justification in the OIE Terrestrial Animal Health Standards Code for the imposition of trade measures on the importation of pigs or their products. However it is important that Veterinary Authorities should collaborate with human health counterparts to monitor pig herds for any signs of unusual illness with suspected linkages to human cases of A/H1N1 influenza."

FAO Press Releases

27.04.09, “FAO acts over H1N1 human crisis”, http://www.fao.org/news/story/en/item/13002/icode/.

30.04.09, “FAO monitors A/H1N1 situation around the clock”, http://www.fao.org/news/story/en/item/19335/icode/.

04.05.09, “FAO urges countries to closely monitor H1N1 in pigs”, http://www.fao.org/news/story/en/item/19365/icode/.

FAO Agriculture and Consumer Protection Department – Animal Production and Health Division – Influenza A/H1N1 webpages, http://www.fao.org/AG/AGAInfo/programmes/en/empres/AH1N1/Background.html.

OIE press releases:

27.04.09, “A/H1N1 influenza like human illness in Mexico and the USA: OIE statement”, http://www.oie.int/eng/press/en_090427.htm.

28.04.09, “OIE position on safety of international trade of pigs and products of pig origin”, http://www.oie.int/eng/press/en_090428.htm.

30.04.09, “The OIE strongly counsels against the culling of pigs”, http://www.oie.int/eng/press/en_090430.htm.

03.05.09, “Joint WTO/OIE/WHO/FAO statement on A/H1N1 influenza”, http://www.oie.int/eng/press/en_090503.htm.

04.05.09, “OIE comments on the findings of ‘A/H1N1’ in pigs in Canada”, http://www.oie.int/eng/press/en_090504.htm.

07.05.09, “OIE reaction to trade restrictions imposed following transmission of virus ‘A/H1N1’ from humans to pigs”, http://www.oie.int/eng/press/en_090507.htm.

07.05.09, “Joint FAO/WHO/OIE statement on influenza A(H1N1) and the safety of pork”, http://www.oie.int/eng/press/en_090507_bis.htm.

11.06.09, “Novel influenza A/H1N1 pandemic: the OIE maintains its recommendations to animal health authorities worldwide”, http://www.oie.int/eng/press/en_090611.htm.

13.07.09, “Pandemic (H1N1) 2009: the OIE reiterates its recommendations to animal health authorities worldwide”, http://www.oie.int/eng/press/en_090713.htm.

WHO

WHO, 2008, *Addressing Ethical Issues in Pandemic Influenza Planning – Discussion Papers*, including:

- Equitable access to therapeutic and prophylactic measures
- Isolation, quarantine, border control and social-distancing measures
- The role and obligations of health-care workers during an outbreak of pandemic influenza
- Pandemic influenza planning and response – transnational issues for governments

http://www.who.int/eth/cds_flu_ethics_5web.pdf.

WHO, 2007, *Ethical Considerations in Developing a Public Health Response to Pandemic Influenza*, http://www.who.int/entity/csr/resources/publications/WHO_CDS_EPR_GIP_2007_2c.pdf.

WHO, June 2009, *IHR News No.7*, including “WHO response to pandemic (H1N1) 2009 virus”, http://www.who.int/ihr/ihrnews/ihrnewsissue7/en/.

WHO, latest guidance relating to H1N1 influenza, http://www.who.int/csr/disease/swineflu/en/index.html.

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

The Codex Alimentarius Commission now has 182 member states plus the European Community. The International Plant Protection Convention now has 173 contracting parties.

4) ENVIRONMENTAL PROTECTION

Final Report of the 7th Meeting of the Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing, 05.05.09, (http://www.cbd.int/doc/?meeting=abswg-07)

The meeting was attended by observers from various international organisations including: FAO, the Global Environment Fund, International Treaty on Plant Genetic Resources, United Nations Conference on Trade and Development, United Nations Environment Programme, WHO, World Intellectual Property Organisation and WTO.

Three contact groups formed at the meeting covered: (i) objective and scope; (ii) compliance; and (iii) fair and equitable benefit-sharing and access. They were expected to produce finalised working documents for the Working Group's final session. The outcome documents from the contact groups were all approved by the Working Group and have been compiled in an Annex to the Report. This will serve as "the basis for further negotiations on those issues" at the 8th and 9th Meetings of the Working Group. A substantial amount of bracketed text remains.

Report of the First Meeting of the Ad Hoc Technical Expert Group on Risk Assessment and Risk Management under the Cartagena Protocol on Biosafety, (http://www.cbd.int/doc/meetings/bs/bsrarm-01/official/bsrarm-01-03-en.pdf)

The meeting produced an advanced draft roadmap for intersessional consideration, and this is presented in Annex I to the Report (see below). Agenda item 3.2 covered 'development of further guidance materials on specific aspects of risk assessment and risk management'. The group worked through a prioritisation process for topics (results presented in Annex II to the Report) and:

> "agreed to produce modalities for development of guidance documents on risk assessment and risk management and that the following topics should be addressed first: (i) living modified crops tolerant or resistant to abiotic stress; (ii) living modified mosquitoes; and (iii) LMOs with stacked genes or traits." (.28)

And that the documents should provide: "(i) points to consider; (ii) rationales for the points to consider; and (iii) relevant bibliographies and supporting documents." (.29)

Procedures for review of the modalities before the next meeting are presented in Annex III to the Report.

Annex I – Initial Draft Roadmap for Risk Assessment

The aim of the roadmap for risk assessment "is to complement and improve the utility of Annex III of the Protocol and assist risk assessors in conducting risk assessment of living modified organisms" (p.1). It is intended to incorporate a structured, step-wise, but non-linear process, that will be transparent and accessible, and include mechanisms for stakeholder dialogue, communication between risk assessors and risk managers, and for increasing public awareness (p.1).

Points to consider in agreeing the roadmap, include its scope and context – including existing policies, regulations and international obligations – and aims and intended outcomes (pp.1-2). Five steps are suggested for the risk assessment process:

Step 1. An identification of any novel genotypic or phenotypic characteristics associated with the living modified organism that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health.

This includes consideration of the living modified organism (LMO)'s characteristics, the receiving environment's characteristics, and interactions between the LMO and receiving environment including any adverse impacts.

Step 2. An evaluation of the likelihood of adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism.

This includes consideration of the information from step 1, plus intended use and regional information, 'exposure and pathway analyses', and 'level of likelihood'.

Step 3. An evaluation of the consequences should these adverse effects be realized.

This includes consideration of 'consequences in the receiving environment', 'experience with consequences of comparable existing practices', and 'level of consequences'.

Step 4. An evaluation of the overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized.

This combines consideration of the assessments in steps 1-3 and should also include consideration of 'cumulative… and synergistic/combinatorial… effects', 'risk to biodiversity, ecosystem and human health' and an 'uncertainty analysis'.

Step 5. A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks.

Including consideration of management practices, 'methods for detection and identification of the LMO', 'methods for environmental monitoring strategies', and contingency measures.

Towards the end of the Annex, related issues are listed. These include: decision procedure; unintentional transboundary movement; capacity-building; public awareness and participation; socio-economic considerations; and liability and redress.

The Action Plan in Annex III includes details of composition of sub-working groups and bureau, a 'timeline for the tasks of the sub-working groups on the roadmap and specific topics', and a 'monitoring and review plan' which is simply that: "Based on the progress reports of the SWGs, the Bureau will review the action plan, and may adjust the activities and timelines as appropriate."

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

There are now 156 states parties to the Cartagena Protocol on Biosafety.

5) TRADE

WIPO – Simplification of International Patent Classification System, (http://www.wipo.int/pressroom/en/articles/2009/article_0008.html).

A WIPO international expert meeting on reform of the international patent classification system was held in March 2009. Simplification of the system is intended to "ensure more consistent search results and their wider use by industrial property offices" (http://www.wipo.int/pressroom/en/articles/2009/article_0008.html).

The international patent classification system (IPC) is used to classify inventions so that searches for prior art can be more focused. The system organises "information concerning inventions… into indexed, manageable structures for easy retrieval" (http://www.wipo.int/classifications/en/). It is used by "the industrial property offices of more than 100 States, four regional offices and the International Bureau of WIPO under the Patent Cooperation Treaty (PCT)" (http://www.wipo.int/classifications/ipc/en/general/preface.html).

The latest changes to the system include:

- Simplification of the structure "by abolishing the distinction between the core and advanced level from January 2011";
- Annual publication of an updated version of the IPC;
- Progressive integration of local classification systems into a unified IPC; and
- Increased use of an e-forum facility "through which experts conduct technical consultations in pursuit of greater efficiency and quality of revision work" (http://www.wipo.int/pressroom/en/articles/2009/article_0008.html).

WIPO – Launch of Access to Research for Development and Innovation (aRDi), (http://www.wipo.int/ardi/en)

WIPO will be coordinating the Access to Research for Development and Innovation (aRDi) programme launched in July 2009. The aims of the programme are to:

> "reinforce the capacity of developing countries to participate in the global knowledge economy; and support researchers in developing countries in creating and developing new solutions to technical

challenges faced on local and global level" (http://www.wipo.int/ardi/en)

And this will be done by: "improving access to scholarly literature from diverse fields of science and technology" (http://www.wipo.int/ardi/en). It currently involves collaboration with twelve publishers and provides "access to over 50 journals for 107 developing countries." This is either done free-of-charge or on a low-cost basis. FAO, WHO, the UN Environment Programme and the International Association of Scientific, Technical and Medical Publishers are partners in the WIPO programme. There are some similar programmes already established, these include:

- HINARI (Health Internetwork Access to Research Initiative) – http://www.who.int/hinari/en/;
- AGORA (Access to Global Online Research in Agriculture) – http://www.aginternetwork.org/en/; and
- OARE (Online Access to Research in the Environment) – http://www.oaresciences.org/en/.

WIPO – 3rd Session of the Commission on Development and Intellectual Property

Several documents are available from the meeting, including:

- General Report, http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_3/cdip_3_9_prov.pdf.
- Progress Report on Recommendations for Immediate Implementation, http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_3/cdip_3_5.pdf.
- Thematic Projects, http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_3/cdip_3_4.pdf.
- Recommendations 12, 20, 22 and 23, http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_3/cdip_3_3.pdf.
- Recommendation 6 (Roster of Consultants), http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_3/cdip_3_2.pdf.
- Project Documents for Implementation of Recommendations 2, 5, 8, 9 and 10, http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_3/cdip_3_inf_2.pdf.
- Proposed Methodology for Implementation of the Development Agenda Recommendations, http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_3/cdip_3_inf_1.pdf.

The Progress Report on Recommendations for Immediate Implementation covers the period 2007-2008 and provides information on 'implementation strategies', 'examples of activities', and 'progress/achievements' for nineteen of the forty-five recommendations of WIPO's Development Agenda. (The full list of recommendations can be found at: http://www.wipo.int/ip-development/en/agenda/recommendations.html.)

In the Thematic Projects document the Secretariat outlines a proposal for a thematic approach that might be taken to improve the effectiveness and coherence of implementation of the recommendations, addressing concerns of delegations "about the lack of information on clear objectives, suggested timeframes and monitoring and evaluation mechanisms" for implementation activities." (.1).

The Secretariat has begun this process by outlining four thematic projects:

- Intellectual Property and the Public Domain: Development Agenda Recommendations 16 and 20;
- Intellectual Property and Competition Policy: Development Agenda Recommendations 7, 23, and 32;
- Intellectual Property, Information and Communication Technologies and the Digital Divide: Development Agenda Recommendations 19, 24, and 27; and
- Developing Tools for Access to Patent Information: Development Agenda Recommendations 19, 30 and 31.

If delegations approve the thematic approach the Secretariat intends to submit further thematic projects.

For each of the thematic projects an Annex is provided giving information on *inter alia*:

- Project code and title
- Development agenda recommendations
- Budget
- Duration and timeline
- Key WIPO sectors involved and links to WIPO programmes
- Description of the project, including delivery strategy
- Review and evaluation

The 'Project Documents for Implementation of Recommendations 2, 5, 8, 9 and 10' has annexes providing information including on budget, duration, objectives, and delivery strategy for nine projects relating to the implementation of those recommendations. The projects are:

- Conference on Mobilizing Resources for Development;
- Intellectual Property Technical Assistance Database;
- Specialized Databases' Access and Support;
- IP Development Matchmaking Database;
- A Pilot Project for the Establishment of "Start-Up" National IP Academies;
- Smart IP Institutions Project;
- Innovation and Technology Transfer Support Structure for National Institutions;
- Strengthening the Capacity of National IP Governmental and Stakeholder Institutions to Manage, Monitor and Promote Creative Industries, and to Enhance the Performance and Network of Copyright Collective Management Organizations; and
- Improvement of National, Sub-Regional and Regional IP Institutional and User Capacity.

International Treaty on Plant Genetic Resources for Food and Agriculture - 3rd Session of the Governing Body, (http://www.planttreaty.org/meetings/gb3_en.htm)

The Report of the 3rd Session of the ITPGR Governing Body is now available at ftp://ftp.fao.org/ag/agp/planttreaty/gb3/gb3repe.pdf. A summary of the meeting provided by the International Institute for Sustainable Development states that:

> "Delegates agreed to: a set of resolutions for implementation of the funding strategy, including a target of US$ 116 million between July 2009 and December 2014; a resolution on implementation of the multilateral system, including setting up an intersessional advisory committee on implementation issues; a resolution on farmers' rights; and procedures for the Third Party Beneficiary… and established an intersessional working group to finalize the procedures and operational mechanisms to promote compliance

and address issues of non-compliance."
(http://www.iisd.ca/biodiv/itpgrgb3/).

Among other actions of the 3rd Session the following resolutions were adopted:

- Resolution 2/2009 – Adoption of procedures and operational mechanisms to promote compliance and to address issues of non-compliance

This convenes an Ad Hoc Working Group to "negotiate and finalise the procedures and operational mechanisms to promote compliance and address issues of non-compliance" for the consideration of the 4th Session of the Governing Body (.2). The Group will meet twice before the 4th Session (.5). It will base its work on *Draft Procedures and Operational Mechanisms to Promote Compliance and Address Issues of Non-Compliance* published in an annex to the Resolution.

- Resolution 3/2009 – Implementation of the Funding Strategy of the International Treaty

The Governing Body agreed that the *Strategic Plan for the Implementation of the Benefit-Sharing Fund of the Funding Strategy* developed by the Ad Hoc Committee on the Funding Strategy "will constitute a basis for the implementation of the Benefit-Sharing Fund" (.2). A target for funding of priority activities of $116 million between July 2009 and December 2014 was set. The Governing Body also adopted Annex 4 to the Funding Strategy – Information and Reporting Requirements Under the Funding Strategy – this covers: periodicity of information and reporting; and information and reporting on resources under and not under the direct control of the Governing Body (Annex 4 is reproduced as an annex to Resolution 3/2009).

- Resolution 4/2009 – The Multilateral System of Access and Benefit-Sharing

This Resolution notes the importance of documenting plant genetic resources in the Multilateral System, of information being provided on use of the Standard Material Transfer Agreement, and of developing countries being supported in both these tasks. It also notes the "urgency of obtaining appropriate information it needs to assess progress in the inclusion in the Multilateral System of plant genetic resources for food and agriculture held by natural and legal persons within the jurisdiction of Contracting Parties" (.8).

- Resolution 5/2009 – Procedures for Third Party Beneficiary

The FAO will act as a third party beneficiary for Standard Material Transfer Agreements "under the direction of the Governing Body" (Article 1.1). It will have a dispute settlement role relating to possible non-compliance. A three stage procedure is outlined: the first stage is 'amicable dispute settlement' involving negotiation between parties (Article 5); the second stage is mediation, which may be used if, after six months of negotiation the issue has not been resolved (Article 6); and the third stage, for use if mediation fails, is arbitration (Article 7).

- Resolution 6/2009 – Implementation of Article 9, *Farmers' Rights*

This requests information from Contracting Parties and collected by the Governing Body on experience with implementation of Article 9, and that Contracting Parties review their national implementation measures where necessary.

- Resolution 7/2009 – Cooperation with the Commission on Genetic Resources for Food and Agriculture

The Resolution encourages the continuation of this cooperative relationship, particularly in the areas of:
- development of an updated *State of the World's Plant Genetic Resources for Food and Agriculture*
- Global Plan of Action for the Conservation and Sustainable Use of Plant Genetic Resources for Food and Agriculture
- International Plant Genetic Resources Networks
- Genebank Standards
- Global Information System on Plant Genetic Resources for Food and Agriculture
- Funding Strategy

- Resolution 8/2009 – Cooperation with Other International Organisations, including Agreements between the Governing Body and the International Agricultural Research Centres of the Consultative Group on International Agricultural Research and other Relevant International Institutions

This resolution asks the Secretariat to continue cooperation with other international organisations, including, in particular: with the Convention on Biodiversity Secretariat including in its work negotiating an International Regime on Access and Benefit-Sharing; and participating in relevant meetings of the World Intellectual Property Organisation, International Union for the Protection of New Varieties of Plants, and World Health Organisation.

It was agreed that the 4th Session of the Governing Body will be hosted by Indonesia in 2011 (pgh.60 of the Report).

A working document for the meeting – *Progress Report on Partnerships and Synergies and Cooperation with Other Organisations* (ftp://ftp.fao.org/ag/agp/planttreaty/gb3/gb3w18e.pdf) gives – "an overview of the different partnerships the Treaty has established through its Secretariat and the mechanisms and frameworks through which it has facilitated and maintained them" (.6).

For example, the Secretary of ITPGR attended sessions 5 and 6 of the Convention on Biodiversity's Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing; sessions 12 and 13 of its Subsidiary Body on Scientific, Technical and Technological Advice; and its Ninth Conference of the Parties (.13 and .15). The International Regime on Access and Benefit Sharing which is currently being negotiated under the auspices of the CBD references ITPGR, and the Progress Report notes that the regime "may have significant implications for the operation of the Multilateral System in the future" (.15). ITPGR's Secretary has also participated in CBD meetings relating to negotiation of the regime (.17).

Representatives from ITPGR also attended the 12th and 13th Sessions of the World Intellectual Property Organisation's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC). The ITPGR Secretariat has provided information to WHO "on the experiences, functioning and practical operation of the Multilateral System of the Treaty, in light of recent work of their own on virus-sharing and benefit-sharing" (.30); kept track of relevant developments within discussion of the TRIPS Council of the WTO (.34); and has initiated work on potential collaboration with the Secretariat of the United Nations Framework Convention on Climate Change (.35).

It is believed that such cooperative activities are:

> "fundamental for,
> - recognition of the Treaty in other multilateral arenas as a new instrument that plays an important role regarding plant genetic resources for food and agriculture;
> - the establishment of the Treaty as a model or reference point for other sectors in order to achieve coherent policies at a global level;
> - global policy coherence in genetic resources policy and the policy environment of the Treaty;
> - the political momentum of the Treaty within the field of international genetic resources policy making." (.36)

The ITPGR Secretariat also collaborates with other groups within the Food and Agriculture Organisation.

A Working Document – *Review of the Implementation of the Multilateral System* was provided for the Governing Body to consider, ftp://ftp.fao.org/ag/agp/planttreaty/gb3/gb3w13e.pdf. It concluded that the System can be considered to be a success "in that over 100,000 accessions are being exchanged annually, through the Standard Material Transfer Agreement" but notes that most of this activity relates to "the collections of the International Agricultural Research Centres of the Consultative Group on International Agricultural Research and other international institutions, and of established genebanks in developed countries" (.53) and that "there is a major information deficit, of all types and at all levels, and that improving all aspects of the information base is an immediate priority" (.55).

This information deficit has arisen partly because "Many Contracting Parties appear to have not yet taken the steps necessary to document their relevant plant genetic resources, and to facilitate access to them." And it has been noted that support is particularly needed to assist developing countries to undertake these actions. Further support in terms of technical and legal advice also appears to be required (.56). There is also too little information available for the Governing Body to effectively monitor implementation of the Multilateral System or "undertake the reviews foreseen in the Treaty" (.57).

The Report therefore states the following as key short-term priorities:

- "to promote the complete documentation of Materials 'in' the Multilateral System";
- "to document exchange under the Multilateral System through SMTA operations"; and
- "to assist users… to resolve the legal and technical uncertainties that are impeding the inclusion of plant genetic resources in the Multilateral System." (.58)

Changes in the number of states parties to the trade regulations

The Patent Cooperation Treaty now has 141 states parties and the Patent Law Treaty now has 20. The International Treaty on Plant Genetic Resources now has 120 states parties.

6) DRUGS CONTROL

Changes to the number of parties to the drugs control regulations

There are now 184 states parties to the UN Convention on Narcotic Drugs and Convention Against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances. The International Convention Against Doping in Sport has 124 states parties.

SECTION II: DEVELOPMENT IN THE INTERNATIONAL REGULATION OF BIOTECHNOLOGY

Introduction

Science and technology have a vital role to play in development and biotechnology is a key field in this regard. Many of the international regulations relevant to biotechnology contain development related provisions, and information on these is given below. Generally these provisions relate to technical and financial assistance, technology transfer and capacity-building. Information is also provided on development related activities of international organisations associated with the regulations. (Summary information on each of the regulations can be found in Issue 1 of the *Genomics Monitor* - http://www.brad.ac.uk/acad/sbtwc/gateway/monitor/genomicsmonitorissue1.pdf.)

Of the thirty-seven regulations listed in the highlights section above, the following contain no clauses that are specifically development related:

- 1925 Geneva Protocol;
- Terrestrial Animal Health Code;
- Aquatic Animal Health Code;
- Manual of Diagnostic Tests and Vaccines for Terrestrial Animals;
- Manual of Diagnostic Tests for Aquatic Animals;
- Guidance on Regulations for the Transport of Infectious Substances;
- Laboratory Biosafety Manual;
- Biorisk Management: Laboratory Biosecurity Guidance;
- the three Codex Guidelines on Food Safety Assessment;
- Patent Law Treaty,
- Budapest Treaty on the Deposit of Microorganisms for the Purpose of Patent Procedure;
- International Convention for the Protection of New Varieties of Plants;
- Convention on Psychotropic Substances;
- World Anti-Doping Code; and
- International Convention Against Doping in Sport.

The information provided below is organised by issue area (arms control, health and disease control, environmental protection, trade, drugs control, and social and ethical

impacts), however some of the development related initiatives cut across these issue areas. Because the majority of resources consulted are available online, citations are given with the text, rather than as in a list of references.

Arms Control

The Biological Weapons Convention
(http://www.opbw.org/convention/documents/btwctext.pdf)

In Article X of the Biological Weapons Convention (BWC) a general commitment is made by states parties to: "facilitate, and have the right to participate in, the fullest possible exchange of equipment, materials and scientific and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes" (Article X.1)

And states parties are instructed that implementation of the Convention should not hinder development or peaceful cooperation activities in relevant scientific fields:

> "This Convention shall be implemented in a manner designed to avoid hampering the economic or technological development of States Parties to the Convention or international cooperation in the field of peaceful bacteriological (biological) activities, including the international exchange of bacteriological (biological) and toxins and equipment for the processing, use or production of bacteriological (biological) agents and toxins for peaceful purposes in accordance with the provisions of the Convention." (Article X.2)

The Review Conferences of the Convention have repeatedly emphasised the importance of this article in promoting economic and social development, requesting increases in international cooperative activities, while noting concern about: "the increasing gap between the developed and the developing countries in the field of biotechnology, genetic engineering, microbiology and other related areas" (Final Declaration of the Second Review Conference, p.8; Final Declaration of the Third Review Conference, p.12; Final Declaration of the Fourth Review Conference, p.11).

The 2009 Intersessional* Meeting of Experts (in August) and Meeting of States Parties (in December) aim to:

> "discuss, and promote common understanding and effective action on 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."
> (http://www.unog.ch/80256EE600585943/(httpPages)/F7C77C704B89856AC12572BC003225AC?OpenDocument)

The BWC's Implementation Support Unit has provided background documents for this meeting relating to capacity building in the above areas, which provide relevant information on development activities. These include:

- Recent Developments in Intergovernmental Organizations Relevant to Disease Surveillance, Detection, Diagnosis and Containment;
- Recent International, Regional and Non-Governmental Developments Relevant to Disease Surveillance, Detection, Diagnosis and Containment; and
- Previous Agreements and Understandings Under the Convention Relevant to Capacity Building in the Fields of Disease Surveillance, Detection, Diagnosis and Containment

These documents are available through: http://www.unog.ch/80256EE600585943/(httpPages)/F1CD974A1FDE4794C125731A0037D96D?OpenDocument.

Chemical Weapons Convention

The Chemical Weapons Convention (CWC) contains similar clauses relating to development. These include:

* This is part of the second series (2007-2010) of meetings that form an intersessional process at which experts and states parties meet annually to discuss certain issues related to the Convention.

> "The provisions of this Convention shall be implemented in a manner which avoids hampering the economic or technological development of States Parties, and international cooperation in the field of chemical activities for purposes not prohibited under this Convention including the international exchange of scientific and technical information and chemicals and equipment for the production, processing or use of chemicals for purposes not prohibited under this Convention." (Article XI.1)
>
> "States Parties shall…
> (b) Undertake to facilitate, and have the right to participate in, the fullest possible exchange of chemicals, equipment and scientific and technical information relating to the development and application of chemistry for purposes not prohibited under this Convention;
> (c) Not maintain among themselves any restrictions, including those in any international agreements, incompatible with the obligations undertaken under this Convention, which would restrict or impede trade and the development and promotion of scientific and technological knowledge in the field of chemistry for industrial, agricultural, research, medical, pharmaceutical or other peaceful purposes;" (Article XI.2)

The Organisation for the Prohibition of Chemical Weapons, which serves the Convention, undertakes various activities relating to development. These include provision of training courses and support programmes, such as:

- Analytical Skills Development Course, http://www.opcw.org/our-work/international-cooperation/analytical-skills-development-course/, for which funding for some developing country participants is provided, and which aims to enhance national capacities in analytical chemistry and good laboratory practice;
- Conference Support Programme, http://www.opcw.org/our-work/international-cooperation/conference-support-programme/, "aimed at providing financial support for organising conferences, workshops and seminars on special topics relevant to the Chemical Weapons Convention", and enabling citizens from developing States Parties to participate in them;
- Research Projects Support Programme, http://www.opcw.org/our-work/interantional-cooperation/research-projects-support-programme/, which "supports small-scale research in Member States with developing economies

for the development and promotion of scientific and technical knowledge in the field of chemistry for industrial, agricultural, research, medical, pharmaceutical or other peaceful purposes which are relevant to the Chemical Weapons Convention" and

- Equipment Exchange Programme, http://www.opcw.org/our-work/international-cooperation/equipment-exchange-programme/, "supports the voluntary transfer of laboratory equipment… from institutions in developed countries to institutions in other countries" and "may also support the training of technicians to maintain such equipment".

EnMod Convention

The EnMod Convention (Convention on the Prohibition of Military or Any Other Hostile Use of Environmental Modification Techniques) uses very similar language to the BWC and CWC in Article III.2:

> "The States Parties to this Convention undertake to facilitate, and have the right to participate in, the fullest possible exchange of scientific and technological information on the use of environmental modification techniques for peaceful purposes. States Parties in a position to do so shall contribute, alone or together with other States or international organisations, to international economic and scientific cooperation in the preservation, improvement, and peaceful utilization of the environment, with due consideration for the needs of the developing areas of the world."

It has no associated international organisation and there has not been a review conference for the Convention since 1992.

Health and Disease Control

Human Health

The International Health Regulations

Article 44 of the International Health Regulations (IHR) covers collaboration and assistance. States Parties agree to collaborate in:

> "(a) the detection and assessment of, and response to, events as provided under these Regulations;
> (b) the provision or facilitation of technical cooperation and logistical support, particularly in the development, strengthening and maintenance of the public health capacities required under these Regulations;
> (c) the mobilization of financial resources to facilitate implementation of their obligations under these Regulations; and
> (d) the formulation of proposed laws and other legal and administrative provisions for the implementation of these Regulations."

And the World Health Organisation (WHO, which oversees the IHR) agrees to collaborate, inter alia, in: "the mobilization of financial resources to support developing countries in building, strengthening and maintaining the capacities provided for in Annex I". (The capacities in Annex I relate to surveillance and response to disease outbreaks.)

World Health Organisation

"unequal development in different countries in the promotion of health and control of disease… is a common danger" (Preamble of the WHO Constitution)

In addition to its specific responsibilities under the IHR (mentioned above), the WHO views development to be of central concern to its work on health, because of the significant interactions between the two areas. It recognises both "the impact of better health on development and poverty reduction" and "the impact of development policies on the achievement of health goals" (WHO, Health and Development, http://www.who.int/hdp/en/).

In relation to health and development, WHO produces publications and reports, runs training courses, assists in policy design and implementation, produces recommendations on best practice, and advises on the inclusion of health in poverty reduction strategies (see http://www.who.int/hdp/poverty/en). WHO also works to promote more and better aid for developing countries, for example through development of best practice principles for global health partnerships (see http://www.who.int/hdp/aid/en/).

In 2005 WHO set up a Commission on Social Determinants of Health to "analyse the social causes of ill health… and actively promote new policies to address them" (http://www.who.int/about/brochure_en.pdf). It produced its final report *Closing the Gap in a Generation: Health Equity Through Action on the Social Determinants of Health in 2008*, which is available through http://www.who.int/social_determinants/thecommission/finalreport/en/index.html.

The WHO's Laboratory Biosafety Manual, Biorisk Management: Laboratory Biosecurity Guidance, and Guidance on Regulations for the Safe Transport of Infectious Substances do not contain development related provisions, but the general work of WHO on development will sometimes be of relevance to them.

Animal Health

Office International des Epizooties/World Animal Health Organisation (OIE)

"The OIE considers Veterinary Services to be a Global Public Good and… a public investment priority" (http://www.oie.int/eng/oie/organisation/en_vet_serv.htm).

The standards of the OIE (the Terrestrial and Aquatic Animal Health Codes, and Terrestrial and Aquatic Manuals) do not contain specific development-related provisions, but the OIE is concerned with the subject. One of the organisation's objectives is "international solidarity", under which it provides technical support and expertise to developing countries in the area of animal disease control (http://www.oie.int/eng/OIE/en_objectifs.htm#3). A 2008 editorial by the OIE's Director-General, examined the links between food security (an important contributor to development) and animal disease control (http://www.oie.int/eng/edito/en_edito_sept08.htm), noting that "access to an adequate supply of good quality food is not just an agricultural problem; it is also a worldwide public health problem and must also be approached from this point of view". The need for cooperation with other international organisations in this endeavour was recognised – particularly with the WHO and Food and Agriculture Organisation – and it called for greater private and public sector involvement in "research programmes to develop the tools needed to reduce losses from… various animal diseases" (http://www.oie.int/eng/edito/en_edito_sept08.htm).

An earlier editorial (September 2002) examined the topic of the OIE, science and international solidarity (http://www.oie.int/eng/edito/en_edito_sept02.htm). It mentioned North-South collaboration facilitated by its network of Collaborating Centres and Reference Laboratories including "access to the best human resources in the field…the best diagnostic technologies, standard reagents, and training systems in the form of workshops, seminars and conferences".

Many of OIE's capacity-building activities are implemented by its regional representatives (one each in Africa, the Americas, Asia-Pacific, Eastern Europe and the Middle East). Activities can thus be better tailored to local or regional needs (http://www.oie.int/eng/oie/organisation/en_vet_rr.htm). The representatives provide, inter alia, information, advice and support on:

- "rights and obligations";
- "the structure and quality of National Veterinary Services";
- "implementation of animal health standards";
- "disease notification, surveillance and control"; and
- "vaccination, food safety, environmental protection" (http://www.oie.int/eng/oie/organisation/en_vet_rr.htm).

OIE has also organised capacity-building projects through the Standards and Trade Development Facility. These have included work on training of trainers, evaluation of compliance of veterinary services with OIE quality standards, and "strengthening of Veterinary Services in Africa" (http://www.oie.int/eng/oie/organisation/en_vet_serv.htm). The latter is part of the World Bank's ALive Project –which "aims to map existing programs" on African livestock, "fill gaps between them, and initiate others focused on poverty reduction, economic growth, regional and international market access, and sustainable institutions including veterinary services" (http://www.oie.int/eng/oie/organisation/en_vet_alive.htm). FAO is also a partner in the project. Further information on ALive can be found at http://www.alive-online.org.

Plant Health

International Plant Protection Convention

Article XX of the International Plant Protection Convention (IPPC) covers technical assistance. Parties "agree to promote the provision of technical assistance to

contracting parties, especially those that are developing country parties, either bilaterally or through the appropriate international organizations, with the objective of facilitating the implementation of this Convention."

Food and Agriculture Organisation

The IPPC is a treaty of the Food and Agriculture Organisation (FAO). The main aim of the FAO is "achieving food security for all" (http://www.fao.org/about/mission-gov/en/). According to FAO's constitution, this involves:

- "raising levels of nutrition and standards of living…
- securing improvements in the efficiency of the production and distribution of all food and agricultural products;
- bettering the condition of rural populations;
- and thus contributing towards an expanding world economy and ensuring humanity's freedom from hunger." (http://www.fao.org/docrep/010/k1713e/k1713e01.htm#1)

FAO has a Technical Cooperation Department which "combines the expertise, the funding and the development partners to produce sustainable results in the fight against hunger" and "implements and coordinates FAO's field activities" (http://www.fao.org/tc/). The Technical Cooperation Department covers such areas as:

- policy assistance;
- emergency response, relief and rehabilitation;
- promotion of increased agricultural investment;
- food security programmes; and
- sharing of technical knowledge.

(http://www.fao.org/tc/ and http://www.fao.org/tc/about_en.asp).

FAO's Technical Cooperation Department also provides online policy making resources through EASYPol (http://www.fao.org/tc/easypol/output/) and runs a Project on Negotiation for Agriculture which "helps developing countries strengthen their technical negotiation skills in agricultural policies and multilateral trade negotiations through capacity-building workshops and training materials" (http://www.fao.org/tc/tca/). More information on the negotiation project can be found at http://www.fao.org/tc/tca/negotiation/index.asp?lang=en.

Emergency relief and rehabilitation efforts should reduce the detrimental impacts of food crises on long-term development and food security. FAO has several mechanisms/tools in this area, including for: information gathering and assessment; classification of crises; response planning; distribution of materials such as seeds, livestock and tools; provision of training in farming and animal health; management of animal health emergencies; and evaluation and feedback on past efforts. Further information on these can be found through: http://www.fao.org/emergencies/home0/emergency-relief-and-rehabilitation/post-disaster-needs-assessment-tools/en/.

Food Safety

Codex Alimentarius Commission

The three Codex guidelines relating to food safety assessment of R-DNA foods[†] do not contain specific development-related provisions but all refer to supporting the Codex Alimentarius Commission's Principles for the Risk Analysis of Food Derived from Modern Biotechnology, which do. Point 27 of the Principles reads:

> "Efforts should be made to improve the capability of regulatory authorities, particularly those of developing countries, to assess, manage and communicate risks, including enforcement, associated with foods derived from modern biotechnology or to interpret assessments undertaken by other authorities or recognised expert bodies, including access to analytical technology. In addition, capacity building for developing countries either through bilateral arrangements or with assistance of international organizations should be directed toward effective application of these principles."

A 2002 evaluation of the Codex process, found that there was a need for both "increased inclusiveness of developing member countries in the Codex standard development process" and "more effective capacity-building for development of national food control systems" (CAC, 2006, p.4). This Guide mentions the Standards

[†] Guideline on Food Safety Assessment of Foods Produced Using R-DNA Microorganisms; Guideline on Food Safety Assessment of Foods Derived from R-DNA Plants; and Guideline on Food Safety Assessment of Foods Derived from R-DNA Animals.

and Trade Development Facility as a source of technical assistance on sanitary and phytosanitary standards (CAC, 2006, p.34). There is also a joint FAO/WHO[‡] trust fund for participation in Codex, which was launched in 2003 and aims to assist:

> "regulators and food experts from all areas of the world to participate in international standard-setting work in the framework of Codex; and enhancing their capacity to help establish effective food safety and quality standards and fair practices in the food trade, both in the framework of the Codex Alimentarius and in their own countries."

The WHO provides detailed information about the trust fund, including application procedures, and this can be found through the following webpage - http://www.who.int/foodsafety/codex/trustfund/en/index.html.

FAO and WHO both generally grant technical assistance for participation in and implementation of food safety standards and measures (CAC, 2006, pp.33-34). There are also online sources of information on international standards relating to food safety including the International Portal on Food Safety, Animal and Plant Health (http://www.ipfsaph.org), which is a collaboration between several international organisations and the International Food Safety Authorities Network (http://www.who.int/foodsafety/fs_management/infosan/en/), a network of over 177 authorities, managed by the WHO in collaboration with FAO (CAC, 2006, p.35). It "disseminates important global food safety information, and improves national and international collaboration" (http://www.who.int/foodsafety/fs_management/infosan/en/).

Environmental Protection

Convention on Biodiversity

"The extent to which developing country Parties will effectively implement their commitments under this Convention will depend on the effective implementation by developed country Parties of their commitments under this Convention related to financial resources and transfer of technology." (Article 20.4)

[‡] The Codex Alimentarius Commission is a joint body of FAO and WHO.

The Convention on Biodiversity (CBD) contains several detailed provisions relating to development, these include:

- Article 16. Access to and Transfer of Technology

Which is to take place "under fair and most favourable terms" to developing countries (.2) and may involve joint work with the private sector (.4).

- Article 18. Technical and Scientific Cooperation

Technical and scientific cooperation is to be promoted with developing countries and "special attention should be given to the development and strengthening of national capabilities, by means of human resources development and institution building" (.2)

- Article 20. Financial Resources

Developed countries agree to "provide new and additional financial resources to enable developing country Parties to meet the agreed full and incremental costs to them of implementing measures which fulfil the obligations of this Convention and to benefit from its provisions." (.2).

- Article 21. Financial Mechanism

A financial mechanism is to be established to provide funds to developing countries for the purposes of the Convention.

Cartagena Protocol on Biosafety

Likewise, the Cartagena Protocol on Biosafety to the Convention on Biodiversity contains detailed development provisions, including:

- Article 22. Capacity-Building

Parties commit to "cooperate in the development and/or strengthening of human resources and institutional capacities in biosafety… in developing country Parties" (.1). This cooperation is expected to "include scientific and technical training in the proper and safe management of biotechnology and in the use of risk assessment and risk management for biosafety, and the enhancement of technological and institutional capacities in biosafety" (.2).

- Article 28. Financial Mechanism and Resources

This incorporates the financial mechanism of the CBD.

The Protocol also has a Biosafety Clearing House which facilitates exchange of information on living modified organisms.

Convention on Biodiversity Secretariat

"Biodiversity and development are closely linked: biodiversity sustains development and development has an impact on biodiversity, either positive or negative" (http://www.cbd.int/development)

The CBD Secretariat oversees both the Convention and the Protocol; the CBD's Conference of the Parties also serves as the Meeting of the Parties to the Protocol. The Secretariat gives prominent recognition to the importance of biodiversity to development.

The 9th Conference of the Parties to the Convention established a Biodiversity for Development Initiative. It is overseen by the CBD's Implementation and Technical Support Division. The Initiative's aims include:
The Initiative has several more specific objectives, including the following activities:

"*At the Global level*

- Establishment of a professional network;
- Organization of international workshops;
- Development of partnerships;
- Elaboration of guidelines/guidance;
- Development of communication tools: newsletters, leaflets, exhibits, etc.

At the Regional level

- Establishment of partnerships with regional organizations;
- Organization and assistance with regional workshops;
- Strengthening linkages with the United Nations Resource Centre (UNRESC), United Nations Development Programme/Global Environment Facility (UNDP/GEF), UNEP and IUCN Regional Offices;
- Promoting South-South Cooperation (SSC): exchange of information on biodiversity issues, dissemination of lessons learned (good practices, case studies), and organization of workshops;
- Development of joint information material.

At National and local levels

- Elaboration of training modules focusing on selected economic development sectors;
- Collection of case studies and constitution of a database on good practices and lessons learned;
- Review of national cross-sectoral policies;
- Dissemination of information and capacity-building material to CBD NFPs [national focal points], sectoral ministries and NGOs."

(http://www.cbd.int/development/programme/workplan.shtml - N.B. the text on this webpage has been altered since it was accessed in early August)

Information on training and guidelines being produced by the Initiative can be found at http://www.cbd.int/development/implementation/training.shtml.

In its background information on the Biodiversity for Development Initiative, the CBD Secretariat notes that:

> "efforts to link biodiversity and development are facing a number of obstacles, including: a lack of information on these interlinkages at the international, regional and national levels; insufficient biodiversity mainstreaming within development strategies; and a weak framework for scaling-up good practices and lessons learned" (http://www.cbd.int/development/programme/background.shtml)

The 9th Conference of the Parties (COP-9) adopted several other decisions of direct relevance to biodiversity for development, including references to the links between biodiversity, poverty and the millennium development goals (http://www.cbd.int/development/programme/copdecisions.shtml - N.B. the text on this webpage has changed since it was viewed in early August). More detail is given on this in the September 2008 special issue of the *Biodiversity for Development Newsletter* (see http://www.cbd.int/development/newsletters/newsletter-bd-03-en.pdf). The Secretariat has also provided a document that gives an overview of COP-9 decisions referring to poverty alleviation and the millennium development goals - https://www.cbd.int/doc/poverty/cop9-decisions-en.doc.

The Secretariat is also "developing a number of information documents focusing on the role biodiversity can play in relation to poverty alleviation and development", these are available through http://www.cbd.int/development/implementation/tools.shtml. And has set up "an online database of case studies demonstrating the links between biodiversity, poverty alleviation and economic development" – http://www.cbd.int/development/casestudies/.

Capacity building is viewed as essential to the effective implementation of the Cartagena Protocol– "Parties need appropriate institutional mechanisms and infrastructure, well-trained human resources, adequate funding as well as easy access to relevant information." (http://www.cbd.int/biosafety/issues/cap-build.shtml). The first Conference of the Parties serving as the Meeting of the Parties to the Protocol (COP-MOP-1) adopted an *Action Plan for Building Capacities for the Effective Implementation of the Protocol*, which is available at http://bch.cbd.int/doc/ACTION%20PLAN-CPB-EN.doc. Further information on the action plan is available at http://www.cbd.int/biosafety/issues/actionplan.shtml.

A revised Action Plan was adopted by COP-MOP-3, this is available as an Annex to Decision BS-III/3 - http://www.cbd.int/decision/mop/?id=11059. COP-MOP-4 "approved a revised set of indicators for monitoring the Action Plan" and "adopted measures to promote long-term biosafety education and training" (http://www.cbd.int/biosafety/issues/cap-build.shtml). Further details can be found in Decision BS-IV/3 - http://www.cbd.int/decision/mop/?id=11682.

Trade

Agreement on the Application of Sanitary and Phytosanitary Measures

Two articles of the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) have particular relevance to development. Article 9 relates to technical assistance, which Member States are to facilitate, particularly to developing countries. The Article suggests that this assistance may include "advice, credits, donations and grants, including for the purpose of seeking technical expertise, training and equipment to allow such countries to adjust to, and comply

with, sanitary or phytosanitary measures necessary to achieve the appropriate level of sanitary or phytosanitary protection in their export markets" (.1).

Article 10 covers Special and Differential Treatment. Member states are to take needs of developing countries into account "in the preparation and application of sanitary or phytosanitary measures" (.1), including possible use of "longer time-frames for compliance" (.2). The Article also gives the SPS Committee[§] the ability to grant developing country Members "specified, time-limited exceptions in whole or in part from obligations" under the Agreement, in view of "their financial, trade and development needs" (.3)

Because the SPS Agreement refers to standards of other international organisations (the CAC, OIE, and IPPC Secretariat) as an acceptable basis for SPS measures, Article 10 also asks member states to "encourage and facilitate the active participation of developing country Members in the relevant international organisations" (.4).

Agreement on Technical Barriers to Trade

The Agreement on Technical Barriers to Trade (TBT Agreement) also has provisions on technical assistance (Article 11) and special and differential treatment (Article 12). These include instructions to member states to advise and/or grant technical assistance on preparing, meeting, and assessing conformity with technical regulations and on establishment of bodies, institutions and laws to support these functions. Member states should also "provide differential and more favourable treatment to developing country Members" (12.1) and take into account their particular needs when implementing the Agreement "with a view to ensuring that… technical regulations, standards and conformity assessment procedures do not create unnecessary obstacles to exports from developing country Members" (12.3). The should also "recognise that developing country Members should not be expected to use international standards as a basis for their technical regulations or standards… which are not appropriate to their development, financial and trade needs." (12.4).

[§] The SPS Committee was established to administer the SPS Agreement, it monitors its implementation, and provides a forum for discussion and negotiation on SPS issues.

In addition the TBT Committee[**], in order to facilitate compliance of developing country Members "is enabled to grant, upon request, specified, time-limited exceptions in whole or in part from obligations under this Agreement" (12.8).

Agreement on Trade Related Aspects of Intellectual Property Rights

The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) also has several provisions relating to development. Article 65 covers Transitional Arrangements. These initially allowed developing countries and economies in transition to postpone application of the Agreement apart from Articles 3, 4, and 5 – which relate to the granting of 'national treatment' and 'most-favoured-nation treatment') for four years from "the date of entry into force of the WTO Agreement" which was 1st January 1995 (65.2 and 65.3) and an additional five year delay in extending the product patent protection aspects of the Agreement to areas not previously given such protection (65.4). Some extensions to the transition periods have since been granted.

Article 66 covers Least-Developed Country Members. It grants a delay in applying the Agreement of ten years from entry into force of the WTO Agreement (aside from Articles 3, 4, and 5). It also directs developed country members to "provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base" (66.2).

Article 67 covers Technical Cooperation. Developed states are expected to provide "technical and financial cooperation in favour of developing and least-developed country Members", which is to "include assistance in the preparation of laws and regulations on the protection and enforcement of intellectual property rights as well as on the prevention of their abuse… the establishment or reinforcement of domestic offices and agencies relevant to these matters, including the training of personnel".

World Trade Organisation

> "many countries simply don't have the human, institutional and infrastructural capacity to participate effectively in international

[**] The TBT Committee fulfils some administrative roles in relation to the Agreement and provides a forum for discussion between Member States.

> trade… WTO Members have recognised that the multilateral system needs to be accompanied by improvements in trade capacity."
> (http://www.wto.org/english/tratop_e/devel_e/build_tr_capa_e.htm)

The World Trade Organisation (WTO) recognises that trade and development are closely connected issues. Development became a central issue in the Organisation's ongoing work in 2001 with the adoption of the *Doha Development Agenda* (http://www.wto.org/english/tratop_e/devel_e/devel_e.htm). WTO budgets around 30 million Swiss Francs (around US $29 million) a year for technical assistance. The majority of funding for WTO's technical assistance activities is 'extra-budgetary' and "one of the key challenges for the Secretariat is to enhance stability and predictability in financing" this (http://www.wto.org/english/tratop_e/devel_e/teccop_e/ta_factsheet_e.htm).

Most of this funding is directed "towards helping officials better understand complex WTO rules and disciplines" (http://www.wto.org/english/tratop_e/devel_e/build_tr_capa_e.htm). Among its activities, WTO works in cooperation with other international organisations that provide assistance relevant to trade capacity for example through investment in infrastructure (http://www.wto.org/english/tratop_e/devel_e/build_tr_capa_e.htm) and runs various training courses aimed at enhancing trade capacity (http://www.wto.org/english/tratop_e/devel_e/teccop_e/ta_factsheet_e.htm).

Alongside the *Doha Development Agenda*, WTO is working to build trade capacity of developing country members, including through its Aid for Trade initiative (see http://www.wto.org/english/tratop_e/devel_e/a4t_e/aid4trade_e.htm). Developed member states have pledged billions of dollars under Aid for Trade (http://www.wto.org/english/tratop_e/devel_e/build_tr_capa_e.htm) – this counts as part of their Official Development Assistance, and most is granted on a bilateral basis (http://www.wto.org/english/tratop_e/devel_e/a4t_e/a4t_factsheet_e.htm). Aid for Trade provides technical assistance beyond that of WTO, extending into areas such as:

> "Infrastructure – building the roads, ports and telecommunications that link domestic and global markets. Productive capacity – investing in industries and sectors so countries can diversify

> exports and build on comparative advantages. And adjustment assistance – helping with the costs associated with tariff reductions, preference erosion, or declining terms of trade" (http://www.wto.org/english/tratop_e/devel_e/a4t_e/a4t_factsheet_e.htm)

It is therefore an important complement to WTO activities. While WTO cannot directly provide such forms of assistance it believes that it has a "catalytic role" in getting "existing development assistance mechanisms to work together more effectively" by "ensuring that agencies responsible for development understand the trade needs of WTO members, and encouraging them to deliver solutions" (http://www.wto.org/english/tratop_e/devel_e/a4t_e/a4t_factsheet_e.htm). (Summary information on WTO's first *Global Aid for Trade Review* can be found in Issue 5 of the *Genomics Monitor*.)

WTO also chairs a joint international programme the 'Integrated Framework'. This involves six agencies – the International Monetary Fund, International Trade Centre, United Nations Conference on Trade and Development, United Nations Development Programme, World Bank and WTO. It works "with LDCs and their development partners to identify and address their trade development needs to assist them in becoming full and active players and beneficiaries of the multilateral trading system." (http://www.wto.org/english/tratop_e/devel_e/teccop_e/if_factsheet_e.htm).

36 LDCs are part of the framework programme, and eight more are preparing to join it (http://www.wto.org/english/tratop_e/devel_e/teccop_e/if_factsheet_e.htm). The framework's trust fund has received donations of US $50 million of which $27 million has been allocated to diagnostic activities and implementation of priority actions. It is hoped that an enhanced version of the framework will have a five-year budget of $400 million (http://www.wto.org/english/tratop_e/devel_e/teccop_e/if_factsheet_e.htm).

In the TRIPS area, there has been work in the WTO relating to the public health aspect of development, starting with the *Doha Declaration* and the *Declaration on the TRIPS Agreement and Public Health*, both adopted in November 2001. Paragraph 17 of the *Doha Declaration* reads:

> "17. We stress the importance we attach to implementation and interpretation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) in a manner supportive of public health, by promoting both access to existing medicines and research and development into new medicines and, in this connection, are adopting a separate declaration."
> (http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm#trips)

The full text of the *Declaration on TRIPS and Public Health* is available at: http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm. Actions initiated under this process include:

- Extension of the transition period for LDCS in relation to pharmaceutical product patents, so that protection now does not have to be given until 2016 (this provided for the Declaration and confirmed by a 2002 decision of the TRIPS Council – see http://www.wto.org/english/tratop_e/trips_e/art66_1_e.htm).
- The General Council of the WTO in a related decision, waived until 2016 the TRIPS requirements relating to exclusive marketing rights (see http://www.wto.org/english/tratop_e/trips_e/art70_9_e.htm).
- In 2003 the General Council established a procedure by which a state which requires a pharmaceutical product to address a public health issue, but lacks the capacity to manufacture it, can request another state to produce the pharmaceutical under compulsory licence and export it to the requesting state (see http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm).
- In 2005 the General Council adopted an amendment to TRIPS which incorporates into the Agreement very similar provisions to those in the 2003 Decision – see http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm. The amendment requires acceptance by two-thirds of WTO members by 31st December 2009 to enter into force (for those members). The 2003 Decision stands until the amendment enters into force for each member. Currently only 25 states (out of 153) plus the European Community have accepted the amendment (http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm).

World Intellectual Property Organisation

Of the three relevant agreements of the World Intellectual Property Organisation (WIPO) – the Patent Cooperation Treaty, Patent Law Treaty, and Budapest Treaty on the Deposit of Microorganisms for the Purpose of Patent Procedure – only the Patent Cooperation Treaty has specific development-related provisions. These are found in Article 51 – Technical Assistance. This established a Committee for Technical Assistance which is given the task of organising and supervising "technical assistance for Contracting States which are developing countries in developing their patent systems individually or on a regional basis", this assistance is intended to include "training of specialists, the loaning of experts, and the supply of equipment both for demonstration and operational purposes".

WIPO does extensive work on intellectual property (IP) and development; it formally adopted a *Development Agenda* (incorporating forty-five recommendations) and created a Committee on Development and Intellectual Property (CDIP) in 2007. All member states of WIPO can participate in the CDIP, which is mandated to "develop a work programme for" and "monitor, assess, discuss and report on" the *Development Agenda* recommendations (for the full list of these see http://www.wipo.int/ip-development/en/agenda/recommendations.html) and to "discuss other IP and development related issues" (http://www.wipo.int/ip-development/en/agenda/cdip/). It reports to WIPO's General Assembly. (Summary information on the first and second sessions of CDIP can be found in Issues 7 and 8 of the *Genomics Monitor*.) A history of the Development Agenda is outlined at http://www.wipo.int/ip-development/en/agenda/background.html.

More recently WIPO established a Development Agenda Coordination Division (see – http://www.wipo.int/ip-development/en/dacd/html), which acts as CDIP's Secretariat and helps coordinate development work within WIPO (http://www.wipo.int/ip-development/en/agenda/overview.html).

International Treaty on Plant Genetic Resources for Food and Agriculture

Many of the Articles of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR) relate to development. These include:

- Article 6. Sustainable Use of Plant Genetic Resources

This is listed as including “promoting… plant breeding efforts which… particularly in developing countries, strengthen the capacity to develop varieties particularly adapted to social, economic and ecological conditions, including in marginal areas”.

- Article 7. National Commitments and International Cooperation

This instructs that international cooperation should “be directed to:…
5 (a) establishing or strengthening the capabilities of developing countries and countries with economies in transition with respect to conservation and sustainable use of plant genetic resources for food and agriculture”

- Article 8. Technical Assistance

States agree “to promote the provisions of technical assistance… either bilaterally or through the appropriate international organisations, with the objective of facilitating the implementation of this Treaty”

- Article 13. Benefit-Sharing in the Multilateral-System

The Multilateral System is a core part of the Treaty and facilitates access to plant genetic resources for food and agriculture. Article 13.b provides information on access to and transfer of technologies, which is to be facilitated for use of the resources in the System, to “improved varieties, and genetic material”. Mechanisms suggested for this include collaborations in R&D and in commercial activities, “human resource development, and effective access to research facilities” (13.b.ii). Where access to and transfer of technology involves developing countries, LDCs and economies in transition it is to be “provided and/or facilitate under fair and most favourable terms” (13.b.iii)

In a similar way to the Convention on Biodiversity, ITPGR member states “recognise that the ability to fully implement the Global Plan of Action, in particular of developing countries and countries with economies in transition, will depend largely on the effective implementation of this article and the funding strategy” (13.5).

- Article 15. Ex Situ Collections of Plant Genetic Resources for Food and Agriculture held by the International Agricultural Research Centres of the Consultative Group on International Agricultural Research and Other International Institutions

It is expected that any benefits arising from creation and use of ex situ collections will go particularly to conservation and sustainable use of the relevant plant genetic resource, especially in developing countries.

- Article 18. Financial Resources

Funding is aimed particularly at developing countries and economies in transition, with recognition that effective implementation by these countries depends on 'effective allocation' of this funding. Priority is to be given to "farmers in developing countries… who conserve and sustainably utilize plant genetic resources for food and agriculture". Information on ITPGR's benefit-sharing fund can be found at http://www.planttreaty.org/funding_en.htm.

- Article 21. Compliance

This directs the Treaty's Governing Body to consider compliance procedures and mechanisms at its first meeting and to include in this "offering advice or assistance, including legal advice or legal assistance… in particular to developing countries"

ITPGR is a Treaty of the FAO; information on FAO's development activities is provided earlier in this section. The FAO's Commission on Genetic Resources for Food and Agriculture works closely with ITPGR's Governing Body and provides "a permanent forum where governments discuss and negotiate matters relevant to biodiversity for food and agriculture"; like the ITPGR it has the aims of ensuring "conservation and sustainable utilization of genetic resources for food and agriculture, as well the fair and equitable sharing of benefits derived from their use" http://www.fao.org/nr/cgrfa/en/.

In November 2008 ITPGR's Governing Body launched a capacity-building project in relation to Legal and Technical Assistance to Developing Countries on Implementing the ITPGR with Particular Reference to the Multilateral System of Access and Benefit-Sharing (ftp://ftp.fao.org/ag/agp/planttreaty/noti/NCP_GB3_JIP1_e.pdf).

Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising Out of Their Utilization

The aims of the Bonn Guidelines include: capacity-building, transfer of technology, and provision of financial assistance, particularly for developing countries, in relation to arrangements for genetic resources access and benefit sharing (E.11). The

Guidelines were adopted by the CBD's Conference of the Parties in 2002. Details of the CBD Secretariat and Conference of the Parties' development activities are provide earlier in this section. An International Regime on Access and Benefit-Sharing is currently being negotiated under the CBD, see http://www.cbd.int/abs/ir/regime.shtml and information in Issue 9 of the *Genomics Monitor* and in Section I – Environmental Protection in this Issue.

Drugs Control

The Single Convention on Narcotic Drugs in Article 14 bis Technical and Financial Assistance allows the International Narcotics Control Board "with the agreement of the Government concerned" to "recommend to the competent United Nations organs and to the specialized agencies" that such assistance "be provided to the Government in support of its efforts to carry out its obligations under this Convention". The Convention Against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances has a provision for assistance for transit states "through programmes of technical cooperation on interdiction and other related activities" in Article 10.

Social Impacts

Universal Declaration on the Human Genome and Human Rights

The Universal Declaration on the Human Genome and Human Rights contains several development-related provisions, including recommendations relating to:

- Dissemination of scientific knowledge;
- Promotion of scientific cooperation;
- Capacity building in risk assessment;
- Capacity building for R&D in human biology and genetics;
- Benefit-sharing from scientific and technological advances with developing countries; and
- "free exchange of scientific knowledge and information in the areas of biology, genetics and medicine to be promoted." (Article 19).

International Declaration on Human Genetic Data

Similarly there are various development related clauses in the International Declaration on Human Genetic Data. These, more specifically to human genetic and proteomic data, include recommendations on:

- Dissemination of knowledge;
- Promotion of scientific cooperation;
- Benefit sharing "with the society as a whole and the international community" (Article 19.a); and
- Scientific capacity building.

Universal Declaration on Bioethics and Human Rights

The development provisions of the Universal Declaration on Bioethics and Human Rights have a slightly different focus, and include promotion of:

> "equitable access to medical, scientific and technological developments as well as the greatest possible flow and the rapid sharing of knowledge concerning those developments and the sharing of benefits, with particular attention to the needs of developing countries" (Article 2.f)

It also includes the following statements:

> "progress in science and technology should advance:
> (a) access to quality health care and essential medicines…
> (b) access to adequate nutrition and water;
> (c) improvement of living conditions and the environment;
> (d) elimination of the marginalization and the exclusion of persons on the basis of any grounds;
> (e) reduction of poverty and illiteracy" (Article 14.2);

> "Benefits from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries." (Article 15.1); and

> States should "promote cultural and scientific cooperation and enter into bilateral and multilateral agreements enabling developing

countries to build up their capacity to participate in generating and sharing scientific knowledge, the related know-how and benefits." (Article 24.2)

United Nations Declaration on Human Cloning

There is one development related provision in point F of the United Nations Declaration on Human Cloning: "Member states… in their financing of medical research, including of life sciences, to take into account the pressing global issues such as HIV/AIDS, tuberculosis and malaria, which affect in particular the developing countries."

UNESCO

UNESCO adopted the Universal Declaration on the Human Genome and Human Rights; International Declaration on Human Genetic Data; and Universal Declaration on Bioethics and Human Rights. Among its other tasks, UNESCO's Bioethics Programme:

- "acts as an adviser to Member States wishing to promote reflection and debate on bioethics, to set up national ethics committees and to define national standards and/or legislation in the field";
- "contributes to national and regional capacity building by facilitating the establishment of networks of institutions and specialists concerned with bioethics";
- "encourages the establishment or strengthening of regional bioethics information and documentation centres"; and
- "endeavours to identify ethical issues for specific regions in an effort to define and implement appropriate strategies for the promotion and development of ethical reflection in these areas."

(http://portal.unesco.org/shs/en/ev.php-URL_ID=6750&URL_DO=DO_TOPIC&URL_SECTION=201.html#3)

UN General Assembly

The UN General Assembly adopted the United Nations Declaration on Human Cloning. One of the General Assembly's roles is to:

> "Initiate studies and make recommendations to promote international political cooperation, the development and codification of international law, the realization of human rights and fundamental freedoms, and international collaboration in the economic, social, humanitarian, cultural, educational and health fields; " (http://www.un.org/ga/about/background.shtml)

The General Assembly is also mandated to consider, discuss, and make recommendations on any issue relating to international peace and security. Development comes under both these roles. Also the Executive Boards of the UN Development Programme and World Food Programme are subsidiary bodies of the General Assembly (http://www.un.org/ga/subsidiary.shtml).

Much of the General Assembly's development work falls under the remit of its Second Committee – Economic and Financial Committee (http://www.un.org/ga/second/index.shtml); in its most recent session it gave particular consideration to:

> "issues relating to economic growth and development such as macroeconomic policy questions (including international trade, international financial system and debt), financing for development, sustainable development, human settlements, poverty eradication, globalization and interdependence, operational activities for development, and information and communication technologies for development." (http://www.un.org/ga/second/index.shtml).

Two of the General Assembly's nine agenda points for its 63rd (2008) Session related to development – B. Economic Growth and Sustainable Development and C. Development of Africa, similar points are suggested in the provisional agenda of the 64th Session (http://www.un.org/ga/search/view_doc.asp?symbol=A/64/150). It adopts many development related resolutions in each session.

Summary

There are a substantial range of development related provisions in many of the international regulations relevant to control of the biotechnology revolution. In

addition, the related international organisations conduct various capacity building activities. The fulfilment of the regulatory provisions and effectiveness of capacity building activities rely on the actions of states, particularly developed states. Initiatives established under one regulation or organisation have the potential to overlap with others, because there are many cross-cutting issues. This may produce duplication of effort, and be wasteful of resources, however, it is also the case that capacity building in one area will often have potential to produce benefits in multiple areas. The key to promoting the latter over the former will be appropriate coordination between the relevant international organisations and their member states.

SECTION III – EVENTS AND RECENT PUBLICATIONS

ARMS CONTROL

Background papers for BWC Expert Meeting August 2009 –

- *Recent Developments in Intergovernmental Organisations Relevant to Disease Surveillance, Detection, Diagnosis and Containment*, http://www.unog.ch/80256EDD006B8954/(httpAssets)/2B5A538429D51589C125760000459ADD/$file/BWC_MSP_2009_MX_Adv_ISU.1.pdf.
- *Recent International, Regional and Non-Governmental Developments Relevant to Disease Surveillance, Detection, Diagnosis and Containment*, http://www.unog.ch/80256EDD006B8954/(httpAssets)/5904BCE9D767E074C1257600004652BB/$file/BWC_MSP_2009_MX_Adv_ISU.2.pdf.
- *Previous Agreements and Understandings Under the Convention Relevant to Capacity-Building in the Fields of Disease Surveillance, Detection, Diagnosis and Containment*, http://www.unog.ch/80256EDD006B8954/(httpAssets)/6003C86D3FFD8F2BC1257600004659B2/$file/BWC_MSP_2009_MX_Adv_ISU.3.pdf.

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OPCW Quarterly Review, 2009 Second Quarter, May 2009, http://www.opcw.org/news/publications/opvw-quaterly-update/may-2009.

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laboratory biosecurity"; and providing "practical advice that will ensure the secure handling, management and storage of biological materials." (p.1). http://books.sipri.org/files/misc/SIPRI09HAB.pdf.

Workshop on the Biological Weapons Convention – Supporting Global Health: Reducing Biological Risk by Building Capacity in Health Security, 18th-19th June 2009, Oslo. Speeches and presentations available at: http://www.regjeringen.no/en/dep/ud/campaign/bwc/resources.html?id=565487.

20-21 October 2009, Riyadh, Workshop on the Biological Weapons Convention. Programme includes: the threat; responding to the threat; the BWC and resolution 1540; national implementation; assistance, cooperation and coordination; confidence-building measures; scientific and technological developments; regional perspectives – the BWC in the Middle East; and national perspectives in Saudi Arabia. http://www.unog.ch/unog/website/disarmament.nsf/(httpPages)/EB654D49DFA8435CC12575E10051A04A?OpenDocument&unid=87CF9BFD24A8D05FC1257574004B285B.

30th November – 4th December 2009, 14th Session Conference of the States Parties to the Chemical Weapons Convention, The Hague.

7th-11th December 2009, Meeting of States Parties, Biological Weapons Convention Intersessional Process, Geneva.

HEALTH AND DISEASE CONTROL

Codex Alimentarius Newsletter No.2, March-May 2009, including a 'facts and fiction' box on genetically modified foods, ftp://ftp.fao.org/codex/Newsletters/Newsletter_02_March2009_web.pdf.

FAO, May 2009, *Algae-Based Biofuels: A Review of Challenges and Opportunities for Developing Countries*, ftp://ftp.fao.org/docrep/fao/011/ak333e/ak333e00.pdf.

FAO, *Animal Genetic Resources Information Bulletin* No. 43, available through http://www.fao.org/AG/AGAInfo/resources/en/pubs_gen.html.

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7th Meeting of the Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing, 2-8 April 2009:

- Report – http://www.cbd.int/doc/?meeting=abswg-07
- Presentations – http://www.cbd.int/abs/ir/se-abs7.shtml
- Statement by Executive-Secretary – http://www.cbd.int/doc/speech/2009/sp-2009-04-02-abs-en.pdf
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