codex alimentarius commission

E

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00153 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 3 **CX/FBT 07/7/3**
August 2007

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX *AD HOC* INTERGOVERNMENTAL TASK FORCE ON FOODS DERIVED FROM BIOTECHNOLOGY

Seventh Session
Chiba, Japan, 24 – 28 September 2007

REVIEW OF THE WORK BY INTERNATIONAL INTERGOVERNMENTAL ORGANIZATIONS RELATED TO FOODS DERIVED FROM BIOTECHNOLOGY

Submission from CBD, ICGEB, FAO, OECD, OIE and WHO

The purpose of this document is to provide the Task Force with information on activities of the international intergovernmental organizations working in the field of the evaluation of foods derived from biotechnology and their related areas.

CONVENTION ON BIOLOGICAL DIVERSITY (CBD)

A. Background

1. Both the Convention on Biological Diversity (CBD) and its Cartagena Protocol on Biosafety address issues related to biotechnology. However, it is the Biosafety Protocol that deals most directly with the issues that are of relevance to the work of the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology.

2. The objectives of the CBD are (i) the conservation of biological diversity, (ii) the sustainable use of its components and (iii) the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies. Article 16 of the Convention states that access to and transfer of relevant technology, including biotechnology, are essential elements for the attainment of the CBD's objectives. Accordingly, it requires Parties to provide and/or facilitate access for and transfer to other Parties of the technologies that are relevant to the conservation and sustainable use of biodiversity or make use of genetic resources and do not cause damage to the environment. Article 19 of the CBD addresses the issue of the handling of biotechnology and the distribution of its benefits. It requires Parties to take measures to provide for effective participation in biotechnology research and promote fair and equitable access to the results and benefits arising from biotechnologies based upon genetic resources provided by other Parties. Paragraphs 3 and 4 of Article 19 address the issue of the safety of living modified organisms resulting from biotechnology.

3. The Cartagena Protocol on Biosafety was negotiated within the context of Article 19 of the Convention. The Protocol, which was adopted in January 2000, entered into force in September 2003 and, as of 30 May 2007, had 141 contracting Parties. The objective of the Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.

4. The Protocol sets out rules and procedures to regulate the transboundary movement of LMOs, including those intended for direct use as food or feed, or for processing (LMOs-FFP) in order to ensure their safe transfer, handling and use. It requires Parties to follow an Advance Informed Agreement (AIA) procedure with respect to the transboundary movement (import and export) of LMOs intended for release into the environment and take decisions in accordance with science-based risk assessment. Article 11 of the Protocol provides for a simpler procedure for LMOs-FFP.

5. Furthermore, Article 18 of the Protocol requires Parties to take measures to ensure that LMOs subject to transboundary movement are handled, packaged and transported under conditions of safety. In this regard, paragraph 2 of Article 18 sets out the identification requirements for the documentation that must accompany shipments of different categories of LMOs, i.e. (i) LMOs for direct use as food or feed or for processing (LMOs-FFP); (ii) LMOs destined for contained use; and (iii) LMOs for intentional introduction into the environment.

6. The Protocol also establishes an information sharing mechanism, the Biosafety Clearing-House (BCH), to facilitate the exchange of scientific, technical, environmental and legal information and experience on LMOs and biosafety, and assist Parties to implement the Protocol. The BCH contains decisions taken by Parties with regard to LMOs, including decisions taken by Parties concerning domestic use and the placing on the market of LMOs-FFP.

B. Recent relevant developments under the Biosafety Protocol

7. As reported in the CBD Secretariat's contribution to the sixth session of the Task Force, the Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP), in its decision BS-II/6, requested the Executive Secretary to reinforce cooperation with the Codex Alimentarius Commission on issues of mutual relevance. At its third meeting, held 13-17 March 2006 in Curitiba, Brazil, COP-MOP took a number of decisions on issues that are of direct relevance to the work of the Codex Ad Hoc Intergovernmental Taskforce on Foods Derived from Biotechnology. These include decisions on: 1) detailed identification requirements for documentation accompanying LMOs-FFP (decision BS-III/10); 2) the need for and modalities of developing standards with regard to identification, handling, packaging and transport practices for the transboundary movement of LMOs (paragraph 3 of Article 18 of the Protocol) in consultation with other relevant international bodies (decision BS-III/9); and 3) risk assessment and risk management of LMOs (decision BS-III/11). These, and the other COP-MOP decisions, were communicated to the Codex Secretariat.

8. Steps are being taken to implement the above-mentioned decisions. First, in terms of decision BS-III/10, the Secretariat is developing a training module on LMO identification and documentation requirements under Article 18, paragraph 2, of the Protocol. This is designed to assist in building the capacities of Parties in the implementation of those requirements. Second, in May 2007, the Secretariat conducted a training session, in Shanghai, China, on LMO identification and documentation requirements at the Green Customs Train-the-Trainer Workshop. It was attended by 26 participants from 8 countries in the Asia Pacific region. The workshop was organized by the UNEP-coordinated Green Customs Initiative.

9. Pursuant to paragraph 11 of decision BS-III/10, the CBD Secretariat is also currently collecting submissions from Parties, other Governments and relevant international organizations regarding (i) their experiences in the use of sampling and detection techniques and (ii) the need for and modalities of developing acceptable criteria for harmonizing the sampling and detection techniques of LMOs. The Secretariat will compile the information received and prepare a synthesis report for consideration at the fourth meeting of the COP-MOP to be held 12-16 May 2008 in Bonn, Germany.

10. In Bonn, COP-MOP will also consider the need for and modalities of developing standards with regard to identification, handling, packaging and transport practices for the transboundary movement of LMOs. The Secretariat is currently awaiting submissions from Parties, other Governments and relevant international organizations on their views. These submissions will contain (i) information on the adequacy of existing rules and standards for identification, handling, packaging and transport of goods and substances, (ii) any concerns relating to LMOs and (iii) existing gaps that may justify a need to develop new rules and standards, or the need to call upon relevant international bodies, including Codex, to modify or expand their existing rules and standards.

11. With respect to risk assessment and risk management, the Secretariat is collecting additional guidance documents on risk assessment and risk management and making them available through the Biosafety Information Resource Centre which accessible through the Biosafety Clearing-House (http://bch.biodiv.org/resources/resources.shtml). The Secretariat is also planning on organizing regional workshops on capacity-building and exchange of experiences on risk assessment and risk management of LMOs for Africa, Asia-Pacific, Central and Eastern Europe and Latin America and the Caribbean.

12. In addition to the above activities, a number of tools have been developed to assist in the implementation of the Protocol. Some of these tools may be of relevance to the work of the Taskforce. For example, the Secretariat has developed a central LMO Registry and a registry of gene inserts and characteristics of the modification when used in LMOs. These registries are available through the BCH at http://bch.biodiv.org/organisms/default.shtml. The Secretariat is also producing a bi-annual newsletter, titled 'Biosafety Protocol News', which is designed to promote awareness about the Protocol and its processes and to increase the engagement of biosafety stakeholders. It is available at http://www.biodiv.org/doc/newsletters/bpn/bpn-issue01h.pdf.

C. Recent relevant developments under the CBD

13. In order to implement provisions on technology transfer and scientific and technological cooperation, including biotechnology, the Conference of the Parties to the CBD developed, in 2004, a programme of work on technology transfer contained in Decision VII/29. The programme of work specifies key strategic considerations to be taken into account by the various actors. It also sets out a number of operational targets and related activities under following four programme elements: 1) technology assessments; 2) information systems for technology transfer; 3) creation of enabling environments; and 4) capacity-building and enhancement. Activities being undertaken to implement this programme of work, some of which might be of relevance to the work of the Codex Ad Hoc Intergovernmental Taskforce on Foods Derived from Biotechnology, include the following:

a. The Secretariat has collected a number of case studies and other information on technology impact assessments and risk analysis. These case studies are available at http://www.cbd.int/tech-transfer/assessment.shtml.

b. A meeting of the Ad Hoc Technical Expert Group on Technology Transfer and Scientific and Technological Cooperation will be convened on 10-12 September 2007 in Geneva. One focus of the meeting will be to explore options for the development of a "Biodiversity Technology Initiative". This Ad Hoc Technical Expert Group was established by the COP to collect, analyse and identify ongoing tools, mechanisms, systems and initiatives to promote the implementation of Articles 16 to 19 and to propose strategies for practical implementation of the programme of work.

14. Initiatives have also been launched to promote private sector engagement in technology transfer and technological and scientific cooperation and to strengthen enabling environments for investment in the implementation of the Convention at the national level. For example, the Secretariat has launched a newsletter on business and biodiversity which is available at http://www.biodiv.org/doc/newsletters). The September 2007 issue will focus on technology transfer.

THE INTERNATIONAL CENTRE FOR GENETIC ENGINEERING AND BIOTECHNOLOGY (ICGEB)

CAPACITY-BUILDING ACTIVITIES IN GMO BIOSAFETY AT ICGEB

INTRODUCTION

1. The safe and sustainable use of biotechnology in agriculture is having an increasingly important role in developing countries. International research centres have an obligation to enhance their research activities aimed at identifying new technologies (including biotechnology) for the advancement of agriculture worldwide. The introduction of these new technologies, especially in developing countries, needs to be carried out in a safe and socially-conscious manner, respecting the local conditions for the sustainable improvement of agricultural productivity. Adding impetus to this situation is the adoption of national regulatory frameworks by Parties to the Cartagena Protocol on Biosafety (CPB) which came into force in 2003. There is no doubt that several of these Governments are in great need of acquiring specific scientific expertise in this field and for access to crucial information and tailor-made initiatives in capacity-building.

2. The International Centre for Genetic Engineering and Biotechnology (ICGEB), an international organisation, currently comprises two Components, one located in Trieste, Italy and one in New Delhi, India, with an additional Component in Cape Town, South Africa due to come into operation later in 2007. Since 1987, ICGEB has been operating within the United Nations System, offering a centre of excellence for research and training in this advanced scientific field, with special attention to the needs of the developing countries. Currently 74 countries are signatories of the Statutes of ICGEB, the international treaty that established the Centre. ICGEB carries out activities aimed at scientific co-operation by means of Research Programmes, 3-4 year training courses, short-term training courses (maximum 3 months) and offers an informatic network containing all the databases on genetic sequences currently available world-wide.

3. Among the research activities developed by ICGEB in its laboratories, many are oriented towards the improvement of agriculture by means of molecular biology technologies, i.e. stress resistance (soil salinity and draught), insect resistance, improvement of nutritional value in agricultural products, the development of new technologies for genetic transformation and the expression of proteinaceous compounds with high added value for agriculture and/or industry. The entry into force of the Cartagena Protocol has led to formal requests for access to information and capacity-building activities offered by the ICGEB and for extending its co-operation with other international organisations involved in this arena. In 1997, the ICGEB established a Biosafety Unit within the Directorate to provide institutional services related to genetically modified organisms (GMOs) and their environmental release in Member States. The Unit is involved in two major sectors, namely: (i) information dissemination and the establishment of a biosafety clearing-house; and (ii) scientific training in risk assessment for the environmental release of GMOs (capacity-building and technology transfer);

1. Dissemination of information

4. The Centre has established, and continually updates, the Biosafety Webpages (http://www.icgeb.org/biosafety), a functional portal through which currently available information of importance to biosafety is accessible. The *Library* webpages (http://www.icgeb.org/biosafety/bsflib.htm) provide access to a vast quantity of official documents issued by major international organisations operating in this field, as well as access to national and international websites related to biosafety. In addition, ICGEB has complied specific information in the following freely-accessible databases:

5. The *Biosafety Bibliographic Database* (http://www.icgeb.org/biosafety/bsfdata1.htm) contains more than 6,000 scientific articles (full references and abstracts), published in international, peer-reviewed, scientific journals since 1990. These are selected and classified by ICGEB scientists according to their relative merits in contributing to the various scientific debates arising from the environmental release of GMOs, and including the introduction of GM-derived products into the human food chain. The database is fully accessible through the Biosafety Clearing House of the Convention on Biological Diversity and is consistently the most visited section of the entire ICGEB website.

6. In addition, with the support of the Italian Ministry of the Environment (IMoE), ICGEB has developed and maintains the *Risk Assessment Searching Mechanism* (RASM; www.icgeb.org/biosafety/rasm.html). It provides access to existing online risk assessment documents related to official governmental decisions for the commercial release of GMOs, and which are authored by national competent authorities. To date, it contains links to nearly 700 individual documents, relating to over 150 different transgenic events from 20 plant species issued by 27 official authorities (of which more than 75 % are non-CPB parties). RASM is a searchable interlinked database, with the majority of records providing further links to online databases when relevant, for information concerning inserted nucleotide (transgene and/or regulatory) sequences and OECD unique identifiers.

7. ICGEB is also involved in efforts to make public and manage a web-based, public-access database of past and current projects in GMO biosafety research, to help improve communication within the scientific community, as well as between researchers and the public at large.

8. Further, the collaboration with the IMoE also extends to the publishing of the free-to-download *Collection of Biosafety Reviews* (http://www.icgeb.org/biosafety/publications.htm), which is a compilation of commissioned scientific studies in areas of major interest for biosafety and risk assessment, and authored by internationally recognised scientists. Also, the ICGEB Biosafety Outstation at Ca' Tron now houses the editorial office of a multidisciplinary international journal focused on GMO biosafety research, *Environmental Biosafety Research* (www.edpsciences.org/ebr/), which is the official journal of the International Society for Biosafety Research (www.isbr.info/) that has appeared quarterly since late 2002.

2. Capacity-building in biosafety

Organisation of workshops and training courses

9. The Centre provides its constituency with the technical instruments and qualified information required in biosafety and risk assessment for Member States to gain advantage from biotechnology, and to be informed as to its benefits and potential risks. ICGEB has long-standing invaluable experience in the development and training of human resources in biotechnology, playing a central role in capacity-building and technology transfer in GMO biosafety. Since 1991, nearly 1000 scientists from over 80 different countries have attended ICGEB's annual biosafety workshops, based primarily at our premises in Italy, as well as at accredited centres in selected member states in the developing world.

10. These workshops have centred on the general principles of GMO risk assessment, and more recently, on providing experience in the examination of the scientific data that are evaluated to produce an environmental risk assessment report. The training courses have attracted an extremely diverse group of participants, including both members of the competent authorities involved in the evaluation of proposed releases of GMOs, as well as scientists active in biotechnology. Participants receive a thorough grounding in the concept of risk, and become knowledgeable in risk assessment for the deliberate release of GMOs, with regard to accepted concepts, procedures and protocols. Additionally, the participants are tutored in many basic biological mechanisms and science underlying the possible impacts of GMOs on *inter alia*, human health, agricultural practices, and the wider environment. The 2007 training programme includes both an introductory and an advanced course at our Ca' Tron outstation, as well as two regionally-based courses held in Khartoum (Sudan) and Belo Horizonte (Brazil) which ICGEB is sponsoring and co-organising.

Collaboration with local authorities

11. At the request of individual member states and as an extension of our usual activities, the ICGEB Biosafety Unit has begun tailored support of local biosafety capacity-building initiatives, through direct commissions from the respective government ministries. The collaboration with the Italian Ministry for the Environment is an excellent example of direct assistance to local authorities in an ICGEB Member State. The collaboration commenced in 1999 with the publication of a report describing the main issues arising from the environmental release of GMOs. From this initial success, the collaboration then extended to the development of RASM (described above), the continuing publication of the "Collection" (above), and the elaboration of Italy's Biosafety Clearing House, an internet-based portal (http://bch.minambiente.it) required of Parties of the CPB.

Biosafety training and research at the ICGEB Biosafety Outstation

12. ICGEB has been operating its new facility for training and research in risk assessment and management of the environmental release of GMOs since October 2004. The Outstation, equipped for studies in molecular genetics and with a high-containment greenhouse, is located in Ca' Tron, close to Venice. It comprises new laboratories and guesthouse for trainees, which have been totally refurbished and equipped by the "Fondazione Cassamarca", an Italian non-profit organisation. The main research activities, implemented by two research groups, Plant Virology and Plant Bacteriology, are focusing on biosafety issues relating to GM plants and their associated pathogens. One prime objective focuses on the creation of pathogen-resistant transgenic plants expressing transgenes designed to minimise potential epidemiological and environmental risks. Through the hosting and academic training of scientists from developing countries, supported by ICGEB collaborative research funding, these studies will demonstrate how biosafety concerns can be integrated into projects of relevance to the scientists' home countries.

CONCLUSION

13. As shown here, ICGEB is progressively putting in place a unique resource in the area of GMO biosafety, including several web-based public-access databases, and both theoretical and practical training. This ambitious overall programme can only be carried out fully with the support of other organisations. It will also only reach its greatest usefulness if it is developed to respond to the most pressing needs for training, and this must be done in close cooperation with other organisations involved in providing capacity-building. Overall, this implies developing biosafety capacity-building in the context of collaboration with a broad range of partners worldwide.

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS (FAO)

1. FAO's work in the area of biotechnology is coordinated by an internal working group, including representatives from the different FAO departments and covering various issues related to biotechnology in food and agriculture, including the safety of foods derived from genetically modified organisms (GMOs). The working group has been quite active in provision of science-based information about biotechnology through e.g. FAO-BiotechNews, an e-mail newsletter posted in English, French, Russian, Spanish and, since June 2007, in Chinese. Its news and event items regularly cover food safety issues and Codex activities (in particular those of the Codex Committee on Food Labelling, the Codex Committee on Methods of Analysis and Sampling and the Codex Ad Hoc Intergovernmental Task Force on Foods derived from Biotechnology). These items, as well as recent FAO biotechnology documents, are also available from the multi-lingual FAO Biotechnology website (www.fao.org/biotech/).

2. In February 2007, FAO published a book containing the background and summary documents from a series of six moderated e-mail conferences hosted by the FAO Biotechnology Forum from 2002 to 2005 (ftp://ftp.fao.org/docrep/fao/009/a0744e/a0744e00.pdf). Three of the conferences focused on GMOs, dealing with gene flow from GM to non-GM populations; regulation of GMOs; and participation of the rural people in decision-making regarding GMOs. In April 2006, the FAO Glossary of Biotechnology for Food and Agriculture was also published in Arabic, in partnership with the United Arab Emirates University, and in May 2007 a CD-ROM was published containing the Arabic, English, French and Spanish versions of the Glossary (http://www.fao.org/biotech/index_glossary.asp).

3. On 31 October and 1 November 2006, a training-of-trainers workshop on "Safety assessment of foods derived from modern biotechnology – Biosafety within a Biosecurity framework" was held in Ottawa, Canada, organized by FAO in collaboration with the Government of Canada. The workshop was held as one of a series of biosafety-related activities within a Biosecurity framework. The overall objective of the project is to provide a standardized training package to assist countries in implementing international texts related to the food safety assessment of products derived from modern biotechnology. The purpose of the workshop was to pilot test the training package (ftp://ftp.fao.org/ag/agn/food/meetings/2006/canada_ws_report.pdf). FAO, in collaboration with the National Center for Genetic Engineering and Biotechnology (BIOTEC), National Science and Technology Development Agency (NSTDA), Ministry of Science and Technology, Thailand, later organized an expert meeting in Bangkok, Thailand on 23-25 May 2007 to peer review the newly developed Training-of-Trainers Tool on GM Food Safety Assessment. The main objectives of the meeting were to review the materials, to suggest possible improvements and to finalize the tool for publication.

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT (OECD)

1. The OECD has had projects related to the safety of biotechnology since the mid-1980s. Until the early 1990s, this work was undertaken by the Group of National Experts on Safety in Biotechnology (GNE) and its Working Group on Food Safety and Biotechnology. The objective of these activities was the elaboration of scientific principles for assessing the safety of new foods or food components produced by means of biotechnology. The flagship publication was "*Safety Evaluation of Foods Derived by Modern Biotechnology – Concepts and Principles*" (www.oecd.org/dataoecd/57/3/1946129.pdf). In this document, the concept of *substantial equivalence* was internationally adopted for the first time as the most practical approach to food safety of biotechnology-derived products. Subsequently, there were a number of follow-up activities between 1993-1997, most of which addressed the application of the concept of substantial equivalence and the role of *comparative approach* in food safety assessment.

2. Recent OECD activities on the safety of biotech foods have been undertaken by the *Task Force for the Safety of Novel Foods and Feeds*, established in 1999. Its main goal is to promote international harmonisation in the safety assessment of novel foods and feeds, especially the products of modern biotechnology, ensuring adequate safety of these products. In other words, it is an attempt to ensure that information used in risk- safety assessments, as well as methods to collect such information, are as similar as possible. Delegates to the Task Force are those from Ministries and Agencies of OECD member countries responsible for food safety. The Task Force has invited a number of observers from non-OECD member countries and other intergovernmental organisations to its regular meetings.

3. The main output of the Task Force has been its Consensus Documents on compositional considerations of new varieties of crops. These documents provide information that OECD member countries believe – on a consensus basis – is important in the risk/ safety assessment of novel foods/ feeds. To this end, the documents compile information on the major nutrients, toxicants, anti-nutrients and allergens of specific crops. Accordingly, the Task Force has completed and published 13 different documents, including those on soybean, canola, maize, cotton, rice, bread wheat, sugar beet, potato, barley, sunflower, mushroom, alfalfa, and animal feedstuffs (www.oecd.org/findDocument/0,3354,en_2649_34391_1_119829_1_1_1,00.html). Recently, an introduction to these documents was published. This explains the concept, purpose and the drafting process of the Consensus Document.

4. The Task Force is currently drafting some other documents. These include Consensus Documents on tomato, cassava, papaya and sweet potatoes. Of note is the participation of non-OECD member countries who have had active roles in these projects: the papaya document has been led by Thailand and cassava and sweet potato by South Africa. In addition, the Task Force has started updating those published Consensus Documents for which new information is available. At its last meeting held in June this year, it was agreed that the Consensus Documents on low erucic acid rapeseed (canola) and soybean should be updated.

5. Another major activity of the Task Force is a project on "molecular characterisation." The objective is to complete a document which explains the scientific basis underlining the use of molecular characterisation information in food, feed and environmental safety assessment of transgenic plants. This work is being carried out in coordination with the *Working Group on Harmonisation of regulatory Oversight in Biotechnology*, the body of the OECD dealing with biosafety issues of biotech products.

6. Dissemination of information relevant to aforementioned activities is another key component of the Task Force. This has been implemented mainly through a website: *BioTrack Online* (www.oecd.org/biotrack/). Amongst other things, this website contains published Consensus Documents and the *Product Database* (www.oecd.org/biotrack/productdatabase/). Recently, the OECD agreed with the FAO to introduce a system to exchange information/ data stored in this database and a new component of FAO's International Portal on Food Safety, Animal and Plant Health, which is planned to accommodate information/ data for the food safety assessment of biotech products.

THE WORLD ORGANISATION FOR ANIMAL HEALTH (OIE)

1. The World Organisation for Animal Health (OIE) expresses its appreciation to the Codex Alimentarius Commission (CAC) and the Codex *ad hoc* Intergovernmental Task Force on Foods Derived from Biotechnology (TFFBT) for the opportunity to contribute as an Observer Organisation to its standards development process.

2. Following our previous reports (CRD 16 for 6th TFFBT), we have the honour to update you on recent and ongoing OIE activities related to biotechnology and animal production:

3. The OIE has been working on issues related to biotechnology and animal production since 1996 at the request of its International Committee. Important steps were taken by the OIE on biotechnology during the 73rd OIE General Session in May 2005 with the presentation of a technical item on *Applications of Genetic Engineering for Livestock and Biotechnology Products* and the adoption of Resolution XXVIII on the *Applications of Genetic Engineering for Livestock and Biotechnology Products* (see ANNEX) by the OIE International Committee. This Resolution provides the OIE with the guidance and mandate to continue working on the development and adoption of standards in the field of biotechnology. Notably it recommends the constitution of an *ad hoc* Group on Biotechnology to support the work of OIE Specialist Commissions and related Working Groups.

4. Following the two meetings held last year, the OIE *ad hoc* Group on Biotechnology met a third time at the OIE headquarters in Paris in June 2007. At this meeting, the Group finalised its draft "Guidelines for Somatic Cell Nuclear Transfer in Production Livestock and Horses" and draft "Guidelines on DNA Vaccines" both of which will be reviewed by relevant Specialist Commissions and presented for future adoption by the International Committee as new OIE standards. The focus of these guidelines are animal-health based and support the context of the above-mentioned Resolution.

5. It was agreed that the Group will contribute to and cooperate with the work of the OIE *ad hoc* Group on Animal Identification and Traceability by identifying issues relevant to the tracing of such animals/animal products resulting from biotechnological interventions.

6. It was also noted that animal welfare considerations for animals resulting from biological interventions and food safety considerations for products from animals subject to treatments involving biotechnology will be dealt with in cooperation with OIE Animal Welfare Working Group and OIE Animal Production Food Safety Working Group, respectively. At this meeting, no issue was yet identified for immediate cooperation with these Working Groups.

7. During the *ad hoc* Group meeting, discussions began on other international arena, including TFFBT. However, the OIE noted that its mandate does not necessarily cover all the fields related to food safety or those already clearly provided for in the mandate of the Codex Intergovernmental Task Force.

8. The report of the meeting of the *ad hoc* Group on Biotechnology will be available after adoption of the report at the September 2007 meeting report of the Biological Standard Commission at http://www.oie.int/bsc/eng/en_reports.htm. The Group will meet again in November 2007.

9. The TFFBT should note that the OIE as co-organiser will be hosting an International Symposium "Animal Genomics for Animal Health" at the OIE Headquarters in Paris scheduled for 23–25 October 2007. The OIE will also participate in the 8th OIE/WAVLD (World Association of Veterinary Laboratory Diagnosticians) Seminar on Biotechnology entitled "Applications of Biotechnology to the Diagnosis and Pathology of Animal Diseases" to be held in Melbourne, Australia, 13 November 2007.

WORLD HEALTH ORGANIZATION (WHO)

1. In food safety area, it is one of the WHO's tasks to support member countries as well as Codex work, by providing the scientific basis for health in relation to the use of biotechnology for food production. The summary of the Joint FAO and WHO Expert Consultation on Recombinant DNA animals[1] is prepared in a separate working document CX/FBT 07/7/3 Add.1. Information of WHO's work related to biotechnology in food production including activities for scientific advice is available at http://www.who.int/foodsafety/biotech/en).

2. WHO continues its effort to improve human health and mitigate burden of diseases in member countries through relevant programmes on food safety in general and has implemented the priority area identified in the 11th General Programme of Work.[2] In relation to the WHO's Medium-Term Strategic Plan 2008-2013[3], Strategic Objective 9 (SO9) requires improvement of nutrition, food safety and food security through out the life course for health and sustainable development. To achieve this SO9, food safety and food security must play a central role in national development policies, in agricultural development, and in animal- and food-production process, with special emphasis on reaching the most biologically and socially vulnerable population.

[1] This consultation was held to provide scientific advice on the requests made by the 6th Session of the Codex *ad hoc* Intergovernmental Task Force on Foods derived from Biotechnology.

[2] Adopted by the Health Assembly in May 2006, available at http://whqlibdoc.who.int/publications/2006/GPW_eng.pdf

[3] Approved by the World Health Assembly May 2007, available at http://www.who.int/gb/e/e_amtsp.html.

ANNEX

RESOLUTION No. XXVIII

Applications of Genetic Engineering for Livestock and Biotechnology Products

CONSIDERING THAT

The development of animal health applications for biotechnology is accelerating at a rapid pace and has the potential for significant advances in animal and veterinary public health.

A survey of the OIE 167 Member Countries conducted in 2005 identified a number of potentially beneficial applications of biotechnology and noted the absence of uniform guidance or international standards for assessment.

Responses received from this survey of OIE Member Countries indicated broad consensus that comprehensive regulatory controls are required and that ethical issues and societal concerns will need to be addressed in order to ensure responsible introduction and social acceptance of these technologies.

The maximising of benefits and minimising of negative consequences are best achieved through transparency and an international engagement to ensure that science-based standards are developed to direct the application of emerging technologies and to protect animal and public health.

THE COMMITTEE

RESOLVES THAT

OIE continue to provide scientific advice and support to enable countries to develop harmonised technical standards for regulation of biotechnology-derived animal health products, and genetically modified production animals through:

- The constitution of an Ad hoc Group on Biotechnology to support the work of OIE Specialist Commissions and related Working Groups.
- Maintaining and expanding collaboration with other international organisations including, but not limited to, the FAO, WHO, VICH, and IETS.
- Facilitating international collaboration among regulatory agencies.
- The standardisation of the techniques of assessment of bioengineered animals or products and training Member Countries to conduct risk analysis through the recognition of international collaborating centre(s).

These objectives will be reached by the OIE taking into account the following priorities:

1. Development and adoption of standards and guidelines for research on the use of live attenuated vaccines in animal health.
2. Development of recommendations and guidelines for use of DNA vaccines.
3. Development of guidelines and recommendations for the animal health risks linked with somatic cell nuclear transfer cloning.
4. Develop objective criteria for assessing the health of embryos and production animals derived from cloning, and associated safety of cloned production animals and their products.
5. Develop policy guidelines for exclusion of unapproved animals and products from the livestock population, and segregation from the feed and food supply.
6. Develop identification, testing, and certification guidelines for international trade in production animals and their products for which biotechnology procedures have been employed.
7. Development of guidelines relevant to the application of Nanoscience/Nanotechnology as it relates to animal health

---

(Adopted by the International Committee of the OIE on 26 May 2005)