codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 3

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX AD HOC INTERGOVERNMENTAL TASK FORCE ON FOODS DERIVED FROM BIOTECHNOLOGY

Fifth Session
Chiba, Japan, 19-23 September 2005

REVIEW OF THE WORK BY INTERNATIONAL ORGANIZATIONS ON THE EVALUATION OF THE SAFETY AND NUTRITION ASPECTS OF FOODS DERIVED FROM BIOTECHNOLOGY

Submission from CBD, FAO, ICGEB, OECD, WHO

INTRODUCTION

1. The purpose of this document is to provide the Task Force with information on activities of the international organizations working in the field of the evaluation of the safety and nutritional aspects of foods derived from biotechnology and their related areas, with emphasis on those taken after the closure of the fourth Session of the Task Force.

CONVENTION ON BIOLOGICAL DIVERSITY (CBD)

2. The Cartagena Protocol on Biosafety to the Convention on Biological Diversity was adopted in January 2000, entered into force in September 2003, and has 119 contracting Parties as of 15 June 2005. Its objective 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.

3. The Biosafety Protocol is relevant to those products of biotechnology that may be subject to transboundary movement and which meet the definition of “living modified organism” (LMO) contained in Article 3 of the Protocol. Article 3 also contains specific definitions for the terms “living organism” and “modern biotechnology”.

4. The Biosafety Protocol requires that decisions regarding the import of LMOs intended for release into the environment be taken in accordance with science-based risk assessment. A modified procedure is specified in the Protocol for LMOs intended for direct use as food or feed, or for processing (LMOs-FFP). Import of LMOs-FFP may also be subject to risk assessment. Detailed guidance on the methodology and considerations for risk assessment are given in Annex III of the Protocol. The Protocol also contains provisions for risk management.

5. At its second meeting from 30 May to 3 June 2005, the Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP) considered risk assessment and risk management. A key issue on its agenda was to consider the possible development of guidance and a framework for a common approach in risk assessment and risk management. In its decision BS-II/9, the COP-MOP established an Ad

Hoc Technical Expert Group on Risk Assessment to consider the nature and scope of existing approaches to risk assessment, to evaluate those approaches and identify gaps, and to identify specific areas where limitations in capacity are an impediment to implementation of the risk assessment provisions of the Protocol at national level. The group is scheduled to meet in late 2005.

6. Existing guidance materials related to risk assessment and risk management of LMOs were reviewed in advance of the second meeting of the COP-MOP, in document UNEP/CBD/BS/COP-MOP/2/9. That document includes discussion of various options for development of guidance on risk assessment and risk management of LMOs; differences in terminology related to risk analysis, risk assessment and other terms; and similarities between the risk assessment methodology of the Biosafety Protocol with the conventional paradigm for risk assessment.

7. In decision BS-II/6, the COP-MOP requested the Executive Secretary to reinforce cooperation with the Codex Alimentarius Commission. In this regard, the third meeting of the COP-MOP, scheduled for March 2006, will consider at least two items of potential interest to Codex. The first is risk assessment and risk management, as described above. The second item is consideration of the need for and modalities of developing standards with regard to identification, handling, packaging and transports practices for LMOs, in consultation with other relevant international bodies (Article 18, paragraph 3).

FOOD AND AGRICULTURE ORGANIZATION (FAO) AND WORLD HELATH ORGANIZATION (WHO) AND THEIR JOINT ACTIVITIES

FAO

8. FAO's work in the area of biotechnology is coordinated by the FAO Inter-Departmental Working Group on Biotechnology in Food and Agriculture: http://www.fao.org/biotech/. This Working Group includes representatives from each FAO department working on aspects related to biotechnology, including intellectual property, application of biotechnology to agricultural production, environmental safety, and the safety of foods derived from biotechnology. FAO has also recently released a number of publications related to biotechnology, including the 2004 FAO State of Food and Agriculture Report on the subject of "Biotechnology: meeting the needs of the poor?". These publications are all available from the above-mentioned website.

9. The FAO Biotechnology group, along with FAO's Inter-departmental working group on Biosecurity in Food and Agriculture http://www.fao.org/biosecurity/, recently implemented a smaller joint working group focusing specifically on biosafety. Under the auspices of this group, FAO is planning to hold an expert consultation on biosafety in food and agriculture in the fall of 2005. The objectives of the consultation are as follows: 1) provide advice to FAO on what role it should have in the area of biosafety, especially regarding regulatory aspects and capacity building needs, so that FAO can better provide policy guidance on how Biosecurity risk managers should handle issues related to biosafety and 2) to better define the role of FAO in biosafety in food and agriculture.

10. FAO is currently developing a project, in collaboration with WHO, the Canadian government and OECD, for capacity building in biosafety. The objective of the project is to provide a standardized training package to assist countries in implementing Codex texts related to the risk analysis of products derived from modern biotechnology. The project will develop a training tool and conduct training of trainer (TOT) courses. The tool will be peer reviewed and pilot tested before it is utilized in the training courses.

11. FAO is planning a workshop on the safety of genetically modified foods to be held at FAO Headquarters in Rome, on 13th and 14th October 2005. The workshop is being organized under the auspices of the FAO Working Group on Biosafety and aims primarily to improve the awareness of FAO staff of a range of expert opinions on selected issues related to the safety of genetically modified foods. The workshop will also generate ideas that will contribute to the planning of future activities related to the building of international consensus on the safety of genetically modified foods.

12. FAO implemented a workshop for countries of the Gulf Cooperation Council (GCC) from 14 to 15 September 2004 in Rome, Italy, on modern biotechnology and its application in food and agriculture. The focus of the workshop was on food safety and related regulations in the area of foods derived from modern biotechnology. The workshop was intended to provide a platform for the Member States of the GCC to discuss a common regulatory framework for genetically modified foods within the GCC region. More information on the workshop is available from: www.fao.org/es/ESN/food/capacity_workshops2004_en.stm

13. FAO publishes the FAO-Biotech News (http://www.fao.org/biotech/news_list.asp?thexpand=1&cat=131) , an e-mail newsletter posted in English, French and Spanish to over 3,400 subscribers, containing news and events items that are relevant to applications of biotechnology in food and agriculture in developing countries. Since its launch in January 2002, it has e.g. carried 20 items about Codex activities, mainly on the Codex committee on Labelling, the CCMAS, the ad hoc task force on biotechnology. The Archives (http://www.fao.org/biotech/archive.asp) suggest that about one third of items are relevant to food safety. The items are put on the homepage of the FAO Biotechnology website (ca. 40,000 visits per month) in 5 languages. In July 2005, FAO-BiotechNews was launched in Russian.

14. FAO also implements the FAO Biotechnology Forum (http://www.fao.org/biotech/forum.asp), established in 2000 with the aim of providing quality balanced information on agricultural biotechnology in developing countries and to make a neutral platform available for people to exchange views and experiences on this subject. Thirteen moderated e-mail conferences have been hosted by the Forum so far. While no conference has specifically addressed evaluation of safety and nutrition of GM foods, some have been very relevant, such as Conference 9 (on regulation of GMOs - http://www.fao.org/biotech/C9doc.htm) or Conference 12 (on public participation in decision-making regarding GMOs - http://www.fao.org/biotech/C12doc.htm, with the Background Document providing details on the 1998 joint FAO/WHO expert consultation on the application of risk communication to food standards and safety matters as well as the recent Codex principles on risk analysis).

WHO

15. WHO's work in the area of biotechnology falls in two areas of work, one relates to the use of biotechnology in human medicine, the other relates to the use of biotechnology in food production. Only activities related to the latter area will be reported here.

16. As a response to anxiety and uncertainty amongst Member States related to the use of GM food as emergency food aid WHO developed the "20 Questions on GM Food", October 2002. These questions - and answers - contain direct statements related to the safety of GM foods, concluding that such foods currently on the international market are not likely to present risks for human health. It is also stated that "Different GM organisms include different genes inserted in different ways. This means that individual GM foods and their safety should be assessed on a case-by-case basis and that it is not possible to make general statements on the safety of all GM foods." Finally, the continuous use of risk assessments based on the Codex principles is advocated. The document also briefly touches upon issues related to intellectual property rights as well as concerns related to the influence of chemical industries on the global seed market. The document is available at http://www.who.int/foodsafety/publications/biotech/20questions/en/index.html.

17. WHO has recently (June, 2005) released a report on Modern food biotechnology, human health and development. Data for the study were gathered through traditional methodology as well as through an open questionnaire and a web-based electronic discussion process. Preliminary results were discussed at a broad stakeholder meeting held in 2003, informing further data search and revision. The report suggests that the development of Genetically Modified (GM) foods can contribute directly or indirectly to enhancing human health and development. The report also suggests that GM foods, if not properly assessed before marketing, may involve potential risks for human health and the environment, and refers to the Codex guidelines for safety assessment as the international benchmark. The report states that available GM foods have passed risk assessments and are not likely to present risks for human health and the consumption of such foods have not caused negative effects. Finally it is concluded that in the future, modern technologies should be assessed through broad evaluations if they are to constitute a true improvement in the way food is

produced, including assessments of human health and environmental risk, benefit, and social and ethical concerns. The report is available at http://www.who.int/foodsafety/biotech/who_study/en/index.html

JOINT FAO/WHO ACTIVITIES

18. WHO and FAO have published a number of reports on GM Foods, all focused on the human health safety and risk assessment of GM foods. The most recent string of such reports is from 2000-2004 and includes reports on GM Plants, GM Animals, GM Microorganisms and the issue of Allergenicity testing. While three of these reports were available for the deliberations of the 1st Task Force on Foods derived from biotechnology, the latest report on GM animals was published after the conclusion of the 1st Task Force. The joint FAO/WHO Expert Consultation on the Safety Assessment of Foods Derived from genetically Modified Animals, 2003 is available at http://www.who.int/foodsafety/biotech/meetings/ec_nov2003/en/index.html The Consultation focused on discussing what strategies are appropriate and applicable to the food safety assessment of GM animals, but also addressed specific issues originating from the production of GM animals as well as certain environmental and ethical issues. It was concluded that rigorous pre-market safety assessment of foods derived from GM animals should provide sufficient safety assurances. The Consultation also recommended participatory deliberation by all stakeholders and the general public, starting at an early stage, including communication about potential benefits, risks, and uncertainties posed by genetic modification of animals.

INTERNATIONAL CENTRE FOR GENETIC ENGINEERING AND BIOTECHNOLOGY (ICGEB)

19. The International Centre for Genetic Engineering and Biotechnology (ICGEB) is dedicated to advanced research and training in molecular biology and biotechnology. It provides information and training on biosafety and risk assessment for the environmental release of GMOs with special regards to the need of the developing world. These are outlined below:

20. A number of resources for GMO biosafety information dissemination are available on their website:

- A Biosafety Bibliographic database (http://www.icgeb.org/~bsafesrv/db/biosafety.html) on biosafety studies is maintained for on-line searching, and monthly updates are distributed freely; as of July 2005, the database contained more than 5000 records (full reference with abstracts) of scientific articles published in international, peer-reviewed, scientific journals since 1990. All the articles are selected and classified by ICGEB scientists in accordance with the main "topics of concern" for the environmental release of genetically modified organisms (GMOs);

- The Risk Assessment Search Mechanism (RASM; http://www.icgeb.org/~bsafesrv/db/rasm.php), funded by the Italian Ministry of the Environment, gives access to the greatest collection of actual risk assessment documents related to official governmental decisions concerning the commercial release of GMOs available on the Internet, irrespective of individual authority's CBD signatory status. It contains more than 430 records of 131 transgenic events from 15 plant species, with more than 70 % of records from non-CPB party authorities;

- As of 2003, ICGEB is also involved, together with partners from France, Germany and Hungary, in a European initiative to enhance communication regarding GMO biosafety research. The project, named GMO RES COM, is funded under the 5th European Framework Programme "Quality of Life and Management of Living Resources". It aims at the creation of a web-based, public-access database of past and current projects in GMO biosafety research (availablr at http://www.versailles.inra.fr/europe/gmorescom/). This database should improve communication within the scientific community, as well as between researchers and the public at large, while providing access to information to world-wide stakeholders. Following the initial phase, when projects were entered by the GMO RES COM participants, the database is now public and biosafety research project leaders are encouraged to enter their projects directly into the database. A direct link between the GMO RES COM database and the existing ICGEB bibliographic database is being created.

- The ICGEB is playing an increasing a role in publication of scientific articles in the area of GMO biosafety. The Italian Ministry of the Environment also funds the publication of the *Collection of Biosafety Reviews* (http://www.icgeb.org/~bsafesrv/publications.htm; an annual compilation of scientific studies on areas of major interest for biosafety and risk assessment, prepared by internationally recognised scientists summarising the state of the art in their field of biosafety expertise, edited by ICGEB scientists and available for free download from the ICGEB website), as well as an information booklet on GMOs. In addition, the ICGEB Biosafety Outstation at Ca' Tron houses the editorial office of a multidisciplinary international journal, *Environmental Biosafety Research* (EBR: http://www.edpsciences.org/ebr/), which is the official journal of the International Society for Biosafety Research (ISBR: http://www.isbr.info/), and has appeared quarterly since late 2002.

21. Since 1992, ICGEB organises and hosts annual or biannual workshops focussed on general principles of GMO risk assessment, at both introductory and advanced levels, with the participation of scientists, designated experts and officers in governmental agencies working in risk assessment of GMOs at the official level (governments, scientific institutions, private sector, etc.). In collaboration with the Italian Institute for Overseas Agronomy (IAO) and starting in 2005, an additional workshop has been offered which focuses on addressing the issues raised when evaluating individual Environmental Risk Assessment reports.

22. Research at the ICGEB Biosafety Outstation focuses on biosafety questions related to GM plants and their associated pathogens. Its development projects aim to create pathogen-resistant transgenic plants expressing transgenes that are designed –in the light of the fundamental research- to minimise the potential epidemiological and environmental risks arising from their use.

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT (OECD)

SUMMARY OF OECD'S WORK ON THE SAFETY OF NOVEL FOODS AND FEEDS

23. 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 this activity was the elaboration of scientific principles for assessing the safety of new foods or food components produced by means of biotechnology. One of the main outputs of this work was the publication, Safety Evaluation of Foods Derived by Modern Biotechnology - Concepts and Principles (1993). The concept of substantial equivalence was introduced in this document as the most practical approach to food safety. 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 the comparative approach in food safety assessment.

24. Recent OECD activities related to the safety of biotechnology-derived foods and feeds have been undertaken by the Task Force for Safety of Novel Foods and Feeds, which was established in 1999. The main goal of the Task Force is to promote international harmonisation in the safety assessment of novel foods and feeds, especially products of modern biotechnology. In other words, it is the attempt to ensure that the information used in risk/ safety assessments, as well as methods used to collect such information, are as similar as possible. Delegates to the Task Force are from those ministries and agencies, which have responsibility for the safety of transgenic products, from a human food and animal feed safety perspective. Importantly, the Task Force also includes a number of observer delegations from non-member countries, other intergovernmental organisations and invited experts.

25. The main output of the Task Force is its Consensus Documents on food and feed safety. These documents provide information that OECD member countries believe – on a consensus basis – is important in the risk assessment of novel foods/ feeds. To this end, the documents compile information on the major nutrients, toxicants, anti-toxicants and allergens of specific crops. Accordingly, the Task Force has completed and published 11 consensus documents, including soybean, canola, maize, cotton, rice, bread wheat, sugar beet, potato, barley and alfalfa. (A full list of the publications and events of the Task Force is shown in the Annex.) The Task Force has also undertaken special projects, such as the report it prepared for the G8 Summit in 2000, following a request from the G8 Heads of State and Government.

26. In October 2004, the Task Force held a special focus session on the use of Consensus Documents to exchange experiences in their use and identify needs for future work. In this session, amongst other things, it was emphasised that crops of importance to non-members should be considered as future topics. Based on this discussion, the Task Force decided at its last meeting held in June 2005, to start work on two new consensus documents of particular interest to developing countries, that is, papaya and cassava. The concept of drafting these documents was proposed by observer delegations from non-member countries and these delegations have now begun work on these documents as lead countries.

27. Another major activity of the Task Force is a project on molecular characterisation. This work is being carried out in coordination with OECD's Working Group on Harmonisation of Regulatory Oversight in Biotechnology. 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.

28. Dissemination of information relevant to the risk assessment of novel foods/ feeds is another key component of the work of the Task Force. This has been implemented mainly by the use of a website: BioTrack Online (http://www.oecd.org/biotrack/). One of the main components of the website is a product database, which provides ready access to information on those products that have been approved for commercialization in member countries in terms of food, feed or environmental safety. To identify each product in this database, a unique coding system for transgenic plants has been developed. This coding system of Unique Identifiers was developed by OECD's Working Group and has since been recognised as an appropriate identification system of products included in the Biosafety Clearing House of the Cartagena Biosafety Protocol. BioTrack Online also contains the food safety consensus documents, a database for field trials of transgenic organisms, and information concerning the national regulatory systems of each member countries.

ANNEX

LIST OF PUBLICATIONS AND EVENTS OF THE OECD TASK FORCE

Published Documents

To date, 12 documents (including 10 consensus documents) have been published as part of the OECD *Series on the Safety of Novel Foods and Feeds:*

- *Consensus Document on Key Nutrients and Key Toxicants in Low Erucic Acid Rapeseed (Canola) (2001);*
- *Consensus Document on Compositional Considerations for New Varieties of Soybean: Key Food and Feed Nutrients and Anti-nutrients (2001);*
- *Consensus Document on Compositional Considerations for New Varieties of Sugar Beet: Key Food and Feed Nutrients and Anti-Nutrients (2002);*
- *Consensus Document on Compositional Considerations for New Varieties of Potatoes: Key Food and Feed Nutrients, Anti-Nutrients and Toxicants (2002);*
- *Report of the OECD Workshop on the Nutritional Assessment of Novel Foods and Feeds (2002);*
- *Consensus Document on Compositional Considerations for New Varieties of Maize: Key Food and Feed Nutrients and Anti-nutrients and Secondary Plant Metabolites(2003)*
- *Report on the Questionnaire on Biomarkers, Research on the Safety of Novel Foods and Feasibility of Post-Market Monitoring (2003);*
- *Considerations for the safety of Animal Feedstuffs Derived from Genetically Modified Plants (2003);*
- *Consensus Document on Compositional Considerations for New Varieties of Rice: Key Food and Feed Nutrients and Anti-nutrients;*
- *Consensus Document on Compositional Considerations for New Varieties of Cotton: Key Food and Feed Nutrients and Anti-nutrients (2004);*

- *Consensus Document on Compositional Considerations for New Varieties of Barley: Key Food and Feed Nutrients and Anti-nutrients (2004);*
- *Consensus Document on Compositional Considerations for New Varieties of Alfalfa and Other Temperate Forage Legumes: Key Food and Feed Nutrients and Anti-nutrients (2005)*

Previously Published Documents

Although the Task Force did not hold its first meeting until September 1999, there were a number of previous activities, which involved many of the participants to the Task Force. The Task Force has been building on these activities in its current work. They include:

- *Safety Evaluation of Foods Derived by Modern Biotechnology (1993);*
- *Aquatic Biotechnology and Food Safety (1994);*
- *Food Safety Evaluation (1996);*
- *Safety Assessment of New Foods: Results of an OECD Survey of Serum Banks for Allergenicity Testing, And Use of Databases [SG/ICGB(1997)1)FINAL] (1997); and*
- *Report of the OECD Workshop on the Toxicological and Nutritional Testing of Novel Foods [SG/ICGB(1998)1/FINAL] (1998)*

Response to a request from the G8 Heads of State and Government

In the communiqué following their Cologne Summit in June 1999, the Heads of State and Government of the G8 countries invited the Task Force and Working Group to undertake a study of the implications of biotechnology and other aspects of food safety. Subsequently, the Task Force published *The Report of the Task Force for the Safety of Novel Foods and Feeds* [C(2000)86/ADD1], which was forwarded (along with other OECD documents) to the G8 Okinawa Summit in 2000.

Conferences, Workshops and Other Meetings

In addition to the regular meetings of the Task Force held at OECD Headquarters in Paris (at approximately 6-9 monthly intervals) the Task Force has also organised the following Workshop:

- *The OECD Workshop on the Nutritional Assessment of Novel Foods and Feeds, Ottawa, Canada, 2001.*
- *The Workshop on the Safety of Novel Foods and Feeds, Moscow, 2002*

The Task Force (through its bureau and other delegates) also played a role in organising the following OECD events:

- *The OECD Consultation with NGOs, Paris, November 1999;*
- *The OECD Conference on the Scientific and Health Aspects of Genetically Modified Foods - GM Food Safety: Facts, Uncertainties and Assessment, Edinburgh, UK, February/March 2000; and*
- *New Biotechnology Foods and Crops: Science, Safety and Society, Bangkok Conference, Thailand, July 2001*