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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 1

CX/FBT 05/5/1
June 2005

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

To be held in the International Conference Hall at "Makuhari Messe", Nakase, Mihama-ku, Chiba, Japan, from Monday 19 September at 14.00 hours to Friday 23 September 2005

PROVISIONAL AGENDA

Agenda Item	Subject Matter	Doc. Reference No.
	Opening of the Session	
1.	Adoption of the Agenda	CX/FBT 05/5/1
2.	Matters Referred to the Task Force by the Commission and the Other Codex Committees	CX/FBT 05/5/2
3	Review of the Work by International Organizations on the Evaluation of the Safety and Nutrition Aspects of Foods Derived from Biotechnology	CX/FBT 05/5/3
4	Consideration of the Elaboration of Standards, Guidelines or other Texts for Foods Derived from Biotechnology	CX/FBT 05/5/4
5.	Other Business, Date and Place of the Next Session	
6.	Adoption of the Report	

ANNOTATION TO THE PROVISIONAL AGENDA

Item 1 **Adoption of the Agenda (Doc. Ref. CX/FBT 05/5/1):** In accordance with Rule VI.1 of the Rules of Procedure, the first item on the Provisional Agenda shall be the adoption of the Agenda.

Item 2 **Matters referred to the Task Force by the Commission and the Other Codex Committees (Doc. Ref. CX/FBT 05/5/2):** The item includes matters related to the Task Force arising from sessions of the Commission and the other Codex Committees including the Executive Committee, if there is any matter.

Item 3 **Review of Work by International Organizations on the Evaluation of the Safety and Nutrition Aspects of Foods Derived From Biotechnology (Doc. Ref. CX/FBT 05/5/3)**: The Task Force is invited to take note of the results of work done and/or being done by other relevant international fora and organizations in the field of the evaluation of the safety and nutrition aspects of foods derived from biotechnology.

Item 4 **Consideration of the Elaboration of Standards, Guidelines or other Texts for Foods Derived from Biotechnology (Doc.Ref. CX/FBT 05/5/4; CL 2005/2-FBT):** The working document CX/FBT 05/5/4 compiles comments submitted by members and international organizations in response to CL 2005/2-FBT on this issue. The fifth Session of the Task Force is invited to consider:

- new work items to be undertaken by the succeeding sessions of the Task Force and priorities among them;
- arrangements or mechanisms for facilitating the work agreed on by the Task Force (establishment of inter-sessional working group, etc);
- need for additional scientific advice;

The Task Force shall agree on project document(s) based on the above discussion to be submitted to the Commission

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Item 5 **Other Business, Date and Place of the Next Session:** The Task Force will discuss issues raised under Item 1.

Item 6 **Adoption of the Report:** In accordance with Rule IX of the Rules of Procedure, the Task Force shall adopt the report of its Fifth Session based on a draft provided by the Secretariat.

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Agenda Item 2

CX/FBT 05/5/2
July 2005

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

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

Fifth Session
Chiba, Japan, 19-23 September 2005

MATTERS REFERRED TO THE TASK FORCE BY THE COMMISSION AND THE OTHER CODEX COMMITTEES

A. MATTERS ARISING FROM THE CODEX ALIMENTARIUS COMMISSION

THE 27TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION

ELABORATION OF NEW STANDARDS AND RELATED TEXTS

Draft Terms of Reference and the Project Proposal for the New Ad Hoc Intergovernmental Task Force on Foods derived from Biotechnology[1]

1. The Commission recalled that at its last Session it discussed the establishment of a new Task Force on Foods derived from Biotechnology and asked Japan to prepare a project document and draft Terms of Reference. Noting the view of the 54th Session of the Executive Committee, the Commission agreed to establish a new *Ad Hoc* Intergovernmental Task Force on Foods derived from Biotechnology with the understanding that its final report should be submitted to the Commission in 2009. It also agreed that a Circular Letter[2] be issued to solicit specific proposals for new work and to define priorities and that comments received would be distributed as a working document for the consideration by the first session of the Task Force. The Commission adopted the Terms of Reference with a few amendments (attached as Appendix I to this document).

B. MATTERS ARISING FROM OTHER CODEX COMMITTEES

CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING[3]

2. The Codex Committee on Methods of Analysis and Sampling (CCMAS) has been discussing appropriate methods of detection and analysis for the GM foods since its 24th Session in 2002. In view of the absence of precise provisions for GMOs in Codex and of difficulties with the practical application of

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1 ALINORM 04/27/41 paras 89-91 and Appendix VIII

2 CL 2005/2-FBT

3 ALINORM 03/23 paras 71-81, ALINORM 04/27/23 paras 107-117, ALINORM 05/28/23 paras 108-116

methodology in this area, the CCMAS proposed to develop recommendations with respect to criteria for methods of analysis and for quality control measures that should be introduced in laboratories offering GM analysis.

3. The Working Group led by Germany and the United Kingdom has been working on the text for "Guidelines for the Validations and Quality Control Requirements for the Analysis of Foods derived from Biotechnology" for consideration at the 27th Session of the CCMAS which will be held in May 2006.

C. MATTERS FOR INFORMATION TO THE TASK FORCE

CODEX COMMITTEE ON FOOD LABELLING[4]

4. The Committee on Food Labelling (CCFL) has been considering for a long time appropriate Codex food labelling provisions for foods derived from biotechnology (the Draft Guidelines for the Labelling of Foods obtained through Certain Techniques of Genetic Modification /Genetic Engineering). An amendment to the General Standard for the Labelling of Prepackaged Foods concerning the transfer of allergens in foods derived from biotechnology was adopted by the Codex Alimentarius Commission in 2001.

5. However, as regards general labelling requirements, this draft guideline is still in an early stage of discussion with many sections bracketed due to lack of consensus. As the text has become too complicated as a result of the discussions for a long time, the 37th Session of CCFL held in May 2005 agreed to reconstruct the draft guideline for the consideration at its next session. The most controversial point is whether or not mandatory labelling provisions should be established for the case where the difference between original products and genetically modified products is solely the production method (in this case gene modification).

[4] ALINORM 05/28/22 paras 46-64

APPENDIX I

TERMS OF REFERENCE OF THE AD HOC INTERGOVERNMENTAL TASK FORCE ON FOODS DERIVED FROM BIOTECHNOLOGY

Objectives

To develop standards, guidelines or recommendations, as appropriate, for foods derived from modern biotechnology or traits introduced into foods by modern biotechnology, on the basis of scientific evidence, risk analysis and having regard, where appropriate, to other legitimate factors relevant to the health of consumers and the promotion of fair practices in the food trade.

Time frame

The Task Force shall complete its work within four years. The Task Force should submit a full report in 2009.

Terms of Reference

(a) To elaborate standards, guidelines, or other principles, as appropriate, for foods derived from modern biotechnology, taking account, in particular, of the Principles for the Risk Analysis of Foods derived from Modern Biotechnology;

(b) To coordinate and closely collaborate, as necessary, with appropriate Codex Committees within their mandate as relates to foods derived from modern biotechnology; and

(c) To take account of existing work carried out by national authorities, FAO, WHO, other international organizations and other relevant international fora.

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Agenda Item 3

CX/FBT 05/5/3
August 2005

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*

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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 OIE

OIE CONTRIBUTION TO THE CODEX AD HOC INTERGOVERNMENTAL TASK FORCE ON FOODS DERIVED FROM MODERN BIOTECHNOLOGY

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As an observer Organisation, the World Organisation for Animal Health (OIE) would like to thank the *Codex Alimentarius* Commission and the Codex *ad hoc* Intergovernmental Task Force on Foods Derived from Modern Biotechnology for the opportunity to contribute to its meetings.

The OIE International Committee is the highest authority of the OIE. It comprises all the Delegates (representing all 167 OIE Member Countries) and meets at least once a year. The General Session of the International Committee debates and adopts proposals for new and revised OIE standards. The OIE has been working on the topic of biotechnology and animal production since 1996 at the request of its International Committee (Appendix I). This year, important steps were taken by the OIE on biotechnology during the 73rd OIE General Session with the presentation of a technical item on Applications of Genetic Engineering for Livestock and Biotechnology Products and the adoption of Resolution XXVIII by the OIE International Committee. The technical item was presented by Dr Anne MacKenzie (from the Canadian Food Inspection Agency) and analyses the answers to a survey in all OIE Member Countries in the field of biotechnology and animal health.

The analysis is attached in Appendix II. Subsequently the OIE International Committee debated the issue and resolved to adopt Resolution XXVIII (Appendix III). This Resolution provides the OIE with the guidance to continue working in the development and adoption of standards in the field of biotechnology within its mandate.

In parallel the OIE published this year the Scientific and Technical Review Vol. 24(1) on "Biotechnology Applications in Animal Heath and Production". This Review aims at collecting some of the most promising applications of biotechnology in the field of animal health and production, in areas such as assisted reproduction, increased disease resistance, nano-based diagnostic and 'smart' treatment delivery systems, improved vaccines and refined diagnostic techniques. This Review identifies national, regional and international policies, institutions and regulatory frameworks, and discusses the role of international standard-setting bodies. The full content of the Review can be find on-line at the following address: http://www.oie.int/eng/publicat/RT/A_RT24_1.htm. Please find enclosed the paper copy of this Review.

Resolutions

adopted by the International Committee of the OIE during its 64th General Session

May 1996

PARIS, May 1996

RESOLUTION No. XV

Biotechnology and animal production: advantages and problems

CONSIDERING THAT

Livestock species exhibit considerable genetic variation for resistance/susceptibility to a wide spectrum of pathogens; however, this resistance is currently often poorly defined and quantified

An understanding of such genetic disease resistance might become an essential tool for disease control

Livestock genomics is an emerging and very powerful strategy which could – if properly applied – be ideally suited to dissect the molecular basis of disease resistance

The application of genomics to disease resistance in livestock might result in information which will need to be integrated into existing breeding schemes

The successful implementation of such programmes requires highly-skilled scientists

The intellectual property rights on information resulting from genomics remains an unresolved issue

The implementation of these projects requires full support from decision-makers and the public, who demand to be properly informed of the nature and use of these projects

THE COMMITTEE

RECOMMENDS THAT

1. Regional Commissions encourage and assist research efforts aimed at identifying and quantifying genetic disease resistance which might exist in the livestock breeds encountered in their respective areas. This information would be centralised in appropriate databases in the Central Bureau in coordination with the FAO.

2. Regional Commissions encourage and assist efforts aimed at collecting biological material from informative pedigrees, in which objective evidence for the segregation of a highly heritable resistance for an economically important disease has been demonstrated. This information would be centralised in appropriate databases in the Central Bureau in coordination with the FAO.

3. Regional Commissions encourage and assist efforts aimed at establishing laboratories with competence in livestock genomics in their respective areas.

4. Regional Commissions encourage and assist research efforts aimed at developing breeding schemes which would integrate resulting molecular information and conventional selection strategies.

5. Given the sophistication of genomics, the OIE provide educational support for these projects by encouraging publications and conferences on the topic, by experts in the area, and by encouraging collaboration between institutions with complementary expertise including exchange of scientists (especially between developed and developing countries).

PARIS, May 1996

6. The OIE establish an ad hoc group to establish guidelines for the regulation of intellectual property of the results which will be generated by these projects.

7. The OIE encourage and assist efforts aimed at informing the public and decision-makers of the nature and utility of these efforts to achieve food and nutrition security in a sustainable way.

(Adopted by the International Committee of the OIE on 24 May 1996)

PARIS, May 1996

73rd General Session International Committee Appendix
World organisation for animal health Paris, 22-27 May 2005

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APPLICATIONS OF GENETIC ENGINEERING FOR LIVESTOCK AND BIOTECHNOLOGY PRODUCTS

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Summary: *The influence that biotechnology is having and will have in the future on animal health is now being realised well beyond the researchers' laboratories. An examination of the evolution of reproductive biotechnologies is presented. The latest techniques allow for the use of transgenic farm animals as sources of biologically activated proteins, bio-pharmaceuticals, as donors in xenotransplantations and for further research in gene therapy, all of which are important applications in human medicine. The beneficial applications of embryo transfer include disease control, transboundary movement of livestock and the provision of sexed sperm and sexed embryos. Although cloning of livestock is a multi-step complex process and the technology needs further evaluation, benefits such as the multiplication of desired traits and the conservation of animal germplasm clearly are substantial benefits. With the application of transgenesis in livestock, the benefits of disease resistance, improved meat, milk and wool quality and protein production in milk and meat (biofarm animals) are major benefits. It is predicted that biotechnology-derived vaccines will become common in animal health programmes where they can be shown to have improved efficacy and safety compared to conventional products.*

When carrying out risk assessments for genetically engineered animals, conventional techniques and tools will be useful but it is important to be aware that because limited data are available, the actual hazard identification will be a considerable challenge. As the new technologies with their adherent applications evolve, standard setters and regulators will be faced with the challenge of moving in parallel with technological advances.

In response to a questionnaire sent to Delegates of OIE Member Countries, only 40% of respondents indicated that their animal health regulatory administrations have the capability of conducting risk assessments on biotechnology derived animals or products. Likewise, 20% of respondents do not consider the guidelines for risk analysis adequate to help carry out an import risk analysis on biotechnology-derived animals or products. Furthermore, 50% of respondents do not have a regulatory framework in place to govern cloning, transgenic production or products of biotechnology such as vaccines. Public perception in relation to cloning and biotechnology-derived animals will present considerable challenge to Member Countries with 79% reporting no public support for cloning and 52% reporting biotechnology-derived animals perceived as controversial.

There is considerable work that must be initiated by both Member Countries and the OIE to allow appropriate progression in the very important field of biotechnology and animal health.

1. Introduction

The continued challenge that OIE Member Countries currently face with the globalisation of agriculture is not limited to the animal health issues arising from infectious and zoonotic diseases. The fact that reproductive biotechnologies combined with genetic manipulations have developed animals with varying traits poses a new and different kind of challenge to the OIE and the scientific community. We are entering an era which will see more widespread use of reproductive technologies combined with gene manipulations to develop livestock and aquatic animals that can propagate superior or desired traits. Central to the idea of genetic improvement of domestic animals by selective breeding or cross breeding, the world today is presented with the scientific opportunity through assisted reproductive technologies and genetic manipulations that could have a positive impact on public health and well being.

The techniques of molecular biology provide a great potential for the production of important medical and agricultural products. The production of biotechnology-derived drugs and vaccines relies heavily on recombinant DNA technology for the design of useful products. The production of recombinant proteins in 'transgenic animal bioreactors' is another application of modern biotechnology in agriculture. Preceding the release of any biotechnology-derived animal into the environment, extensive safety evaluations are carried out to verify if it is safe according to currently available expertise. However, as the risk assessments rarely evaluate the risk as zero, biotechnology products in agriculture are regulated, and the purpose of the existing safety guidelines is to assure that these products pose a minimal risk to public health and the environment. The purpose of this OIE Technical Item II is to discuss the technology that is used to develop biotechnology-derived animals, the applications in the fields of animal health and diagnostics, the delicate balance between regulatory frameworks and the ethics of the science, sound risk assessments based on current science and to present to the Member Countries an overview of the applications of biotechnology in the global context.

2. Techniques

The past four decades have witnessed the commercial adaptation of four generations of reproductive biotechnologies, particularly with cattle. It started with artificial insemination and moved to a second level when *in-vivo*-derived embryos were harvested and transferred. The third generation consisted of the *in-vitro* fertilised embryos, sex sorting sperm, ovum pick-up and cloning and finally we are at a stage when we are using functional deletion and addition of specific genes to the offspring's genome through transgenesis, combined with powerful molecular biology techniques of siRNA (small interfering RNAs) and the use of viral vectors. Recently there have been combinations of transgenics being propagated by somatic cell nuclear transfer techniques, thus taking reproductive biotechnologies a step further.

Embryo transfer of *in-vivo*-derived embryos was a huge step to increase the propagation of germplasm of the desired trait. Compounded by the success of multiple ovulation and embryo transfer technology (MOET) there was an upsurge in the transfer of bovine embryos, especially in North America, where 35% of the 538, 312 embryos available worldwide were transferred in 2002 (7). The *in-vitro* embryo production system was instrumental in bringing a spurt in embryo transfer activities across the globe. The data collected in 2002 showed that more than 80,000 *in-vitro* produced (IVP) embryos were transferred. The IVP embryos provided a window of opportunity for 'invasiveness' in terms of techniques to assess the embryo characteristics. This included obtaining an embryo biopsy for the purpose of prenatal sex determination. The use of biopsies for pre-natal genetic diagnosis, blastomere assessment for cloning and for other purposes is still utilised in many settings.

Production of identical offspring with somatic cell nuclear transfer (cloning) was a big step forward, as earlier embryos were split prior to transfer to achieve the same result. As early as the 1980s Steve Willadsen showed that embryonic cells from 8-16 cell embryos could be used for embryonic cell cloning, but the birth of 'Dolly' in 1996 proved that there was a possibility of reprogramming adult differentiated cells. Nuclear cloning is, however, currently an inefficient process with a success rate of 6-10% of embryos transferred to the cattle resulting in a healthy offspring. There are concerns related to higher losses in pregnancy, placental dysfunctions, incorrect epigenetic reprogramming and post natal complications. These abnormalities may be

epigenetic errors that can be corrected during gametogenesis. While the technology is still not beyond the infancy stage, the confidence among the researchers that this could result in genetic preservation and disseminating genetic gains, begs attention both from the scientific point of view as well as other issues related to ethics, welfare and product safety. In contrast to the cloned animal in which some of the anomalies are viewed, the offspring of clones produced following sexual reproduction appear phenotypically normal. Because nuclear cloning can also result in physiologically normal animals, it is anticipated that the initial commercialisation of this technology will focus on producing small numbers of high value animals for breeding purposes, and possibly also transgenic dairy animals capable of producing valuable pharmaceuticals in their milk.

The first transgenic livestock were produced almost 20 years ago by micro-injection of DNA into the pronuclei of zygotes. Pronuclear microinjection of DNA was the standard method for producing transgenic animals until now. However, this is now being replaced by more efficient methods based on somatic nuclear transfer, which also permit targeted genetic modifications. Lentiviral vectors and siRNA technology are also being used for transgenesis. Research has been focussing on chimera generations via injection of pleuripotent cells in early pre-implantation embryos or blastocysts. Transgenesis has also been achieved in livestock by the culture of spermatogonia and their transplantation into recipient males. A novel approach is the use of active siRNA, and the simplicity of this has facilitated adoption of this method to generate permanent or transient knockouts for specific genes. The combination of siRNA and lentiviral vector technology may provide enhanced gene transfer efficiency and specificity in gene knockouts for cattle. Transgenic farm animals are important in human medicine as sources of biologically active proteins, bio-pharmaceuticals, as donors in xenotransplantation, and for research in gene therapy.

3. Applications

For ease of explanation, this part will deal with the applications of technologies in current use that have gained importance in the last three or four decades. The first consideration is the embryo transfer technology which is still the backbone of any assisted reproductive biotechnology. The embryo may be produced *in-vitro*, and may be manipulated or cloned, yet it still has to be transferred to a recipient to bear the offspring.

3.1. Embryo transfer: *in-vivo* and *in-vitro* embryos

The embryo transfer industry grew rapidly in the late 1970s, both in terms of the number of practitioners and in the number of donors flushed. North America has continued to be the centre of commercial embryo transfer activity with more than 190,000 bovine embryos transferred annually. The importance of follicle wave dynamics and methods for the synchronisation of follicular wave emergence has simplified the means by which superovulation might be achieved, resulting in increased embryo production per unit time. Some of the applications that are of clear benefit to the embryo industry are:

3.1.1. Disease control

Several large studies have now shown that the bovine embryo does not transmit infectious diseases, if recommended precautions such as those mentioned in the OIE *Terrestrial Animal Health Code* (the *Terrestrial Code*) are followed. In fact the International Embryo Transfer Society (IETS) – an international embryo biotechnologists association, has categorised disease agents based on the risk of transmission by a bovine embryo. It is noteworthy that none of the infectious diseases studied have been transmitted by *in-vivo*-produced bovine embryos, provided embryo handling procedures were done correctly. Consequently, it has been suggested that embryo transfer could be used to salvage genetics in the face of a disease outbreak, which could also be a useful option in the establishment of disease free herds.

3.1.2. Transboundary movement of livestock

The intercontinental transport of live animals costs a lot, whereas an entire herd can be transported, in the form of frozen embryos, for much less. Added benefits of frozen embryos over live animals include reduced risk of disease transmission, reduced quarantine costs, a wider genetic base, the retention of genetics within the exporting country, and adaptation. The procedures recommended by the IETS for embryo handling that have been endorsed by the OIE, greatly reduce the possibility of infectious agents being transferred in *in-vivo* derived embryos. However, there is still some risk of infectious agent transmission with *in-vitro* derived, abattoir retrieved oocytes, and those with zona breaching.

The development of effective methods of freezing embryos has made embryo transfer a much more efficient technology, that is no longer dependent on the immediate availability of suitable recipients. Researchers have directly addressed the question of using IVP as a substitute for *in-vivo* production of embryos by conventional embryo transfer procedures. However, it is unclear whether IVP is a realistic alternative to conventional superovulation and embryo transfer for production of embryos from reproductively healthy cattle.

3.1.3. Sexed sperm and sexed embryos

Determination of the sex of pre-implantation bovine embryos with the use of the polymerase chain reaction (PCR) is also commonly employed in some situations. However, the removal of the biopsy from the embryo requires a high level of operator skill, and embryo biopsy is an invasive technique that results in the invasion of the integrity of the zona pellucida, and results in some reduction in the viability of the embryo. The flow cytometric technology used to separate X- and Y-bearing sperm into live fractions has been improved over the last 10 years. With a purity of 90%, about 10 million live sperm of each sex can be sorted per hour. In both cases there is a potential to establish embryo banks to obtain the progeny of choice in any setting. This can reduce the unnecessary cost of producing large number of embryos and transfers related to that.

The science and practice of artificial embryo production (*in-vitro*-produced and *in-vivo* derived) has given us insight into the early embryonic period and the later fetal and neonatal development. By studying in greater detail the aberrant features of artificially produced embryos, one may find that these very same mechanisms lie behind the so-called "normal" fetal and neonatal loss. This will not only help to improve the efficiency but also provide us with the possibility of critically analysing the more invasive procedures (like biopsy, pronuclear injections etc.) that precede the embryo transfer.

4. Nuclear transfer cloning

Cloning livestock following somatic cell nuclear transfer involves multiple steps, each with potential for disturbing development of the embryo and foetus, and affecting health during adulthood. For these reasons, the technology needs to be thoroughly evaluated to fully appreciate the longer-term consequences on the animals produced. However the application of this technology, although limited at the present time, shows promise of increased benefits:

4.1. Multiplication of desired traits

Cloning could enable the rapid dissemination of superior genotypes from nucleus breeding flocks and herds, directly to commercial farmers. Genotypes could be provided that are ideally suited for specific product characteristics, disease resistance, or environmental conditions.

4.2. Conservation of animal germplasm

Cloning technology can help salvage the germplasm of indigenous species that are near extinction, including intra-species nuclear transfer procedures which can be used to rescue genes from endangered species.

4.3. Research model

Animals can be cloned for research purposes, to provide a basic research model of genetically identical individuals, reducing variability in the outcome of experiments.

4.4. In association with transgenic applications

Cloning can provide a rapid way to increase the population or number of the transgenic animals, and this can permit the testing of genetic stability with reduced progeny intervals.

An increasing body of international data indicates that the major abnormalities in clones are probably epigenetic in nature and do not appear to be transmitted to offspring, even when male and female clones are mated. However, there is the need for molecular confirmation of this observation, which will be important in providing confidence in large scale breeding applications of genetically elite cloned livestock. Despite the present limitations of cloning, milk or meat from these cloned livestock does not appear to be materially different from conventionally bred animals (1). If the acceptability and utility of this emerging technology are to be improved, it is important to understand the biology behind nuclear cloning to improve the health and viability of the cloned animals produced and their surrogate mothers.

5. Transgenesis

Application of Transgenesis in livestock has been instrumental in the development of animals that are: resistant to diseases, have improved meat, milk or wool quality, can increase proteins in their milk or meat (biopharm animals), or which have characteristics which are environmentally friendly. The production of recombinant proteins is one of the major successes of biotechnology. Milk, egg white, blood, urine, and seminal plasma can be sources for recombinant proteins. Numerous experiments have shown that the prediction of the expression of transgenic proteins is possible to a limited extent. The purification of proteins from the milk or other body fluids is not too difficult except for those present in blood. The available techniques to produce pharmaceutical proteins can be used to add nutriceuticals to milk, and to improve carcass quality or meat composition of the livestock or farm animals. Antibodies seem to be the kind of proteins that will be most frequently used, as they could be a good alternative to antibiotics for some infectious diseases.

The application of techniques related to the production of recombinant proteins in milk has reached a certain degree of maturity but there is much to do yet. The combination of recent advancements in reproductive technologies with tools of molecular biology opens the horizon to a new era in transgenic biotechnology. The growing amount of data from the human genome project will certainly inspire intense genome sequencing in livestock, and somatic cloning will pave the way for the introduction of novel transgenics in livestock.

6. Xenotransplantation

The possibility that xenotransplantation may offer an opportunity to have an alternative to organ transplantation from human donors is very attractive to researchers. The application of transgenic technologies can alter donor animals, so that the stimulus to induce immune rejection in recipient patients is much reduced. The research in this area is focussed on the pig genome, to make organs and tissues more compatible to humans. Disruption of the gene causing hyperacute rejection response (Galactose alpha 1, 3 galactose), by gene targeting in GM pigs, has been achieved and further use of nuclear transfer for propagating them is in progress. This provides immense hope for patients awaiting transplantation and needing organs or tissues to fight major medical conditions such as heart disease and diabetes.

7. Vaccines

There are three major considerations in the registration of vaccines for use in animals, and biotechnology-derived vaccines have both advantages and disadvantages in each of these areas. The OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (the *Terrestrial Manual*) and the *Terrestrial Code* (5) make mention of these conditions. However, considerations are described in different ways in different regulations, but the key elements that must be demonstrated in any vaccine are efficacy (not worthless, satisfactory potency), purity (not contaminated) and safety (not dangerous or harmful to the environment, humans or animals).

Efficacy is usually determined following a challenge of vaccinated and control animals using a specific disease model. The observed protection from clinical disease or death following a specific dose and route of vaccination is used to formulate a claim for the vaccine product. Subsequent batches or serials of vaccine are compared to the original batch used in this study, and a potency test is developed to enable the prediction that each serial with a satisfactory potency test will lead to the same level of protection observed in vaccinated animals in the study. Biotechnology-derived vaccines which incorporate antigens which are known to be targets of a protective immune response and which present those antigens in a manner to maximise the required type of immune protection may enhance efficacy. These vaccines may also have more thermostable antigens, perhaps plant-derived proteins, allowing this vaccine potency to be maintained in the absence of a cold chain in tropical countries. In many disease models, though, the use of live attenuated disease organisms in vaccination leads to the highest level of immune protection, even if there are some residual safety concerns.

Purity is determined by ensuring that the organisms and ingredients used to make the vaccine are not contaminated with other microorganisms, or toxins, or perhaps prions. With many biotechnology-derived vaccines, the platform expressing the antigens of interest is well characterised, and the vaccine can often be produced with a minimal risk of contamination. Growing more conventional pathogens for the production of killed vaccines often requires the use of materials of animal origin in order to maximise the expression of the antigens of interest, which increases risks of contamination of the vaccine. On the other hand, plant-made vaccines grown in open fields risk having undefined contamination such as weeds, fungus or insects, but this may not impact on the safety of the product if administered orally.

Safety is probably the most important potential advantage of biotechnology-derived vaccines. DNA vaccines which do not require oil-based adjuvants are safer to administer by humans and are also safer for animals including fish than some conventional vaccines. Vectors for recombinant vaccines can be selected to minimise any possibility of reversion to virulence which sometime occurs with live attenuated vaccines. Conventional vaccines may also contain toxic elements that are not completely inactivated or removed by the manufacturing process, and which may not be necessary for stimulating immune protection in the animal. Removal of these toxins in biotechnology-derived vaccines improves product safety to both humans handling the vaccine or eating vaccinated animals, and to the animals themselves. The use of genetically-modified vectors or plants in the environment does raise some concerns of environmental safety which may be different than the use of conventional live attenuated vaccines. Steps must be taken in the approval process of these products to evaluate and to minimise all of the potential concerns which can be identified.

Ultimately, the usefulness of vaccines will be determined by their availability. This, in turn, is affected by elements such as cost of production and acceptance of a role of vaccination in disease control programmes. Biotechnology-derived vaccines will become common in animal health programmes in cases where they can be shown to have improved efficacy or safety when compared to conventional products, and if they are available.

8. Risk assessment considerations

Advances in genetic engineering continue to emerge at an accelerating pace, enhancing the potential for its applications. It is anticipated that commercialisation of farm animals genetically engineered to produce unique traits will soon be a reality. Both transgenic and cloned animals raise potentially new concerns about food safety, human health, animal health (and welfare), and the environment. Therefore there is a pressing requirement to develop methodologies to adequately assess the safety of such animals.

To this end, there is a need to bring together scientists, regulators, international organisations, such as OIE, FAO and WHO and other stakeholders to identify and review the science-based data and concerns relevant to science-based risk assessment and management of genetically engineered animals released into the environment. These expert consultations could help design research to solve problems as well as to identify and develop appropriate management practices to minimise risks associated with genetically-engineered animals.

Risk assessment for genetically engineered animals is not much different than that for conventional animals but because of limited data, general uncertainties and unknowns, the paramount point of a risk assessment, hazard identification, remains an enormous challenge for the risk assessors.

The major difference resides in the identification of hazards from potential genetic abnormalities (phenotypically or genotypically) that can be of possible harm. Since animals exhibiting grossly undesirable effects are likely to be eliminated during commercial development, the areas of concern are those caused by subtle dysregulation of genes.

The following questions, arising from these subtle genetic abnormalities, will render risk assessment more complex and probably, in early stages, result in a high degree of uncertainty:

- How would one detect them?
- How would subtle genetic hazards from genetically-engineered animals differ from the gene dysregulation arising in conventional animals?
- How frequent do they occur compared to conventional animals?
- Would these genetic hazards pose a risk?
- Should they pose a risk, how to measure risks if they happen?

In addition to risk assessment, risk analyses pertaining to genetically-engineered animals involves risk communication (throughout the entire process) and risk management. These other components of the analysis must also take economical, ethical and societal as well as animal welfare factors into account.

At this early stage of the development of genetically-engineered animals, assessments will be based upon data extrapolated from related studies done with other genetic modifications or in other species, often utilising material supplied by the companies marketing the products. In this context, Governments must maintain the public trust at a high level through impartiality, integrity and transparency of its decision making process with respect to genetically-engineered animals and their products.

It is perhaps reasonable to believe that in the coming years, the analysis of the risks associated with genetically-engineered animals will become routine, as it has for the import of conventional animals and animal products. Ongoing improvements in the techniques of genetically-engineered animal production will likely reduce the incidence of animal health problems now recognised, and the continued growth of the body of knowledge will reduce the uncertainties that now exist. Additionally new techniques and increased experience will also improve methods of risk management.

Conversely, future research and new techniques will perhaps identify hitherto unknown problems for the risk analyst to deal with - as old issues get resolved, new ones may emerge. It is safe to assume that the challenges presented by animal biotechnology for the risk analyst and other regulatory staff will continue for some time to come.

9. Regulatory Framework

New technologies need to be controlled by guidelines or regulations so as to maximise benefits and minimise risks to humans, animals and the environment. The acceptance of agricultural biotechnology will depend on whether consumers see an obvious personal and societal benefit in the new products. However, the role of the regulators is also to assist the public make an informed decision by critically evaluating the data related to the technology, and determining the level of risk to the consumer, the animal population, and the environment. Development of legislation and the regulatory provisions do not move as quickly as advances in science. In most cases the regulations are developed to address the concerns of the consumers and society and to provide a much needed level of protection.

Since transgenesis and cloning are relatively new scientific techniques, transgenic animals are new organisms for which there is limited information. The issues associated with the regulation and biosafety of transgenic animals pertain to environmental impact, food safety, animal health and welfare, trade and ethics. To regulate this new and powerful technology predicated on limited background information is a challenge not only for the regulators, but also for the developers of such animals, who strive to prove that the animals are safe and merit bio-equivalency to their conventional counterparts. In principle, an effective regulatory sieve should permit safe products, while forming a formidable barrier for those assessed as posing an unacceptable risk.

The regulation of products derived from biotechnology can be based on the principles used for conventionally produced animals. Regulations and standards for determining a responsible use of animal biotechnology in food and agriculture are based on principles that take into account criteria such as benefits and risks, scientific basis of biotechnology and effects on the environment, and must also consider animal welfare and social acceptance (4). Transgenic animals may be viewed as most acceptable if the end result of the genetic manipulation applied is to provide better quality of life for humans, or to provide 'environmentally friendly' alternatives to 'factory farms'. The regulations that each country employs to safeguard the public, the animal population, and the environment from unintended effects of novel products or technologies are specific to the way the regulatory framework is established. For example, some countries may have an approach to regulate the technology, while others may be regulating the products of biotechnology. Some of the salient considerations for sound regulation developments are:

- high standards for human and animal health and welfare
- development of clear standards and guidelines for assessments
- provision of sound scientific basis to evaluate associated risks
- consultation and involvement of stakeholders in the development of regulations
- maintenance of genetic diversity and conservation of environment
- building upon existing regulations

The existing scenario allows us to extrapolate the standards and to develop regulations from the continued research and work being done by international organisations such as the OIE, FAO and the International Embryo transfer Society (IETS). IETS was founded in 1974 with 82 charter members, representing researchers, academics and veterinary practitioners. A growing majority of the IETS membership is composed of basic researchers representing government, industrial or academic institutions, including human medicine. However, the IETS has played a very important role in the dissemination of basic and applied information, allowing for the rapid growth of the embryo transfer industry in the 1980s and 1990s. In particular, the Import/Export Committee of the IETS now referred to as the Health and Safety Advisory Committee (HASAC) has been instrumental in gathering and disseminating scientific information on the potential for disease control by the use of bovine embryo transfer. There was the round table meeting on sanitary issues related to embryo transfers between the IETS and the World Organisation for Animal Health (OIE) in 1985 (*Rev. sci. tech. int. Epiz.*, 1985, **4**, 843-913), resulting in the drafting of sanitary procedures for the international movement of embryos in the OIE *Terrestrial Code*, and the International Embryo Movement Symposium, sponsored by the IETS. These events along with continued close collaboration between the IETS

and the OIE have made the international movement of cattle embryos possible. In this regard, The Manual of the International Embryo Transfer Society *"A procedural guide and general information for the use of embryo transfer technology emphasising sanitary procedures"* (6) has become the reference source for sanitary procedures used in export protocols. Today most of the international movement of embryos are based on the recommendations of IETS many of which are endorsed by the OIE *Terrestrial Code* and the procedures documented in the Manual of IETS are the red book letters for the regulators.

International organisations such as FAO have conducted workshops as technology has progressed, including "Gene-based technologies" (2), and the expert consultation on genetically modified animals (Rome 2003). The recommendations of these consultations and workshops form a solid basis for development of regulations in general. The forums where the food safety of cloned animals and international movement, identification and traceability of the embryos is discussed and standards recommended, takes place under the auspices of different subcommittees of IETS.

In essence the regulatory framework may be very specific to the region and the country, yet the consideration is more towards harmonising the approach, so as to facilitate sharing of safety information, and to help countries prevent the spread of disease or infections through germplasm. The OIE has therefore an important role to play as a standard-setting body in accordance with its mandate under the WTO-SPS Agreement.

10. Questionnaire

The OIE sent a questionnaire to the Delegates of all 167 OIE Member Countries to assemble baseline information on some questions relating to applications of biotechnology for livestock and animal health products. Responses were received from 91 countries, including a broad cross-section of Member Countries from all regions. The results are presented as Appendices I and II and are summarised in this preliminary analysis. The questions and tabulated summary results will be posted on the OIE website. This information will provide a useful baseline to identify topics for discussion in international reference groups and standard setting bodies such as the World Organisation for Animal Health (OIE), and international organisations such as Veterinary International Cooperation for Harmonisation (VICH), and International Embryo Transfer Society (IETS).

The responses to this survey have illustrated a number of common interests and concerns for animal health regulatory agencies as well as livestock producers and consumers. There are many potential opportunities for international collaboration in establishing technical standards and risk assessment procedures for these technologies. It is clear that the OIE and affiliated standard setting bodies will have a key role to play in facilitating the dissemination of information on development of appropriate risk-based regulatory standards, approval processes, and certification procedures for biotechnology-derived livestock and animal health products.

The OIE formed a Biotechnology Working Group in 1989. This Working Group was active until November 2000, however it is no longer functioning, and it has been decided that rather than maintaining an ongoing working group for this topic, the work will now be incorporated into other Ad hoc Groups which will be assigned to study specific topics. It is possible that this survey and the review papers in the Scientific and Technical Review will help to identify issues for further discussion, including some topics which might be referred to *ad hoc* groups for in depth analysis and recommendations.

The following 91 countries provided a response to the questionnaire: Algeria, Andorra, Angola, Argentina, Australia, Austria, Azerbaijan, Belgium, Benin, Bhutan, Bosnia and Herzegovina, Brazil, Brunei, Burkina Faso, Cambodia, Canada, Colombia, Congo (Dem. Rep.), Costa Rica, Cote d'Ivoire, Cyprus, Czech Republic, Denmark, Dominican Republic, Ecuador, Egypt, El Salvador, Eritrea, Estonia, Finland, France, Georgia, Germany, Ghana, Greece, Guatemala, Guinea Bissau, Hungary, Iceland, India, Japan, Kazakhstan, Kenya, Kuwait, Latvia, Lithuania, Luxemburg, Madagascar, Mali, Mauritania, Mauritius, Mexico, Moldavia, Morocco, Myanmar, Namibia, Nepal, Netherlands, New Caledonia, New Zealand, Nicaragua, Norway, Pakistan, Paraguay, Peru, Philippines, Poland, Portugal, Romania, Serbia and Montenegro, Slovakia, Slovenia, Spain, Sudan, Swaziland, Sweden, Switzerland, Taipei China, Tanzania, Thailand, Togo, Trinidad and Tobago, Tunisia, Turkey, Uganda, Ukraine, United Kingdom, United States of America, Uruguay, Venezuela and Zimbabwe.

11. Definitions

Eighty-one of the ninety-one OIE Member Countries (89%) responding to question 1 agreed with the proposed definitions as applicable to livestock biotechnology. Agreement was consistently high across all geographical areas. Where respondents did not agree with the definitions, the most highly suggested sources for definitions were the Cartegena Protocol on Biosafety to the Convention on Biodiversity and Codex Alimentarius in its Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003).

12. Risk Analysis

Fifty-three of the eighty-nine (60%) Member Countries that responded to question 3 reported that the animal health authority in their country does not have the capability to conduct risk analysis on biotechnology-derived livestock and biotechnology products. The two main reasons reported for not performing risk analysis on these commodities are the absence of training (53%) and the lack of knowledge (26%).

Eighty-four per cent (75 of 89) of the respondents indicated that they do not have a dedicated unit conducting risk analyses pertaining to biotechnology commodities (question 4). Risk analyses are being conducted by the epidemiology and surveillance unit in 29% of cases, and 37% of respondents answered that other units conduct these risk analyses. Only 9% use an external consultant to conduct a risk analysis on these commodities. Forty five per cent of the Asian respondents indicated that risk analyses are conducted by the Import-Export unit.

In question 5, the major factors identified by the animal health authorities as being considered when determining the risk associated with these biotechnology commodities are respectively: food safety (26%), animal health (26%) and environmental impact (23%).

Only 25% of the Member Countries have conducted (or received a request to conduct) a risk analysis on biotechnology commodities, for a total of 33 requests (question 6). In 52% of the cases (17 cases out of 33), the risk analyses were conducted (or were requested to be conducted) on biotechnology products, whereas only three were requested on cloned animals and seven were requested on transgenic animals. Most of the requests are from countries in the Americas (13 cases).

Only 29% (25 out 89 respondents) of the Member Countries are willing to make their risk analysis document available for peer review or for public consultation, using official government publication as the main means of dissemination. Peer reviews are mainly conducted internally (45%) within the veterinary services. Only European Member States reported having risk analyses peer reviewed internally (37%) or externally (36%) at approximately the same proportion.

Seventy-seven per cent of the respondents (63 of 81) to question 8 considered that the "Guidelines for risk analysis" contained in the OIE *Terrestrial Code* were adequate to carry out an import risk analysis on a biotechnology commodity. Forty-four per cent of the Member Countries (8 of 18 respondents) that considered that these "Guidelines for risk analysis" were not adequate are from the Americas, and these Member Countries also reported receiving most of the requests (39%) for conducting a risk analysis (question 6).

13. Regulatory framework

Sixty-four per cent (58 of 91) responding OIE Member Countries to question 9 reported that they did not produce biotechnology-derived animals or biotechnology-derived products for use on animals. Out of the 31 Member Countries responding "yes" to question 9 (note that 2 did not answer), 14 countries (45%) are European Member States.

Respondents to question 10 reported having capabilities in the following fields: cloning (17%), transgenic production (20%) and products of biotechnology for use in animals such as vaccines and/or drugs (28%). Thirty-five per cent of respondents to the questionnaire did not provide an answer to this question.

Approximately half of OIE Member Countries responding to question 11 reported having a regulatory framework in place to govern the use of a biotechnology commodity (44 reported having a framework out of 89 respondents). Sixty-two per cent of European Members States and fifty-three per cent of Countries from the Americas responding to question 11 indicated that they have a framework in place to govern the use of such commodities

14. Research

Slightly less than half (47%) of the 91 responding OIE Member Countries to question 12 reported that there is research being conducted in their country into biotechnology-derived animals and products, including vaccines and drugs. At 64%, Asia had the highest percentage of responding countries engaged in animal biotechnology research activities, followed closely by Europe at 59%, the Middle East at 50%, the Americas at 41%, and Africa at 25%. Although this question covers a wide variety of activities, the results indicate that this is an active area of research.

15. Animal Vaccines

Forty out of eighty-nine responding OIE Member Countries (44%) to question 13 reported that they produced or used animal vaccines in their countries that are biotechnology-derived. This may include experimental products that are not currently licensed for general use, since the question did not ask that countries specify the licensing or marketing authorisation status of products.

Twenty-six of the forty countries who replied said that they produced or used viral vectored vaccines (29% of the responders to this question) which included antigen(s) from unrelated organisms. Sixteen countries (18%) reported using bacterial vectored vaccines which include antigen(s) from unrelated organisms. Twenty-two countries (25%) reported using vaccines which have deleted antigen(s) to differentiate infected animals from vaccinates (DIVA). Twenty-six (29%) of countries produced or used vaccines which included recombinant proteins, and six countries reported using DNA vaccines (7%). One other biotechnology-derived vaccine was reported but not described in the questionnaire.

Eighty-seven OIE Member Countries responded to question 14 which asked how biotechnology-derived vaccines and/or drugs are generally perceived by the public in their countries. Twelve countries (14% of responders) indicated they were perceived as safe, twenty-five (28%) said they were controversial, and thirty-nine countries (45%) said that the public was mostly unaware of biotechnology-derived vaccines. Eleven other countries (13%) made a variety of other comments in response to this question.

When examining public opinion research done in individual countries, it seems unlikely that approximately half of the population in the responding countries are truly "aware" of biotechnology-derived veterinary vaccines and drugs. People can be unaware of products but, when asked, think the products are safe and well-regulated. They can also be aware and think the products are not safe and aren't well-regulated. These questions are often separated in detailed polling for that reason.

16. Technologies

Sixty-six per cent of the Member Countries that responded indicated that they do not have livestock cloning and/or transgenic animal production facilities in their country. However the European Region indicated that 50% of the 34 countries that responded (69%) do have livestock cloning and/or transgenic animal production facilities in there country.

Sixty-four out of ninety-one countries (72%) indicated that biotechnology-derived animals or their products are not permitted in the food or feed supply in there country. In the Asian Region the 43% indicated that biotechnology-derived animals or their products are permitted in the food or feed supply in there country.

Eighty-three countries (83 of 91) responded to question 17. 79% of the responders indicated that there was no public support for cloning of animals. Of the 12% that indicated there was public support for cloning of animals the main purpose chosen was for the rescue of endangered species and generating stem cells. (36% each)

When Member Countries were asked if there are transgenic animals present in their country, out of the 54% that replied to the questionnaire 79% indicated that there were no transgenic animals in their country. Of the 24% that indicated there were transgenic animals in that country, 45% reported that the animals were generated for the purpose of biopharmaceuticals.

Of the 89 Member Countries that responded to this question, 56% indicated that their country does not have the laboratory capacity to identify and detect transgenes in the food/feed supply. However, in the Asian Region 50% and the European Region 65% indicated that they do have the laboratory capacity to identify and detect transgenes in the food/feed supply.

17. Public perception

Like question 14 above, this question asked people what they thought about the way other people think. Overall the evidence suggests that as with most applications, people employ the same case-by-case risk/benefit analysis when evaluating these new techniques. In public opinion research on biotechnology, there is a clear hierarchy of support for various applications, and often health applications are at the top of the list, and food applications are nearer to the bottom.

For questions 14 and 20 that asked about public perception, it is very difficult to meaningfully compare data from different public opinion questionnaires (i.e. different questions asked under different circumstances). These questions measure the perception of government workers about public opinion (as opposed to actually measuring public opinion). There are some efforts to create agreed-upon methodology and questions (e.g. by international groups of academics and researchers) and it could be useful if OIE could be informed of the expertise of these people.

18. Conclusion

In conclusion the OIE may wish to consider further work as follows:

1) Development of a definition for Biotechnology which can be agreed by OIE Member Countries.

2) Development of standards and guidelines for research on containment and environmental release of live attenuated vaccines in animal health.

3) Development of recommendations and guidelines for use of DNA vaccines in food animals.

4) Development of guidelines and recommendations for somatic cell nuclear transfer cloning – guidance for interspecies cloning, recognising that this process has the potential to increase the possibility for transmission of diseases between species.

5) Develop objective criteria for assessing the health of embryos and animals derived from cloning, and associated safety of cloned livestock and their products.

6) Develop policy guidelines for exclusion of unapproved animals and products from the livestock population, and segregation from the feed and food supply.

7) Develop identification, testing, and certification guidelines for international trade in livestock animals and their products for which biotechnology procedures have been employed to confer disease resistance.

8) Incorporate standards into relevant OIE documentation such as the *Terrestrial Manual* and the *Terrestrial Code*, as well as the companion standards for aquatic animals.

9) Development of guidelines relevant to the application of Nanoscience/Nanotechnology as it relates to animal health.

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Appendix I

Regional Membership of OIE Member Countries

AFRICA

ALGERIA
ANGOLA
BENIN
BOTSWANA
BURKINA FASO
BURUNDI
CAMEROON
CENTRAL AFRICAN REP.
CHAD
COMOROS
CONGO
CONGO (DEM. REP. OF THE)
COTE D'IVOIRE
DJIBOUTI
EGYPT
EQUATORIAL GUINEA
ERITREA
ETHIOPIA
GABON
GHANA
GUINEA
GUINEA-BISSAU
KENYA
LESOTHO
LIBYA
MADAGASCAR
MALAWI
MALI
MAURITANIA
MAURITIUS
MOROCCO
MOZAMBIQUE
NAMIBIA
NIGER
NIGERIA
RWANDA
SAO TOME AND PRINCIPE
SENEGAL
SIERRA LEONE
SOMALIA
SOUTH AFRICA
SUDAN
SWAZILAND
TANZANIA
TOGO
TUNISIA
UGANDA
ZAMBIA
ZIMBABWE

AMERICAS

ARGENTINA
BARBADOS
BELIZE
BOLIVIA
BRAZIL
CANADA
CHILE
COLOMBIA
COSTA RICA
CUBA
DOMINICAN (REP.)
ECUADOR
EL SALVADOR
GUATEMALA
GUYANA
HAITI
HONDURAS
JAMAICA
MEXICO
NICARAGUA
PANAMA
PARAGUAY
PERU
SURINAM
TRINIDAD AND TOBAGO
UNITED STATES OF AMERICA
URUGUAY
VENEZUELA

MIDDLE EAST

AFGHANISTAN
BAHRAIN
IRAN
IRAQ
JORDAN
KUWAIT
LEBANON
OMAN
QATAR
SAUDI ARABIA
SYRIA
TURKEY
UNITED ARAB EMIRATES
YEMEN

ASIA

AUSTRALIA
BANGLADESH
BHUTAN
BRUNEI
CAMBODIA
CHINA (PEOPLE'S REP. OF)
INDIA
INDONESIA
JAPAN
KOREA (REPUBLIC OF)
KOREA (DEM. PEOPLE'S REPUBLIC OF)
LAOS
MALAYSIA
MONGOLIA
MYANMAR
NEPAL
NEW CALEDONIA
NEW ZEALAND
PAKISTAN
PHILIPPINES
SINGAPORE
SRI LANKA
TAIPEI CHINA
THAILAND
VANUATU
VIETNAM

EUROPE

ALBANIA
ANDORRA
ARMENIA
AUSTRIA
AZERBAIJAN
BELARUS
BELGIUM
BOSNIA AND HERZEGOVINA
BULGARIA
CROATIA
CYPRUS
CZECH REPUBLIC
DENMARK
ESTONIA
FORMER YUG. REP. OF MACEDONIA
FINLAND
FRANCE
GEORGIA
GERMANY
GREECE
HUNGARY
ICELAND
IRELAND
ISRAEL
ITALY
KAZAKHSTAN
KIRGHIZISTAN
LATVIA
LITHUANIA
LUXEMBOURG
MALTA
MOLDAVIA
NORWAY
POLAND
PORTUGAL
ROMANIA
RUSSIA
SERBIA AND MONTENEGRO
SLOVAKIA
SLOVENIA
SPAIN
SWEDEN
SWITZERLAND
TADJIKISTAN
THE NETHERLANDS
TURKMENISTAN
UKRAINE
UNITED KINGDOM
UZBEKISTAN

Appendix II

Do you agree with these proposed definitions as applicable to livestock biotechnology?

Proposed Definitions:

1 *A) "biotechnology" means the application of science and engineering in the direct or indirect use of living organisms or parts or products of living organisms in their natural or modified forms.*

B) "living modified organism" means any living organism that possesses a novel combination of genetic material obtained through the use of:

(i) in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles; or

(ii) techniques involving the fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

	Global		Africa		America		Asia		Europe		Middle East	
Yes	81	89%	23	96%	15	88%	12	86%	29	85%	2	100%
No	9	10%	1	4%	2	12%	2	14%	4	12%	0	0%
Did Not Respond (DNR)	1	1%	0		0	0%	0	0%	1	3%	0	0%

If no – suggest an acceptable definition

Specify	10		1		3		3		3		0	

Key consideration

2 *Please score the following considerations as they pertain to the application of genetic engineering to animals. For each topic listed below circle a score on a scale of 1 to 5, where 1 indicates unimportant considerations, and 5 indicates very important considerations.*

	Global		Africa		America		Asia		Europe		Middle East	
	Total	Average	Total	Average	Total	Average	Total	Average	Total	Average	Total	Average
Animal welfare	303	3,33	66	2,75	65	3,82	41	2,93	124	3,65	7	3,50
Economic aspects	334	3,67	99	4,13	68	4,00	51	3,64	109	3,21	7	3,50
Food safety	365	4,01	88	3,67	72	4,24	53	3,79	142	4,18	10	5,00
Environmental impact	353	3,88	87	3,63	74	4,35	47	3,36	137	4,03	8	4,00
Traceability	348	3,82	91	3,79	73	4,29	49	3,50	125	3,68	10	5,00
Nanotechnology	248	2,73	60	2,50	55	3,24	34	2,43	90	2,65	9	4,50
Human health (other than food)	362	3,98	98	4,08	72	4,24	46	3,29	136	4,00	10	5,00
Animal health	384	4,22	106	4,42	81	4,76	51	3,64	138	4,06	8	4,00
Regulatory controls	351	3,86	92	3,83	74	4,35	52	3,71	127	3,74	6	3,00
Xenotransplantation	308	3,38	66	2,75	69	4,06	43	3,07	123	3,62	7	3,50

3 *Do the animal health regulatory administrations and/or agencies in your country have the capability to conduct risk analysis (risk assessment, risk communication, risk management) on biotechnology derived livestock and biotechnology products?*

	Global		Africa		America		Asia		Europe		Middle East	
Yes	36	40%	4	17%	6	35%	5	36%	20	59%	1	50%
No	53	58%	20	83%	11	65%	8	57%	13	38%	1	50%
DNR	2	2%	0	0%	0	0%	1	7%	1	3%	0	0%

If yes, has a National framework for conducting risk analysis on biotechnology derived livestock and biotechnology products been developed?

Yes	23	64%	1	25%	4	66%	5	100%	13	65%	0	0%
No	12	33%	3	75%	1	17%	0	0%	7	35%	1	100%
DNR	1	3%	0	0%	1	17%	0	0%	0	0%	0	0%

If no, what are the reasons for not performing risk analysis for decision-making process pertaining to biotechnology derived livestock and biotechnology products?

Lack of knowledge	22	26%	6	27%	2	13%	6	50%	6	27%	2	50%
Training	44	53%	10	46%	9	56%	5	42%	10	46%	2	50%
Others (specify):	18	21%	6	27%	5	31%	1	8%	6	27%	0	0%

4 *Do the animal health authorities in your country have a dedicated unit that conducts risk analysis pertaining to biotechnology derived livestock and biotechnology products?*

	Global		Africa		America		Asia		Europe		Middle East	
Yes	14	15%	2	8%	3	18%	3	21%	6	18%	0	0%
No	75	83%	22	92%	14	82%	10	72%	27	79%	2	100%
DNR	2	2%	0	0%	0	0%	1	7%	1	3%	0	0%

If no, which unit is conducting risk analysis?

Import-Export unit	19	23%	6	26%	3	20%	4	45%	5	15%	1	50%
Epidemiology and Surveillance unit	24	29%	7	31%	4	27%	1	10%	11	33%	1	50%
External consultant	9	11%	3	13%	1	7%	0	0%	5	15%	0	0%
Others (specify)	30	37%	7	30%	7	46%	4	45%	12	37%	0	0%

5 *What factors are taken into consideration when determining risk associated with biotechnology derived livestock and biotechnology products?*

	Global		Africa		America		Asia		Europe		Middle East	
Animal Health	66	26%	18	25%	11	25%	9	22%	26	28%	2	34%
Food Safety	69	26%	20	29%	10	23%	10	24%	27	29%	2	33%
Environmental impact	58	23%	15	21%	8	19%	9	22%	24	25%	2	33%
Economic consideration	27	11%	11	15%	2	5%	6	15%	8	8%	0	0%
Others (specify)	24	9%	4	6%	10	23%	5	12%	5	5%	0	0%
DNR	12	5%	3	4%	2	5%	2	5%	5	5%	0	0%

6 *Have the animal health authorities conducted (or received a request to conduct) a risk analysis on biotechnology derived livestock or biotechnology products?*

	Global		Africa		America		Asia		Europe		Middle East	
Yes	23	25%	3	13%	7	41%	4	29%	9	26%	0	0%
No	66	73%	20	83%	10	59%	10	71%	24	71%	2	100%
DNR	2	2%	1	4%	0	0%	0	0%	1	4%	0	0%
If yes, specify what commodity												
Not able to disclose	3	9%	1	33%	1	8%	1	20%	0	0%	0	0%
Cloned animal	3	9%	0	0%	2	15%	0	0%	1	20%	0	0%
Transgenic animal	7	21%	0	0%	3	23%	1	20%	3	60%	0	0%
Biotechnology products (specify)	17	52%	2	67%	6	46%	2	40%	0	0%	0	0%
Others (specify)	3	9%	0	0%	1	8%	1	20%	1	20%	0	0%

7 *Do the animal health authorities in your country make their risk analysis document available for peer review or for public consultation?*

	Global		Africa		America		Asia		Europe		Middle East	
Yes	25	27%	6	25%	7	41%	4	29%	8	24%	0	0%
No	60	66%	16	67%	10	59%	10	71%	23	67%	1	50%
DNR	6	7%	2	8%	0	0%	0	0%	3	9%	1	50%
If yes, what means of dissemination are used:												
Official government publication	14	38%	4	66%	3	23%	3	42%	4	37%	0	0%
Electronic version	10	27%	1	17%	3	23%	2	29%	4	36%	0	0%
Others (specify)	13	35%	1	17%	7	54%	2	29%	3	27%	0	0%
and who conducts the peer review:												
Internally within the Veterinary Services	18	45%	5	72%	6	40%	3	43%	4	37%	0	0%
External reviewers	10	25%	1	14%	4	27%	1	14%	4	36%	0	0%
Others (specify)	12	30%	1	14%	5	33%	3	43%	3	27%	0	0%

8 *Do you consider the "Guidelines for risk analysis" contained in the OIE Terrestrial Animal Health Code, adequate to help carry out an import risk analysis on biotechnology-derived animals or biotechnology-derived products?*

	Global		Africa		America		Asia		Europe		Middle East	
Yes	63	69%	19	79%	8	47%	9	65%	26	76%	1	50%
No	18	20%	3	13%	8	47%	3	21%	4	12%	0	0%
DNR	10	11%	2	8%	1	6%	2	14%	4	12%	1	50%
If no, how can it be improved?												
Specify	18		3		8		3		4		0	

9 *Has your country produced biotechnology-derived animals or biotechnology-derived products for use on animals?*

	Global		Africa		America		Asia		Europe		Middle East	
Yes	31	34%	5	21%	6	35%	6	43%	14	41%	0	0%
No	58	64%	19	79%	11	65%	8	57%	18	53%	2	100%
DNR	2	2%	0	0%	0	0%	0	0%	2	6%	0	0%

10 *Do you have the following capabilities in your country?*

	Global		Africa		America		Asia		Europe		Middle East	
Cloning	23	17%	1	4%	6	23%	6	23%	10	18%	0	0%
Transgenic production	27	20%	2	8%	4	15%	6	23%	15	26%	0	0%
Products of biotechnology for use in animals (e.g. vaccines and/or drugs)	38	28%	6	23%	5	19%	9	35%	18	31%	0	0%
DNR	49	35%	17	66%	11	43%	5	19%	14	25%	2	100%

11 *Do you have a regulatory framework in place to govern the use of the above?*

	Global		Africa		America		Asia		Europe		Middle East	
Yes	44	48%	6	25%	9	53%	8	43%	21	62%	0	0%
No	45	50%	18	75%	8	47%	6	57%	11	32%	2	100%
DNR	2	2%	0	0%	0	0%	0	0%	2	6%	0	0%

If yes, briefly please describe the framework and list the Administrations and/or Agencies and pertinent legislation(s) involved

Specify	39		5		8		7		19		0	

12 *Is research being conducted in your country into biotechnology-derived animals and products including vaccines and drugs?*

	Global		Africa		America		Asia		Europe		Middle East	
Yes	43	47%	6	25%	7	41%	9	64%	20	59%	1	50%
No	46	51%	17	71%	10	59%	5	36%	13	38%	1	50%
DNR	2	2%	1	4%	0	0%	0	0%	1	3%	0	0%

13 *Do you produce or use any animal vaccines in your country that are biotechnology-derived?*

	Global		Africa		America		Asia		Europe		Middle East	
Yes	40	44%	4	17%	7	41%	7	50%	21	62%	1	50%
No	49	54%	19	79%	10	59%	7	50%	12	35%	1	50%
DNR	2	2%	1	4%	0	0%	0	0%	1	3%	0	0%

If yes, what types of biotechnology-derived animal vaccines are available?

Viral vectored vaccines which include antigen(s) from unrelated organisms	26	27%	2	50%	5	28%	4	19%	15	29%	0	0%
Bacterial vectored vaccines which include antigen(s) from unrelated organisms	16	16%	1	25%	2	11%	5	24%	8	15%	0	0%
Vaccines which have deleted antigen(s) to differentiate infected animals from vaccinates (DIVA)	22	23%	1	25%	3	17%	3	14%	14	26%	1	100%
Vaccines which include recombinant proteins	26	27%	0	0%	6	33%	6	28%	14	26%	0	0%
DNA vaccines	6	6%	0	0%	2	11%	2	10%	2	4%	0	0%
Other	1	1%	0	0%	0	0%	1	5%	0	0%	0	0%

14 *How are biotechnology-derived vaccines and/or drugs generally perceived by the public in your country?*

	Global		Africa		America		Asia		Europe		Middle East	
Safe	12	13%	4	17%	1	6%	3	21%	4	11%	0	0%
Controversial	25	27%	5	21%	5	28%	4	29%	10	29%	1	50%
Public mostly unaware	39	41%	11	46%	7	38%	6	43%	15	43%	0	0%
Others (specify)	11	12%	2	8%	5	28%	0	0%	2	6%	1	50%
DNR	7	7%	2	8%	0	0%	1	7%	4	11%	0	0%

15 *Do you have livestock cloning and/or transgenic animal production facilities in your country?*

	Global		Africa		America		Asia		Europe		Middle East	
Yes	28	31%	0	0%	5	29%	6	43%	17	50%	0	0%
No	60	66%	22	92%	12	71%	8	57%	16	47%	2	100%
DNR	3	3%	2	8%	0	0%	0	0%	1	3%	0	0%

16 *Are biotechnology-derived animals or their products permitted in the food or feed supply in your country?*

	Global		Africa		America		Asia		Europe		Middle East	
Yes	22	24%	5	21%	4	24%	6	43%	7	21%	0	0%
No	64	72%	17	71%	13	76%	6	43%	26	79%	2	100%
DNR	4	4%	2	8%	0	0%	2	14%	0	0%	0	0%

17 *Is there a public support for cloning of animals?*

	Global		Africa		America		Asia		Europe		Middle East	
Yes	11	12%	0	0%	2	12%	4	29%	5	15%	0	0%
No	72	79%	22	92%	13	76%	7	50%	28	82%	2	100%
DNR	8	9%	2	8%	2	12%	3	21%	1	3%	0	0%

If Yes, would there be a support for cloning for

Rescue of endangered species	7	39%	0	0%	2	33%	2	33%	3	50%	0	0%
Generating stem cells	7	39%	0	0%	2	33%	2	33%	3	50%	0	0%
Pet cloning	2	11%	0	0%	1	17%	1	17%	0	0%	0	0%
Food product homogeneity	2	11%	0	0%	1	17%	1	17%	0	0%	0	0%

18 *Are there transgenic animals present in your country?*

	Global		Africa		America		Asia		Europe		Middle East	
Yes	22	24%	0	0%	3	18%	4	29%	15	44%	0	0%
No	67	74%	24	100%	14	82%	10	71%	17	50%	2	100%
DNR	2	2%	0	0%	0	0%	0	0%	2	6%	0	0%

If Yes, what purpose are they generated for

Altered Nutrient Content	4	13%	0	0%	1	14%	2	22%	1	53%	0	0%
Biopharmaceuticals	14	45%	0	0%	3	43%	3	34%	8	33%	0	0%
Disease resistance	9	29%	0	0%	1	14%	3	33%	5	7%	0	0%
Environmental benefits	4	13%	0	0%	2	29%	1	11%	1	7%	0	0%

19 *Does your country have the laboratory capacity to identify and detect transgenes in the food/feed supply?*

	Global		Africa		America		Asia		Europe		Middle East	
Yes	38	42%	2	8%	6	35%	7	50%	22	65%	1	50%
No	51	56%	22	92%	11	65%	6	43%	11	32%	1	50%
DNR	2	2%	0	0%	0	0%	1	7%	1	3%	0	0%

20 *How are biotechnology-derived animals generally perceived by the public in your country?*

	Global		Africa		America		Asia		Europe		Middle East	
Safe	2	2%	1	4%	0	0%	0	0%	1	2%	0	0%
Controversial	53	52%	10	41%	10	50%	8	53%	24	59%	1	50%
Public generally unaware	30	29%	9	38%	5	25%	5	33%	11	27%	0	0%
Others (specify	14	14%	4	17%	5	25%	1	7%	3	7%	1	50%
DNR	3	3%	0	0%	0	0%	1	7%	2	5%	0	0%

	Global		Africa		America		Asia		Europe		Middle East	
English	61	67%	12	50%	6	35%	13	93%	28	82%	2	100%
French	18	20%	12	50%	0	0%	1	7%	5	15%	0	0%
Spanish	11	12%	0	0%	11	65%	0	0%	0	0%	0	0%
Other	1	1%	0	0%	0	0%	0	0%	1	3%	0	0%
Country Questionnaire Received	91	54%	24	49%	17	61%	14	54%	34	69%	2	15%
Member Countries	*165*		*49*		*28*		*26*		*49*		*13*	

Appendix II

Resolutions

adopted by the International Committee of the OIE during its 73rd General Session

22 – 27 May 2005

Appendix III

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

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

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 4 **CX/FBT 05/5/4**

May 2005

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

CONSIDERATION OF THE ELABORATION OF STANDARDS, GUIDELINES OR OTHER TEXTS FOR FOODS DERIVED FROM BIOTECHNOLOGY

1. The 27th Session of the Codex Alimentarius Commission agreed to establish a new Ad Hoc Intergovernmental Task Force on Foods derived from Biotechnology with the understanding that its final report should be submitted to Commission in 2009. It adopted the Terms of Reference of the Task Force (ALINORM04/27/41 APPENDIX VIII).

2. The Commission agreed that a Circular Letter be issued to solicit specific proposals for new work and to define priorities and that comments received would be distributed as a working document for the consideration by the first session of the Task Force (ALINORM 04/27/41, para 89).

3. In pursuant to this decision by the Commission, the Circular Letter 2005/2-FBT was issued in February 2005 to solicit proposals for new work.

4. This document includes comments submitted by Argentina, Australia, Brazil, Canada, Iran, Japan, Mexico, New Zealand, United States of America, Venezuela, 49th Parallel Biotechnology Consortium, Biotechnology Industry Organization (BIO), Consumers International (CI). Project Documents for the items proposed as new work were also attached as Annexes to this document.

ARGENTINA

General Comments

Argentina wishes to especially thank the Government of Japan for having committed to chair this new stage of the Task Force on Foods Derived from Biotechnology again. We fully trust its caution and knowledge to effectively achieve the goals set out by Codex Members.

Argentina believes that the documents on biotechnology already approved by Codex should be given special consideration in developing future work, in order to achieve consistency in these matters.

Specific Comments

A. Priority assignments. Preliminary Comments and modifications

Sub-header	Priority
1	2
2	1
3	4
4	3
5	5 (Not in the original Document; See below)

The above assignments must be considered within the context including amendments/corrections as detailed below. Justifications of these are also given.

B. Comments on the "covered areas" as stated under BACKGROUNG, point 2.

Sub-header 1: Foods derived from animals

- Transgenic animals obviously include fish. We propose to delete "including fish".
- Cloned animals are obtained using biotechnology methods not including "modern biotechnology" as defined under the Cartagena Protocol. This discrepancy must be clarified. We would understand that the document is addressed mainly (if not exclusively) to genetically modified organisms. As long as cloned animals are not transgenic, we propose to delete these in this sub-header.

With the above comments, we propose this header to be given priority 2.

Sub-header 2: Foods derived from plants

- The mention of "bioactive substances" needs clarification. Confusion by the use of this wording is seriously increased by ending the sentence with "...of nutritionally-enhanced plants". Even more confusion is added by placing this sub-header under "Foods derived from plants".
- We suggest that this sub-header and the included items be re-organized as proposed below.

Sub-header. Foods and other substances derived from plants (by plant categories).

a) Plants expressing enhanced levels of nutritional or functional compounds already synthesized by the plant.
b) Plants expressing significant levels of nutritional or functional compounds which were not previously produced by the plant and whose synthesis is

made possible through the introduction, complete or partial, of the relevant genes of the biosynthetic pathways.

c) Plant expressing substances with pharmacologic activity in humans or animals.
d) Plants expressing non-food, non-pharmacologically active substances. Includes: food processing aids or industrial compounds.
e) Plants with stacked genes.

We propose the priority order of the above sub-headers: e), a), b), c) and d). We have three additional proposals for modifications of this item:

- items c) and d) should go to a different sub-header (we numbered it here as sub-header 5).

- items e) and a) could eventually share the same priority

- item e) may go to a separate sub-header (desirable, but not proposed here), as the only item.

Sub-header 3: Low level presence of unauthorized genetically engineered foods in authorized foods

We propose to change the wording "genetically engineered foods" by "ingredients derived from genetically modified food sources".

Argentina supports the analysis of this item, as we already know, a number of countries have established thresholds which are not necessarily based on scientific grounds; for this reason, it would be important for Codex to analyze this issue and provide guidance to governments.

Notwithstanding the foregoing, Argentina has made broader comments, in response to CL 2004/22 FL, which is related to this issue.

Sub-header 4: Comparative food composition analysis

We believe this is basically correct. However, use of the concept "Comparative" needs clarification, as it will need unambiguous definitions for the comparator, the standard analytical procedures, accepted statistical methods and ranges of values.

Sub-header 5:

We propose an additional sub-header, which would include items c) and d), as indicated under sub-header 2.

C. Comments on the proposed priorities.

The rationale for the proposal of **priority** *1* is that plants with stacked genes are already in the market in some countries. On the other hand, the development of plants with enhanced levels of nutritionally valuable compounds, as well as plants into which genes of biosynthetic pathways have been introduced will soon reach approval in some countries.

Items c) and d) under sub-header 2 will need a well differentiated treatment and may go separated under a newly defined sub-header (5) with priority 5.

Scope under priority level 1 will include plants with stacked genes already in the market. However, to put them in a separate category (also with a top priority) may be advisable, as their distinctive characteristic is not the product they express but the characteristics of their genetically modified make-up.

Plants expressing nutritionally- or functional-related traits may be placed in a separate category for the sake of simplicity in the treatment by the pertinent Codex Commission. They should also be placed in a top priority.

Priority 2, assigned to sub-header 1, is justified because the development of GM animal-derived foods is still in its infancy, and, possibly, more scientific information is required with the aim of then strengthening an international standard.

Priority 3, assigned to sub-header 4 is justified because already a great deal of data is available on the matter. Their reliability has been already proved in abundant regulatory reviews.

Priority 4, assigned to sub-header 3 is justified because no significant health risks would be derived from the low levels of adventitious presence of unauthorized OVM-derived foods in approved foods. Moreover, this presence should be of relatively low concern. The distinction between unauthorized and authorized foods is country-dependent, as well as the reliability of the regulatory system by which they are approved. If a food has been authorized under a reliable system by a particular country, the "unauthorized" concept claimed by another country may fall within different, non-Codex international agreements.

Priority 5, assigned to sub-header 5 is justified because it deals with non-food products. In the case of pharmacologically active compounds, it is to be considered whether the establishment of requirements for products whose final destination is not foods lies within Codex.

Overall, Argentina believes that if the resulting products are not used as foods, Codex should not establish any provisions on this issue, the responsibility of taking appropriate measures in this respect falling within the OIE or the WHO.

Experts would need to deal with: gene-gene interactions (e.g., in plants with stacked genes), metabolic effects, use of transcriptomic and metabolomic tools, biosafety risks and measures for production of non-food crops. Another items to be consulted would include: the use of specific promoters in order to limit expression to specific tissues, if it is deemed appropriate for biosafety reasons; the possible application of gene-restriction technologies; the biosafety analysis of complex constructs (e.g., those including transcription factors, regulatory proteins, DNA-binding proteins, genes likely to have pleiotropic effects); the research in natural anti-nutritional factors, including the search of currently unknown compounds; the development of advanced bio-informatic algorithms; the development of animal models for allergy testing.

Whether guidelines, annexes or other forms of regulations would be the outcome will depend on the priority and relevance of the conclusions arrived at the discussions, on the availability of the scientific information needed to be certain that no Codex provisions will be adopted if there is not a sufficient, solid scientific basis.

We propose that the Commission adopt a strong proactive approach, so additional topics for the experts would be on the matter of which projections would reasonably be made for the future development of foods derived from genetically modified organisms.

AUSTRALIA

GENERAL COMMENTS

Australia recognises that the previous Task Force was only able to address a subset of issues related to the safety and health impact of foods derived from biotechnology and so welcomes the establishment of a new Task Force to continue this work. While there remains a range of issues for which internationally agreed guidance is not currently available and for which guidance would be of considerable value to Codex Members, Australia considers that the new Task Force should only focus on a few key pieces of work, which can realistically be completed in the four-year timeframe. As with the previous Task Force, Australia believes the Task Force should concentrate on the elaboration of guidance aimed at protecting human health.

To focus the work of the new Task Force, Australia believes that, as a general principle, the texts agreed to under the previous Task Force should not be re-visited.

SPECIFIC COMMENTS

The suggested areas of new work listed in CL 2005/2-FBT have been categorised into those Australia believes should be a high priority for the Task Force, those of lower priority, and those that are outside the scope of the Task Force.

A. High Priority Areas for New Work

(i) Foods derived from transgenic animals

The commercial development of transgenic animals, and fish in particular, is said to be imminent therefore there is a pressing need for international guidance on food from transgenic animals. Australia considers new guidance on food from transgenic animals should be in the form of a guideline, similar to that already produced for plants and microorganisms.

Scope and issued to be addressed

Australia considers there are a number of issues in relation to the scope of any guidance that would need to be resolved before any work could commence. As with the previous guidelines for recombinant-DNA plants and microorganisms, Australia believes the scope of any guidance should be restricted to issues related to food safety assessment.

It needs to be considered whether guidance should be developed for all classes of animals, or whether the Task Force should concentrate on specific classes of animals in the first instance.

Australia recognises that as the commercialisation of transgenic fish is likely to precede that of other animals, there may be some merit in the Task Force focusing first on developing guidance in relation to fish. However, given the safety assessment approach is likely to be similar for most classes of animals, it may be more worthwhile for the Task Force to direct resources towards the development of generic guidance, applicable to all classes of animals.

If there are characteristics of a particular species or class of animals that warrant specific or special consideration, this could be further developed as an annex to the main guideline. Australia's preference would be for the development of generic guidance, with special consideration of fish to be given a high priority within that work.

Australia considers that a logical approach to the development of a generic guideline for food from transgenic animals would be to use the plant guideline as a starting point and identify those aspects of the plant guideline that could be transferable, either directly or with minor modification, to an animal guideline. For example, Australia believes that assessment of possible toxicity and allergenicity would be directly transferable to an animal guideline, whereas the section on compositional analysis is likely to require significant modification.

Australia is aware of a number of reports and publications, which allude to the use of more extensive phenotypic analysis as part of the safety assessment approach, where animal health parameters are considered in conjunction with food composition analysis. Australia notes that such an approach has recently been elaborated for assessing the safety of food from cloned animals[1], and is based on the hypothesis that a healthy animal is likely to produce safe food products. Australia considers such an approach warrants investigation for its applicability to the safety assessment of food from transgenic animals.

A large amount of information is already available which could inform the development of guidance on the safety assessment of food from transgenic animals. Reference is made in particular to the following:

Health Canada (2001). Technical workshop on food safety assessment of livestock animals and fish derived from biotechnology, Report of key findings, Ottawa, Ontario, March 7-9, 2001. Health Canada, Ottawa

National Academy of Science (NAS) (2002). Animal biotechnology: science-based concerns. The National Academies Press, Washington, D.C

Food and Agriculture Organization (FAO) (2004). Safety assessment of foods derived from genetically modified animals, including fish. Report of the FAO/WHO Expert Consultation, Rome, 17-21 November 2003. FAO Food and Nutrition Paper 79, Food and Agriculture Organization of the United Nations, Rome.

After having regard to the available information, Australia has identified a number of questions, which need to be addressed.

- What approach should be used for the molecular characterization of transgenic animals? Is the guidance elaborated in the plant guideline also applicable to animals, or is additional information required? What type of additional information should be required for transgenic animals? Are there any issues related to transgene copy number and homozygosity that need to be taken into account?

- Are there particular methods of transformation that pose greater risks for food safety and should food products from animals produced using these techniques be excluded from the food supply?

- Is sufficient information available on the key constituents of animal-derived food products to undertake compositional analysis? Is sufficient baseline information available? Given the potential for small sample sizes with some species, how should detected differences in composition be interpreted? What developmental stages and tissues should be used for compositional analysis?

[1] Rudenko, L., Matheson, J.C., Adams, A.L., Dubbin, E.S. and Greenlees, K.J. (2004). Food consumption risks associated with animal clones: what should be investigated? *Cloning Stem Cells* **6** (2), 79-93.

- What emphasis should be given to animal health parameters in the food safety assessment? What animal health parameters would be the most informative for a food safety assessment?

(ii) Foods derived from cloned animals

Cloned animals are already, arguably, a commercial reality and are only being withheld from the market place on a voluntary basis. Australia considers that international consideration of, and consensus around, the food safety risks associated with cloned animals is now urgent.

Scope and issues to be addressed

Australia recognises that the term cloning can actually refer to a number of different techniques, but in the present day context refers almost exclusively to somatic cell nuclear transfer (SCNT). Australia believes the scope of any consideration of food from cloned animals should be limited to the use of SCNT and related techniques, as these are the techniques that have been identified as producing abnormalities (e.g. large offspring syndrome) that potentially may impact on food safety.

Australia considers the definition for "modern biotechnology" as appears in the Principles for Risk Analysis of Foods Derived from Modern Biotechnology could be interpreted as including techniques such as SCNT and thus within the Terms of Reference of the Task Force.

Australia proposes that, as a matter of priority, an Expert Consultation be convened to provide advice on the potential food safety issues associated with animal cloning. The outcome of such a consultation could then be used by the Task Force to determine if specific guidance in the relation to the safety assessment of food from cloned animals is necessary.

To ensure that there is no duplication of work being undertaken by other intergovernmental organisations, and equally that there are no gaps, Australia considers that it would be important for the World Organisation for Animal Health (OIE) to participate in the proposed Expert Consultation, as well as any future deliberations of the Task Force on food from cloned animals.

Australia proposes that an Expert Consultation could address the following questions:

- What, if any, are the food safety concerns associated with the use of SCNT and related techniques?
- What scientific approach should be applied to the safety assessment of food from cloned animals?
- What should be the scope of any safety assessment applied to food from cloned animals?
- What role should food composition analysis play in the safety assessment of food from cloned animals and what specific differences between cloned and conventional animals would be significant in terms of food safety?
- What emphasis should be given to animal health parameters in the food safety assessment? What animal health parameters, if any, would be the most informative for a food safety assessment?

Australia notes that there already exists a body of experts (the International Embryo Transfer Society) whose knowledge and expertise in relation to animal cloning could be utilised, if necessary.

Australia also notes that the Centre for Veterinary Medicine within the United States Food and Drug Administration has been undertaking a risk assessment on animal cloning, including the food consumption risks. Should the full report of this risk assessment become available in the near future; it could be a useful resource for an Expert Consultation on the safety of foods from cloned animals.

(iii) Comparative food composition analysis

Australia would support additional work being undertaken in the area of food composition analysis. In particular, Australia considers that additional guidance would be useful in relation to the conduct of studies for the generation of data for compositional analysis – for example, further guidance in relation to study design, sample sizes, number of field trial sites, choice of appropriate comparator, etc. Such guidance could also outline the conceptual approach to interpreting information from these studies. Such work, depending on its nature and scope, may also have relevance to new work on food from transgenic animals. Australia considers additional guidance on comparative food composition analysis should be in the form of an annex to the main guideline, similar to that produced for allergenicity assessment.

(iv) Plants expressing bioactive substances or nutritionally enhanced plants

Australia considers these to be two distinct categories of plants, which potentially raise different issues with respect to safety and nutritional assessment. As a consequence, they are discussed separately below. While this area of new work has been raised in the context of plants, Australia recognises it may also have applicability to any new work on food from transgenic animals. Australia also notes that many of the issues raised could apply equally to novel foods in general, not just those derived from modern biotechnology.

NUTRITIONALLY ENHANCED PLANTS

Australia regards nutritionally enhanced plants as those plants that have been modified to alter either the macro or micronutrient content, for example, 'golden' rice, high oleic acid soybean.

The existing plant guideline provides useful guidance in relation to nutritional modification however Australia considers that further elaboration, in the form of an annex to the main guideline, would be valuable particularly in relation to assessing the impact of the nutritional modification on the whole diet, and the role and usefulness of animal feeding and human studies in assessing nutritional impact and bioavailability. Australia notes that the International Life Sciences Institute (ILSI) has recently published a report on the assessment of food from nutritionally enhanced plants why may prove useful for the Task Force.[2]

PLANTS EXPRESSING BIOACTIVE SUBSTANCES

Australia regards plants expressing bioactive substances to be those plants that have been modified to express substances that offer potential health benefits that go beyond satisfying basic nutritional requirements, e.g., phytosterols, omega-3 fatty acids.

Australia considers that new guidance, in the form of an annex to the main guideline, would be useful on approaches to the assessment of bioactive substances in plants and the types of additional testing that may be required for this category of foods. In particular the types of studies (toxicological, pharmacokinetic) that might be required, and whether and in what circumstances human studies might be warranted or useful. Australia believes the development of guidance in relation to the expression of bioactive substances in plants will require additional scientific advice in the form of an Expert Consultation.

[2] ILSI (2004). Nutritional and safety assessments of foods and feeds nutritionally improved through biotechnology. *Comprehensive Reviews in Food Science and Safety* **3**, 35-104.

B. Areas of work with lower priority

(i) Plants with "stacked" genes

While Australia has previously commented that guidance on assessing the safety of food from recombinant-DNA plants with stacked genes would be useful, given the limited time frame of the Task Force, Australia does not consider this to be a priority area.

(ii) Low level presence of unauthorised genetically engineered foods in authorised foods

Australia considers the low level presence of unauthorised genetically engineered foods in authorised foods to be a broad issue that relates primarily to food production and handling practices and as such it may be more appropriate for it to be considered by a committee such as the Codex Committee on Food Import and Export Inspection and Certification Systems. Australia does not believe this issue should be of high priority for the Task Force.

C. Areas of work outside the scope of the Task Force

(i) Biopharming

(ii) Plants expressing pharmaceutical or other non-food substances

While Australia recognises the importance of issues associated with these plants and plant products, such products would not be regarded as foods and are unlikely therefore to ever be deliberately added to the food supply. Australia considers such work to therefore fall outside the scope of the Task Force.

BRAZIL

Brazil would like to thank for the opportunity to comment the document and supports the work of the Task Force.

Brazil believes that the success of the first developed work of the Task Force is due to the fact that the scope and the objectives of the work were very well defined beforehand. Brazil also believes this should also be the approach for the new Work of the Task Force.

This is an area of fast scientific development therefore Brazil suggests that the priorities should be given to Products derived from Genetically Modified Plants, as following:

1. Plants with "stacked genes"; and

2. Low level presence of unauthorized genetically engineered foods in authorized foods.

Brazil would also like to suggest that this second item be described differently considering that the work of the Task Force is a technical one and that the expression "authorized foods" refers to legislation in place and not to technical aspects. Brazil believes the description refers to presence of new GM foods not yet evaluated in different parts of the world.

The safety of genetically modified plants has already been covered in the Guidelines that came out from the first work of the Task Force therefore Brazil would like to ask for clarification regarding what kind of further consideration is needed for the safety evaluation of plants expressing bioactive substances or nutrionally enhanced plants or plants used to produce other substances or of the third generation. Further regarding this topic, Brazil would like to highlight that there are also nutritionally enhanced plants that are produced by other technologies like conventional breeding and not modern biotechnology. Brazil would like to ask the Task Force how are these differences going to be dealt with in Codex.

On the topic of food safety evaluation of plants producing pharmaceutical substances and other non-food substances, Brazil would like to suggest that the Task Force further consider the scope of the topic in order to limit the work to the evaluation of food related substances that are part of the scope of the group.

Brazil would like to ask for clarification regarding the suggested topic:

comparative food composition analyses since this was already covered in the Guidelines CAC/GL 45-2003 paragraphs 44 and 45.

Brazil also suggests that the work on food derived from GM animals including fishes be initiated only after the work on food derived from GM plants is advanced and has progressed. The new work take as reference the Report FAO/WHO Expert Consultation on the Safety Assessment of Foods Derived from Genetically Animals, including Fish (November 2003).

Finally, Brazil considers that "cloning" is not part of the scope of the modern biotechnology and therefore this topic should not be covered in the work.

CANADA

Canada welcomes this opportunity to provide input in response to Codex Circular Letter CL 2005/2-FBT. We are pleased to submit the following comments for consideration.

Canada continues to believe that the new Codex Ad Hoc Intergovernmental Task Force on Foods derived from Biotechnology should focus on mechanisms aimed at assuring food safety, including developing recommendations, standards or other relevant guidance where supportable by the available science. We also share the view that keeping the scope of the work science-based and focussed on two or three specific topics to further support the *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology* will contribute to the repetition of the success of the previous Task Force.

In addition to the risk analysis principles, the first Task Force developed guidance documents for assessing the safety of foods derived from plants and microorganisms obtained through recombinant-DNA techniques. We believe the focus of the new Task Force should build upon these documents and provide guidance not currently available to Codex members in the area of foods derived from biotechnology in view of the "second generation" products and traits as priorities. These would include work on foods derived from animal origin and on issues related to second generation plants and traits related to the application of recombinant-DNA techniques to plants.

1) Novel foods derived from animal origin

Consistent with the third priority of work identified, but not initiated, by the first Task Force, Canada strongly supports work on foods derived from animal origin as a priority for the new Task Force. We note that the FAO/WHO have already conducted an expert consultation on the topic of foods derived from genetically modified animals and a number of countries have initiated work in the area of foods derived from animal biotechnology. This work would represent a useful resource for any work undertaken by the Task Force in the area of foods derived from animal biotechnology. Additional expert advice may be sought as appropriate.

Recombinant-DNA animals, including fish - Following the approach used for the elaboration of the guidelines for the conduct of safety assessment of foods produced using recombinant-DNA plants, we believe that guidelines on the safety assessment of foods derived from recombinant-DNA animals could be elaborated by the Task Force. This approach would allow the identification of commonalities applicable to the safety assessment of foods derived from these different recombinant organisms as well as the identification and consideration of the particularities of foods derived from recombinant-DNA animals.

Cloned animals - Canada also notes that advances in technologies to produce cloned animals using somatic cell nuclear transfer (SCNT) techniques have been significant over the past few years. Such cloning techniques are likely to be used in conjunction with recombinant-DNA techniques to accelerate the generation of identical offspring from animals genetically modified by recombinant-DNA techniques. Canada would thus see as appropriate that the Task Force to undertake work complementing guidelines on the safety assessment of recombinant-DNA animals and relating to the development of an appropriate approach to assessing the application of SCNT cloning techniques to food production.

2) Novel foods derived from second generation plants and associated novel traits

Canada also supports work addressing issues related to the second generation of recombinant-DNA plants. This work would build on and complement the existing risk analysis principles and supporting guidelines. We also note that there is a body of evidence already available that could be useful to support such undertaking by the new Task Force.

Nutritionally-enhanced plants, including plants expressing food-related bioactive substances - Canada believes there would be significant value for the new Task Force to undertake work relating to the safety assessment of foods derived from plants intentionally modified to change the nutritional attributes of the derived foods as a priority. Examples of such nutritionally-enhanced plants include plants expressing an altered oil composition profile as well as plants expressing food-related bioactive substances, such as a new recombinant-DNA tomato line expressing an elevated level of the antioxidant lycopene. Given that it will be crucial to restrict the work in the new Task Force to that which falls with the mandate of Codex, the scope of this work would not cover plants expressing pharmaceuticals or other non-food substances (also referred to as biopharming or molecular farming) as the primary purpose of these plants is not food use but rather for use as factories to produce industrial or pharmaceutical compounds.

Specifically in this regard, Canada would support the elaboration of further guidance relating to the additional safety and nutritional considerations that the assessment of these nutritionally-enhanced foods may require. In the context of expression of food-related bioactive substances, it may be appropriate for the safety assessment to take into consideration such aspects as the bioavailability, the physiological function and the effectiveness of the food-related bioactive substance.

The approach to complementing the existing guidance might follow the approach taken by the first Task Force to provide detailed guidance on the assessment of potential allergenicity of newly expressed protein(s), through the development of additional text to address aspects related to intentionally introduced changes to the nutritional characteristics of a novel plant compared to its unmodified counterpart. Similarly, further detail with respect to the application of compositional comparison could be elaborated in this manner to complement the current guideline for the safety assessment of recombinant-DNA plants.

3) Other work - Emerging issues related to recombinant-DNA plants

Plants with stacked genes - Canada recognizes that there maybe some benefit to providing guidance as to considerations for establishing the safety of food derived from plant varieties expressing stacked genes (i.e, where two approved recombinant-DNA plants are cross-bred, resulting in the originally introduced gene constructs from both parents being present in the derived progeny). These types of plants have already been developed and commercialized in some jurisdictions, and internationally agreed upon guidance would benefit all members.

In addition, Canada would be ready to support, albeit as a lower priority, work on the low level presence of unauthorized genetically engineered foods in authorized foods. It is critical that such work, if undertaken by the Task Force, be with the sole objective of providing an assurance of safety to consumers.

General Considerations

Canada notes that as part of its terms of reference, the new Task Force will take full account of existing work carried out by national authorities, FAO, WHO, other international organizations and other relevant international fora. For this reason, we thus encourage the Task Force to avoid duplicating work already addressed by such groups as the OECD Task Force on the Safety of Novel Foods and Feeds, the Codex Committee on Food Labeling (CCFL) and the Codex Committee on Methods of Analyses and Standards (CCMAS).

Lastly, as indicated at the fourth session of the previous Task Force, Canada is of the view that the proposals made by some members for the new Task Force to look at broader issues such as ethics, other legitimate factors and socio-economic concerns reflect important considerations, but those considerations fall outside the Codex mandate and encourage FAO and WHO, or other international organizations to consider these topics as appropriate.

IRAN

1- In our opinion, among the areas which have been proposed, guidelines for " Foods derived from GM plants" has the top priority, and "Presence of low level of unauthorized GE foods"," Comparative food composition analysis", are in the next steps.

2- In our opinion the area covers "Foods derived from transgenic animals" and "Cloned animals" has less priority, compared to GM plants, since GM plants cultivated over the world and there are many foods in global market that including these plants.

3- We propose that separate guidelines for "safety assessment of plants expressing bioactive substances and nutritionally-enhanced plants", and also "plants with stacked genes", "plants expressing pharmaceutical or other non-food substances", be prepared and annexed to CAC/GL 45.

4- We support the establishment of a guideline for "food safety assessment of GM animals" and "cloned animals" too.

5- Since there are some questions that have not yet been answered completely we suggest an expert consultation meeting to be held to clarify the issue of composition analysis, and the role and limitation of Substantial Equivalence.

JAPAN

General Comments

The concept of substantial equivalence was discussed in previous Codex Ad Hoc Intergovernmental Task Force on Foods derived from Biotechnology and identified as the basic element of the safety assessment process of foods derived from biotechnology. Therefore, any foods derived from modern biotechnology should be evaluated based on this concept.

The priority of new work should be given to the products that have already been developed and have prospects of practical use as food. Japan considers that plants with "stacked" genes, "nutritionally-enhanced" plants, and recombinant-DNA fish fall under this category.

We believe, however, recombinant-DNA crops for non-food purposes, for example, plants that produce pharmaceuticals (biopharming), industrial compounds (bioplastiques), or plants for restoration of environment (bioremediation) are outside the scope of Codex.

Specific Comments

Japan suggests three items with priority order given below.

1. Foods derived from plants with "stacked" genes
2. Foods derived from "nutritionally-enhanced" plants
3. If foods derived from recombinant-DNA animals are to be discussed, priority should be given to foods derived from recombinant-DNA fish

The specific comments are given as follows, and Project Document for each of these proposed items are attached.

(I) FOODS DERIVED FROM PLANTS WITH "STACKED" GENES

1. The purpose

To develop a guideline for safety assessment of the foods derived from plants with "stacked" genes, as an appendix to the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants.

2. The rationale

Since "stacked" variety has been developed and commercialized in recent years in order to confer different traits in plants, it is important to establish guideline for safety assessment of foods derived from such plants.

3. The scope

The document should address safety assessment of foods derived from plants obtained through conventional breeding of recombinant-DNA plants with other recombinant-DNA plants, both developed for food.

4. The need for additional scientific advice / questions to be answered by experts

- In which combination of parental plants should safety assessment be conducted for individual plants with "stacked" genes? How should comparator be selected?
- How to ascertain gene stability during the production of plants with "stacked" genes?

5. Information on the relation between the proposal and other existing Codex documents and other pertinent documents

Documents listed below would be useful references to the discussion of this issue.

- *The Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants.* (paragraph 46)
- Food Safety Commission, Japan (January 29, 2004), *The Concept of Safety Assessment of the Food Derived from Breeding Recombinant DNA Plants.*
- Report of a Joint FAO/WHO Consultation (1996), *Biotechnology and Food Safety.* (the concept of further strains/varieties)

6. Any other considerations

Methods of quantitative detection of "stacked" variety should be addressed by CCMAS.

(II) FOODS DERIVED FROM "NUTRITIONALLY–ENHANCED" PLANTS

1. The purpose

To develop a guideline for safety assessment of the food derived from "nutritionally – enhanced" plants, as an appendix to the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants.

2. The rationale

"Nutritionally–enhanced" plants have already been developed and commercialized. It is important to elaborate the way in which safety assessment of foods derived from these plants

are performed. The method of comparative safety assessment should be elaborated when the plants have significantly altered metabolism.

3. **The scope**

The document should address plants that express nutritional substances endogenous to the host plants at altered levels, or nutritional substances coded by genes derived from other species. Exposure assessment, i.e., assessment of the potential nutritional and health outcomes should be addressed in other appropriate Codex committee, since the issue is not unique to the foods derived from modern biotechnology.

4. **The need for additional scientific advice / questions to be answered by experts**

- Can the profiling techniques be applied to "nutritionally-enhanced" plants? If yes, how?

5. **Information on the relation between the proposal and other existing Codex documents and other pertinent documents**

Documents listed below would be useful references to the discussion of this issue.

- Report of a Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology (2000), *Safety aspects of Genetically Modified Foods of Plant Origin.* (Application of profiling techniques as non-targeted approach: Section 4.3, paragraph 7)
- ILSI (2004), *Nutritional and Safety Assessments of Foods and Feeds Nutritionally Improved Through Biotechnology.*
- Codex Guidelines on Nutritional Labelling (CAC/GL 2-1985, definition of nutrient: paragraph 2.5)

6. **Any other considerations**

- The issues of assessment of the potential impact on the diet, on human nutrition and health should be addressed by other relevant committee.

(III) FOODS DERIVED FROM FISH (TRANSGENIC FISH)

1. **The purpose**

To develop a guideline for conduct of safety assessment of foods derived from recombinant-DNA Fish.

2. **The rational**

Since recombinant-DNA fish, such as fish inserted with genes coding for growth hormones, has been developed in recent years, it is relevant to elaborate guideline for safety assessment of foods derived from recombinant-DNA fish.

3. **The scope**

The document should address fish intended as food and should not include fish not intended for food, such as aquarium (pet) fish. This document should solely focus on the safety of fish as foods, and not on risk assessment of recombinant-DNA fish on environment.

Animals in general are too broad as a category, and transgenic mammals as food are in early stage of development. With limited national experiences on which to base a guideline, if transgenic animals are considered as a new work, working first on recombinant-DNA fish, which have commercial prospective, would be appropriate.

4. **The need for additional scientific advice / questions to be answered by experts**

- How to choose conventional counterpart taking account of breeding partner, life stages, etc.?
- How should offspring of recombinant DNA-fish be assessed for safety as food?
- Are sufficient compositional analysis data available for assessment of recombinant-DNA fish?

5. Information on the relation between the proposal and other existing Codex documents and other pertinent documents

In addition to the three guidelines from the previous Task Force, documents listed below would be useful references to the discussion of this issue.

- Report of a Joint FAO/WHO Consultation (2004), *Food derived from genetically modified animals, including fish.*
- Draft Code of Practice for Fish and Fishery Products (Aquaculture) (Step 8)
- National Research Council (2002), *Animal Biotechnology.*
- OECD (1993), *Safety Evaluation of Foods Derived by Modern Biotechnology, Concepts and Principles.*
- OECD (1994), *Aquatic Biotechnology and Food Safety.*
- OECD (1995), *Environmental Impacts of Aquatic Biotechnology.*
- OIE (2004), *Aquatic Animal Health Code*

6. Any other considerations

- The effects of recombinant-DNA fish on environmental conditions and ethical issues would better be considered in other relevant international organizations.

MEXICO

a) Mexico agrees with the terms established in the Circular Letter CL 2005/02-FBT Request for proposals for the new task to be undertaken by the Intergovernmental Task Force on Foods Derived from Biotechnology.

b) It is recommended that a connection be established with the Committee on Methods of Analysis and Sampling (CC/MAS) for its work on methodologies of sampling and identification of foods derived from biotechnology.

c) It proposes to be included in the agenda an item on surveillance after the foods derived from biotechnology have been put on the market.

d) It wishes to make a special emphasis on item 4 of the document CL 2005/02-FBT (comparative composition analysis of foods) in order to focus on the application of new technologies for its development since it is essential to count on solid line base information to carry out an adequate risk evaluation of foods derived from biotechnology and in particular the new phenotypes which modify the nutritional composition of the foods.

NEW ZEALAND

New Zealand proposes that *Foods derived from recombinant-DNA Animals* should be the first priority of the new Task Force.

Rationale

New Zealand believes the new Task Force should focus on a topic that is of emerging interest and one which might have relevance from a food safety and regulatory perspective.

Foods derived from recombinant-DNA animals are of growing interest both from regulatory and commercial perspectives. The interest in applying recombinant-DNA technology to fish provides a logical basis for commencing with this topic.

We believe that interest in this area was signalled towards the conclusion of the last Task Force. An FAO/WHO Expert Consultation has also been conducted recently to provide scientific advice on the safety assessment of foods derived from genetically modified animals, including fish[3]. This document provides a useful technical resource to start the Task Force discussions.

Work on foods derived from recombinant-DNA animals would complement the suite of documents developed during the first Task Force (see below).

Scope

The scope of any work on foods derived from recombinant-DNA animals should clearly be limited to developing guidelines for safety assessment along the lines of the documents prepared for foods derived from recombinant-DNA plants, and foods produced using recombinant-DNA microorganisms. This is consistent with the mandate of Codex to develop standards and related texts for health protection and promotion of fair practices in food trade. Matters that do not fall within the mandate of Codex should be considered in other appropriate fora.

Need for additional scientific work

New Zealand believes the Task Force should review the information in the FAO/WHO report on the safety assessment of foods derived from genetically modified animals, including fish to determine if there are areas that need updating or further scientific advice.

Relationship between the suggested issue and other existing Codex documents

The suggestion to focus on developing guidelines for assessing the safety of foods derived from recombinant-DNA animals would complement the outputs of the first Task Force on Foods Derived from Biotechnology. The *"Principles for the Risk Analysis of Foods derived from Modern Biotechnology"* provides a sound overarching framework for the development of specific guidelines for assessing the safety of foods derived from recombinant-DNA animals.

Similarly, the documents developed by the previous Task Force on:

- *"Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants"*; and
- *"Guideline for the conduct of food safety assessment of foods produced using recombinant-DNA microorganisms."*

provide useful models for developing similar guidelines for assessing the safety of foods derived from recombinant-DNA animals. Indeed New Zealand believes that the outputs and experience gained from the first Task Force should enable the Second Task Force to follow a structured approach to the development of guidelines for safety assessment of recombinant DNA animals.

Expected outcome

The expected outcome of new work is the development of Codex guidelines for assessing the safety of foods derived from recombinant-DNA animals.

The first task force was very successful in completing its work within the 4 year time frame. New Zealand recommends that the Codex Alimentarius Commission approve the above proposal as new work so that the first session of the Task Force can proceed as expeditiously as possible.

[3] FAO/WHO Expert Consultation. November 2003. Safety assessment of foods derived from genetically modified animals, including fish. 36 pp.

UNITED STATES OF AMERICA

COMMENTS

The United States welcomes the re-establishment of the Codex *Ad-Hoc* Intergovernmental Task Force on Foods Derived from Biotechnology. We strongly support the objectives of the Task Force to develop international science-based guidance for foods derived from modern biotechnology that is relevant to the health of consumers and the promotion of fair practices in the food trade. The United States also welcomes and appreciates the hosting of the Task Force by the Government of Japan.

The United States notes the Terms of Reference of the Task Force, particularly that the Task Force is to "elaborate standards, guidelines, or other principles, as appropriate, for foods derived from modern biotechnology, taking account, in particular, the *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology*". The United States strongly believes the work of the Task Force should focus only on the safety assessment of foods derived from modern biotechnology. Further, we believe that other issues, including labeling and the environment, should be addressed by other appropriate Codex committees or other international bodies that have the relevant competence to deal with those issues.

The United States has carefully considered the areas of potential new work the re-established Task Force might undertake. In considering new work areas we have noted the suggestions presented in CL 2005/2-FBT and in the report of the final fourth session of the original Task Force (ref: ALINORM 03/34A, paragraphs 81-86). We have considered the availability of sufficient scientific information to undertake specific new work, the feasibility of completing the work within the four-year lifetime of the Task Force and the value of the guidance to both developed and developing countries.

United States Proposed Projects

Food Safety Issues Specific to Staple Food Crops for Developing Countries (Food Composition) The United States believes that it would be useful for the Task Force to identify the key components (e.g. important nutrients, anti-nutrients, and toxins) and other information that would be specific to the safety assessment of staple crops that are important to developing countries. The United States therefore proposes new work, as an annex to the Plant Guideline, to identify information that can assist countries, especially developing countries, in conducting food safety assessments on staple crops.

Low-Level Presence in Food of Plant Material Derived from Recombinant-DNA Plants. The United States believes countries will be increasingly faced with situations where they will be assessing food safety of low-levels of recombinant-DNA plant material in the food supply. Therefore, the United States is proposing new work in this area as an annex to the Plant Guidelines.

Codex Project Documents for each of these proposed new work areas are attached (Attachments 1 and 2).[4]

Consideration of Other Work Areas Identified in CL 2005/2-FBT

Transgenic animals. The United States recognizes that the safety of foods from recombinant-DNA animals is an emerging and important topic of modern biotechnology, but also recognizes that there is relatively limited national experience on which to base a guideline. Therefore, the United States questions whether this would be an appropriate time for the Task Force to begin work in this area. If new work is undertaken in this area, the United States would propose that a step-wise approach be taken by the task force. Such an approach would be based on available science and the capability to develop an appropriate international guidance text, with clear decision points on proceeding further with work on the subject.

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[4] These Project Documents submitted by the United States are attached to this working document as Annex 1 and Annex 2.

Were the Task Force to take on this project, we believe that it should first identify elements of the existing Guidelines that are relevant to food from recombinant-DNA animals. It then could identify any additional concepts that would be relevant to the food safety assessment of foods derived from recombinant-DNA animals, and any topics that might require additional scientific input, such as an FAO/WHO expert consultation.

Based on this work, it could develop a general guidance document, describing the elements common to the safety assessment of foods derived from any recombinant-DNA animal. Once this general guideline had been developed, the Task Force could address particular cases; for example, particular species modified for particular end-uses.

Cloned animals. The United States believes that animal clones would not be an appropriate topic for the task force. If the task force were to take up a project on food from animals, we believe it should parallel that done by the Task Force on foods derived from recombinant DNA plants and foods derived from recombinant DNA microbes, and thus should address foods derived from recombinant DNA animals. Additionally, the United States does not believe that animal cloning fits within the definition of modern biotechnology.

Plants expressing bioactive substances or nutritionally-enhanced plants. The United States recognizes that development and commercialization of such plants may raise issues that governments will need to address. However, the United States believes that the existing guideline for the food safety assessment of foods from recombinant-DNA plants provides an adequate framework for assessing the safety of foods derived from these crops. The United States believes that safety issues related to specific traits, such as an increased level of a nutrient, should be assessed on a case-by-case basis, and the resolution of such issues would be difficult to promulgate as general guidelines. In addition, the United States believes that many of the issues related to health-enhanced foods would involve questions of appropriate labeling that would not fall within the terms of reference of the Task Force. The United States, however, would be willing to consider suggestions from other governments on this topic.

Plants with "stacked" genes. The United States is not aware of substantial safety issues associated with foods derived from "stacked" varieties of rDNA plants that are not covered by the existing recombinant-DNA plant guideline. The United States, however, would be willing to consider suggestions from other governments on this topic.

Biopharming/plants expressing pharmaceutical or other non-food substances. The United States recognizes that these plants raise important issues, but does not believe that they fall within the mandate of the Task Force.

The United States notes that potential new work areas for the re-established Task Force have been suggested that do not focus on foods and/or are not science-based (ref: ALINORM 03/34A, paras. 81-82; CL; CAC/27 Lim.9-Response to CL 2004/7-FBT) . These potential new work areas include work on: ethics and socio-economic considerations of foods derived from modern biotechnology; other legitimate factors related to modern biotechnology; environmental concerns; and, work on recombinant-DNA crops developed for non-food purposes; i.e., to produce pharmaceuticals or industrial compounds. We believe work areas such as those associated with the environment or with the safety assessment of crops developed for non-food purposes are not within the mandate of Codex. Additionally, we believe the areas of socio-economic concerns and other legitimate factors vary extensively from country to country; these work areas should therefore be dealt with at the national level and the United States would not support Codex, as an international food standards-setting body, undertaking these areas of work.

VENEZUELA

Following the request for proposals for the new task to be undertaken by the Intergovernmental Task Force on Foods Derived from Biotechnology, Venezuela would like to make the following recommendations:

- In point 2) "Foods of vegetable origin" it is suggested to incorporate the term "Transgenic Plants" as was established in point 1) "Foods of animal origin" and to differentiate from which transgenic plants they are derived.

- In point 2) "Foods of vegetable origin" it is necessary to note the difference between "Biopharmaceutical Agriculture" and "Producer plants of Pharmaceutical or other non-Nutritive Substances"

- We consider it relevant that "Biopharmaceutical Agriculture" be treated as a separate item to for development by the CX/FBT.

- In point 3) "Presence of Low Concentrations of non authorized Genetically Modified Foods in authorized foods" generates confusion since it is not clear if the low concentrations of genetically modified foods are present in the raw material or in the final product.

- The item on "Traceability" in Foods obtained by Biotechnological Means should be continued.

- The "flow of genes" within the aspects to be treated should be considered.

- The item of "biosecurity" or the effect on the environment should be taken into consideration.

49th PARALLEL BIOTECHNOLOGY CONSORTIUM

The 49th Parallel Biotechnology Consortium is pleased to continue its participation in the important work of Codex relating to Foods Derived from Biotechnology. We appreciate the actions of the Government of Japan in hosting the re-established Task Force. We responded to the earlier circular Letter (2004/7) and are herein commenting on the current one.

(1) We are pleased to note that the Objectives for the Task Force (ALINORM 04/27/41) include *both* of the Codex mandates—protecting consumer health and promoting fair practices in the food trade. While the Terms of Reference direct that the Task Force "(take) into account . . . the Principles for the Risk Analysis of Foods derived from Modern Biotechnology," they thus go beyond those Principles to encompass, for example, the Other Legitimate Factors noted in the Codex statutes. We note below how this is relevant to some of the proposed project work.

(2) The 49 P supports having a project on GE/GM animals. In this project the OLFs should play a role—virtually all societies have norms about animal welfare, especially for sentient beings. These ethical principles must be reflected in the work of the Task Force on this project. We have long progressed beyond the days of Descartes when scientists, believing that dogs had no feelings, nailed them to walls for vivisections and explained the howls and whimpers as merely involuntary reactions, similar to a flower turning towards the light.

(3) We oppose undertaking any project on the low-level presence of unauthorized GE products in foods. In our view, there is nothing to discuss here— "unauthorized" means unauthorized.

If a country has not authorized a substance for consumption, any presence is cause for rejecting the food and destroying it. Any other position makes a sham out of governmental regulatory processes, as well as exposing the population to unknown health risks and the environment to potential contamination, etc. A project on this topic would somehow seem to legitimize contamination which is, in reality, tortious conduct--the interference with people's ownership and control of their own property.

The issues here are ones of detection (technology), monitoring, sanctions, liability—not a policy that says that some amount of contamination is alright. The Task Force should maintain a focus on policy questions; if it decides that these technical issues are important it should recommend to the CAC that the appropriate Codex committee(s) take them up.

In any discussion of this topic, the participants should bear in mind that the implementation of Article 18 of the Cartgena Protocol on Biosafety (dealing with identification and traceability of genetically modified food organisms that move across national borders) will be playing a role in shaping international norms.

(4) In regard to a project on bioactive plants/biopharming/etc., it is not clear to us how the CL is using these terms, so detailed commentary is difficult. However, 49 P believes that pharmaceuticals or industrial chemicals should *never* be produced in food plants, for the obvious reasons that there will be outcrossing, accidental and involuntary medication, the consumption of substances that may be unsuitable as foods, etc.

(5) Other Proposed New Work areas: 49 P supports proposals that the Task Force should consider the ethical, environmental, and socio-economic ramifications of foods derived from modern biotechnology; indeed, a fundamental principle of our organization (and its constituents) is that democratic control over new technologies requires more public discourse on their ramifications. We reject arguments that such topics are inappropriate for Codex because they are not "science-based"—our lengthy conversations about trade issues are, in fact, socio-economic discussions. We cannot agree that only the socio-economic factors of interest to the wealthy and powerful are legitimate Codex concerns.

BIOTECHNOLOGY INDUSTRY ORGANIZATION (BIO)

This letter is submitted by the Biotechnology Industry Organization (BIO), in response to the notice of "Request for proposals for new work to be undertaken by the Codex *Ad Hoc* Intergovernmental Task Force on Foods Derived from Biotechnology". BIO is an international non-governmental organization with Codex Observer Status representing more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations in all 50 U.S. states and 33 other nations. BIO members are involved in the research and development of health-care, agricultural, industrial and environmental biotechnology products, including biotechnology-derived crops.

We appreciate the opportunity to provide these comments. BIO believes that the projects to be considered by the Codex *Ad Hoc* Intergovernmental Task Force on Foods Derived from Biotechnology (TF) should be adequately supported by a scientific, objective and verifiable body of data upon which to consider Codex Guidance or Standards. Further, we believe that projects to be considered must be related to the health and safety of the consumer and with respect to fair practices in food trade.

With regard to the specific new work to be covered by the task force, BIO proposes that the new TF's highest priority be the following:

Guidelines/Principles for the assessment of the inadvertent, intermittent low-level presence of protein(s) in food/food ingredients for

a. approved/authorized within a country/countries that follow Codex risk assessment principles for products of plant biotechnology; and

b. unapproved/unauthorized traits - traits, which may be present but have yet to be approved in a country/countries that follow Codex risk assessment principles for products of plant biotechnology.

We believe that this crucial area is strongly supported by adequate science, is of importance to demonstration of safety of foods and food ingredients derived from modern biotechnology, and also may impact the ability of member governments to fairly trade certain foods/food ingredients.

BIO strongly believes that given the recent work of countries such as the United States to develop a framework and implementation guidelines for the low level, unintended presence of a trait derived from the use of agricultural biotechnology, these countries could provide leadership within the TF to clarify and objectively assess the human health and safety implications of this area of work. The scientific underpinnings for the safety assessment of the inadvertent, intermittent, low-level presence of a biotech trait, such as protein(s) safety would provide a useful foundation upon which to establish the risk analysis model for such components.

The competence and expertise provided by member governments participating in the first TF is amply demonstrated by the work products of that TF. Continued work in the areas of interest in plant biotechnology would best utilize existing competencies and could use the Principles and Guidelines models as reference points from which to continue work in the plant areas.

CONSUMERS INTERNATIONAL

Consumers International (CI) is pleased to have the opportunity to comment on new work to be addressed by the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology. We are pleased that the Objectives of the Task Force (ALINORM 04/27/41, Appendix VIII) includes reference to "having regard, where appropriate, to other legitimate factors [OLFs] relevant to the health of consumers and the promotion of fair practices in the food trade." This reference to OLF is important as the issue will definitely come up in the area of foods derived from transgenic animals, including fish.

Foods derived from animals

In the area of foods derived from animals, CI believes that, for a number of reasons, the new Task Force should work on developing guidelines for food safety assessment for foods derived from transgenic animals, including fish, and we include a project document for new work in this area. First, this work would be important, as transgenic animals, especially fish are being developed in a number of countries and are very close to approval, at least in the United States. Second, the work would fulfill the recommendation of the first session of the Task Force of March 2000 (ALINORM 01/34, para. 28) that a guideline be developed on safety of foods of animal origin derived from biotechnology. An FAO/WHO Joint Expert Consultation on the Safety Assessment of Foods Derived from Genetically Modified Animals, including Fish, was held in 2003, so there is already expert scientific opinion in this area.

Third, work on transgenic animals is important as it raises a range of ethical, religious, animal welfare and other issues that clearly fall under the rubric of OLFs. Guidance on how to "have regard" of OLF's would be very valuable. Many people feel very queasy about the notion of developing transgenic animals. For example, in the United States, surveys have shown that people are far more concerned about the genetic engineering of animals compared to the genetic engineering of plants (ref to come; cite Hoban's work, plus NAS/NRC animal biotech study). Religious issues include various dietary restrictions which could be violated by transgenic animals. For example, a transgenic animal may contain a gene or gene product from a prohibited animal (such as pigs for Jews and Muslims, or

cows for some Hindus), or the mixing of genetic elements from distinct species might be prohibited. Ethical concerns about tampering with human life could also be an issue. A human protein produced by an animal might enter the food chain, or a transgenic animal with genes from a human could theoretically be developed for human consumption. In either case, such food may be unacceptable for consumption for some people who could view it as a form of cannibalism. Ethical issues also include animal welfare. Animal welfare issues are particularly prominent in the European Union, as well as some countries in Asia. The impact of a biotechnology process on animal welfare must be considered; techniques that are considered to increase an animal's suffering may be banned or severely restricted in some countries. For example, as a result of "large birth syndrome" and the high rate of death among animal clones developed via somatic cell nuclear transplants, some countries do not permit the use of this technology for reproducing large food animals. Early experiments with salmon genetically engineered with growth hormones found cranial deformities in the transgenic salmon, which some people might regard as constituting unnecessary suffering.

The FAO/WHO Joint Expert Consultation recognized ethical issues related to transgenic animals, devoted a section of the report to said ethical issues and even talked about ways to incorporate ethical issues into the risk assessment process. CI feels that the Task Force must consider how to deal with ethical, religious and cultural issues as part of the safety assessment process for transgenic animals. Such issues constitute OLFs that are extremely important and very relevant, when discussing transgenic animals.

In looking at the issue of transgenic animals, CI also feels that the Task Force should look carefully at the issue of the food-safety related aspects of environmental issues associated with transgenic animals, including fish. Transgenic fish, shellfish, and fowl (ducks, geese, chickens, etc.), but especially transgenic fish and shellfish, could escape into the wild, may persist in the wild and be consumed by people via hunting and fishing. Some farmed animals are shipped and sold alive, thereby increasing the risk of accidental escape into the environment. The potential exists for significant effects on wildlife; one computer simulation of the possible effect of escape of faster-growing GM/GE fish (such as salmon) into the environment was a possible extinction of wild populations of that fish (Muir and Howard, 1999). Such an outcome could have serious impacts on communities that rely heavily on that fish (e.g. salmon) (or other wildlife species) for food; thus environmental effects could have an indirect impact on public health. It is essential that Codex address integration of such issues into its safety assessment.

CI believes that the Task Force should not develop a project on animal cloning. We feel that animal cloning, especially the somatic cell nuclear transplant technology, does not fit within the Terms of Reference for the Task Force, which has the Task Force focus on "foods derived from modern biotechnology" (ALINORM 04/27/41 Appendix VIII). In particular, a close reading of the definition of "modern biotechnology" seems to preclude the technology involved in cloning. "Modern biotechnology" refers to "(i) in vitro nucleic acid techniques . . . or (ii) Fusion of cells beyond the taxonomic family" (CAG/GL 44, 2003). The techniques involved in cloning necessarily include neither "in vitro nucleic acid techniques" nor "fusion of cells beyond the taxonomic family." So, cloning appears to be outside the scope of the Task Force.

Foods derived from plants

In the area of foods derived from plants, CI believes that a number of the proposed projects should not be taken up by the Task Force. First, a number of the areas listed-particularly "Biopharming," "Plants expressing pharmaceutical or other non-food substance," and perhaps "Plants expressing bioactive substances or nutritionally-enhanced plants"-appear to refer to the same general area, plants that are genetically-engineered/genetically modified to produce pharmaceutical products for humans and/or animals and other non-food products (such as industrial compounds or research chemicals). CI believes that this Task Force should not undertake new work in this area. We note that Codex Alimentarius deals with assuring the safety of food, and so plants that are genetically-engineered/genetically modified to produce non-food substances, such as human and animal drugs, industrial compounds or research chemicals should not be considered as foods and so should not be

within the scope of Codex. As for "nutritionally-enhanced plants," we see no need for the Task Force to undertake new work in this area. CI believes that the present Guidelines for the Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAG/GL 45, 2003) adequately cover "nutritionally-enhanced plants."

CI also believes that no work is needed in the area of "Low level presence of unauthorized genetically engineered foods in authorized foods." First, we do not believe that this is primarily a scientific food safety issue; rather, this is primarily a legal issue. For many countries, if a genetically engineered (GE) food is "unauthorized," then the permitted level of that GE food permitted in an authorized food is zero. Consumers International believes that until an "unauthorized genetically engineered food" completes a full food safety assessment as laid out in the Guidelines for the Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAG/GL 45, 2003), it should not be permitted on the market and that there should be zero tolerance for this food in authorized foods. However this is primarily a legal issue, one which national governments must address.

Annex 1

PROJECT DOCUMENT

Proposal for New Work on Foods Derived from Plants with "Stacked" Genes

Prepared by: Japan

1. The purposes and the scope of the proposed work.

To develop a guideline for safety assessment of the foods derived from **plants with "stacked" genes**, as an appendix to the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants, on the basis of scientific evidence, risk analysis and having regard, where appropriate, to other legitimate factors relevant to the health of consumers and promotion of fair trade practices. It is important to keep the scope of the work science-based in order to facilitate achieving useful outputs.

2. Its relevance and timeliness.

Ad Hoc Codex Intergovernmental Task Force on Food Derived from Biotechnology (2000 – 2003) produced Principles for the Risk Analysis of Foods Derived from Modern Biotechnology and Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants and of Foods Produced Using Recombinant-DNA Microorganisms. The last session of the Task Force in March 2003 and the 26th Session of the Codex Alimentarius Commission noted the opinions expressed by many delegations that the Codex should continue the discussion on foods derived from modern biotechnology, and the 27th Session of the Codex Alimentarius Commission agreed to establish a new Ad Hoc Intergovernmental Task Force on Foods derived from Biotechnology. In view of the proposals and views expressed in the Task Force and the Commission, it is relevant and timely to produce new Codex texts on foods derived from **plants with "stacked" genes** that would further support and complement the above Principles and Guidelines.

3. The main aspects to be covered.

Additional safety assessment for foods derived from **plants with "stacked" genes**

4. An assessment against the criteria for the establishment of work priorities.

As modern biotechnology can be significant powerful tools for the production of food, the safety of foods derived from modern biotechnology must be ensured as much as possible. The safety of foods derived from **plants with "stacked" genes**, its potential risks to consumer health and promotion of its fair trade must be fully considered.

This proposal is consistent with:

(a) Consumer protection from the point of view of health and fraudulent practices

(b) Diversification of national legislations and apparent resultant or potential impediments to international trade.

(d) Work already undertaken by other international organizations in this field.

There is no other international organization that has undertaken international standard setting activities for the foods derived from **plants with "stacked" genes**.

5. Relevance to the Codex strategic objectives.

The new work contributes to the safety of human health and fair trade of foods derived from modern biotechnology by satisfying the following objectives the "Strategic objectives and priorities" (CAC Strategic Framework 2003 - 2007).

Objective 1: Promoting sound regulatory frameworks

Objective 2: Promoting widest and consistent application of scientific principles and risk analysis

Objective 4: Enhancing capacity to respond effectively and expeditiously to new issues, concerns and developments in the food sector

Objective 6: promoting maximum application of Codex standards

6. Information on the relation between the proposal and other existing Codex documents.

The previous Task Force produced the following documents which are related with the other existing Codex documents especially in conjunction with the Working Principles for the Risk Analysis for Application in the Framework of the Codex Alimentarius. The text on the Assessment of Possible Allergenicity was developed as an appendix to the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants and the text on **plants with "stacked" genes** can be developed in a similar manner.

- Principles for the Risk Analysis of Foods Derived from Modern Biotechnology
- Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants
- Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms

7. Identification of any requirement for and availability of expert scientific advice.

- In which combination of parental plants should safety assessment be conducted for individual plants with "stacked" genes. How to select comparator.

- How to ascertain gene stability of plants with "stacked" genes

8. Identification of any need for technical input to the Task Force from external bodies so that this can be planned for.

Necessary, if available.

9. The proposed time-line for completion of the new work, including the start date, the proposed date for adoption at Step 5 and the proposed date for adoption by the Commission; the time frame for developing a standard should not normally exceed five years.

The time frame for the Task Force is four years. Therefore, if the new work is approved by the Commission in 2006, adoptions at Step 5 and at Step 8 will be at the latest in 2008 and in 2009, respectively.

Annex 2

PROJECT DOCUMENT

Proposal for New Work on Foods Derived from "nutritionally-enhanced" Plants

Prepared by: Japan

1. The purposes and the scope of the proposed work.

To develop a guideline for safety assessment of the foods derived from **"nutritionally-enhanced" plants**, as an appendix to the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants, on the basis of scientific evidence, risk analysis and having regard, where appropriate, to other legitimate factors relevant to the health of consumers and promotion of fair trade practices. It is important to keep the scope of the work science-based in order to facilitate achieving useful outputs.

2. Its relevance and timeliness.

Ad Hoc Codex Intergovernmental Task Force on Food Derived from Biotechnology (2000 – 2003) produced Principles for the Risk Analysis of Foods Derived from Modern Biotechnology and Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants and of Foods Produced Using Recombinant-DNA Microorganisms. The last session of the Task Force in March 2003 and the 26th Session of the Codex Alimentarius Commission noted the opinions expressed by many delegations that the Codex should continue the discussion on foods derived from modern biotechnology, and the 27th Session of the Codex Alimentarius Commission agreed to establish a new Ad Hoc Intergovernmental Task Force on Foods derived from Biotechnology. In view of the proposals and views expressed in the Task Force and the Commission, it is relevant and timely to produce new Codex texts on foods derived from **"nutritionally-enhanced" plants** that would further support and complement the above Principles and Guidelines.

3. The main aspects to be covered.

Additional safety assessment for foods derived from **"nutritionally-enhanced" plants**

4. An assessment against the criteria for the establishment of work priorities.

As modern biotechnology can be significant powerful tools for the production of food, the safety of foods derived from modern biotechnology must be ensured as much as possible. The safety of foods derived from **"nutritionally-enhanced" plants**, its potential risks to consumer health and promotion of its fair trade must be fully considered.

This proposal is consistent with:

(a) Consumer protection from the point of view of health and fraudulent practices

(b) Diversification of national legislations and apparent resultant or potential impediments to international trade.

(d) Work already undertaken by other international organizations in this field.

There is no other international organization that has undertaken international standard setting activities for the foods derived from **"nutritionally-enhanced" plants**.

5. Relevance to the Codex strategic objectives.

The new work contributes to the safety of human health and fair trade of foods derived from modern biotechnology by satisfying the following objectives the "Strategic objectives and priorities" (CAC Strategic Framework 2003 - 2007).

Objective 1: Promoting sound regulatory frameworks

Objective 2: Promoting widest and consistent application of scientific principles and risk analysis

Objective 4: Enhancing capacity to respond effectively and expeditiously to new issues, concerns and developments in the food sector

Objective 6: promoting maximum application of Codex standards

6. Information on the relation between the proposal and other existing Codex documents.

The previous Task Force produced the following documents which are related with the other existing Codex documents especially in conjunction with the Working Principles for the Risk Analysis for Application in the Framework of the Codex Alimentarius. The text on the Assessment of Possible Allergenicity was developed as an appendix to the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants and the text on **"nutritionally-enhanced" plants** can be developed in a similar manner.

- Principles for the Risk Analysis of Foods Derived from Modern Biotechnology
- Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants
- Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms

7. Identification of any requirement for and availability of expert scientific advice.

- Can the profiling techniques be applied to "nutritionally-enhanced" plants? If yes, how?

8. Identification of any need for technical input to the Task Force from external bodies so that this can be planned for.

Necessary, if available.

9. The proposed time-line for completion of the new work, including the start date, the proposed date for adoption at Step 5 and the proposed date for adoption by the Commission; the time frame for developing a standard should not normally exceed five years.

The time frame for the Task Force is four years. Therefore, if the new work is approved by the Commission in 2006, adoptions at Step 5 and at Step 8 will be at the latest in 2008 and in 2009, respectively.

Annex 3

PROJECT DOCUMENT

Proposal for New Work on Foods Derived from Recombinant-DNA Fish

Prepared by: Japan

1. The purposes and the scope of the proposed work.

To develop a guideline for safety assessment of the foods derived from **recombinant-DNA fish**, on the basis of scientific evidence, risk analysis and having regard, where appropriate, to other legitimate factors relevant to the health of consumers and promotion of fair trade practices. It is important to keep the scope of the work science-based in order to facilitate achieving useful outputs.

2. Its relevance and timeliness.

Ad Hoc Codex Intergovernmental Task Force on Food Derived from Biotechnology (2000 – 2003) produced Principles for the Risk Analysis of Foods Derived from Modern Biotechnology and Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants and of Foods Produced Using Recombinant-DNA Microorganisms. The last session of the Task Force in March 2003 and the 26th Session of the Codex Alimentarius Commission noted the opinions expressed by many delegations that the Codex should continue the discussion on foods derived from modern biotechnology, and the 27th Session of the Codex Alimentarius Commission agreed to establish a new Ad Hoc Intergovernmental Task Force on Foods derived from Biotechnology. In view of the proposals and views expressed in the Task Force and the Commission, it is relevant and timely to produce new Codex texts on foods derived from **recombinant-DNA fish** that would further support the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology.

3. The main aspects to be covered.

Safety assessment for foods derived from **recombinant-DNA fish**

4. An assessment against the criteria for the establishment of work priorities.

As modern biotechnology can be significant powerful tools for the production of food, the safety of foods derived from modern biotechnology must be ensured as much as possible. The safety of foods derived from **recombinant-DNA fish**, its potential risks to consumer health and promotion of its fair trade must be fully considered.

This proposal is consistent with:

(a) Consumer protection from the point of view of health and fraudulent practices

(b) Diversification of national legislations and apparent resultant or potential impediments to international trade.

(d) Work already undertaken by other international organizations in this field.

There is no other international organization that has undertaken international standard setting activities for the foods derived from **recombinant-DNA fish**.

5. Relevance to the Codex strategic objectives.

The new work contributes to the safety of human health and fair trade of foods derived from modern biotechnology by satisfying the following objectives the "Strategic objectives and priorities" (CAC Strategic Framework 2003 - 2007).

Objective 1: Promoting sound regulatory frameworks

Objective 2: Promoting widest and consistent application of scientific principles and risk analysis

Objective 4: Enhancing capacity to respond effectively and expeditiously to new issues, concerns and developments in the food sector

Objective 6: promoting maximum application of Codex standards

6. Information on the relation between the proposal and other existing Codex documents.

The previous Task Force produced the following documents which are related with the other existing Codex documents especially in conjunction with the Working Principles for the Risk Analysis for Application in the Framework of the Codex Alimentarius. The previous Task Force left the area of foods derived from recombinant-DNA animals, including fish.

- Principles for the Risk Analysis of Foods Derived from Modern Biotechnology
- Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants
- Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms
- Draft Code of Practice for Fish and Fishery Products (Aquaculture) (Step 8)

7. Identification of any requirement for and availability of expert scientific advice.

- How to choose conventional counterpart taking into account breeding partner, life stages, etc?
- How offspring of recombinant-DNA fish should be assessed for safety as food
- Availability of sufficient compositional analysis data for assessment of recombinant-DNA fish

8. Identification of any need for technical input to the Task Force from external bodies so that this can be planned for.

Necessary, if available.

9. The proposed time-line for completion of the new work, including the start date, the proposed date for adoption at Step 5 and the proposed date for adoption by the Commission; the time frame for developing a standard should not normally exceed five years.

The time frame for the Task Force is four years. Therefore, if the new work is approved by the Commission in 2006, adoptions at Step 5 and at Step 8 will be at the latest in 2008 and in 2009, respectively.

Annex 4

PROJECT DOCUMENT

Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology: United States Proposal for New Work: Food Safety Issues Specific to Staple Food Crops for Developing Countries (Food Composition).

Prepared by : The United States of America

1. Purpose and scope of the proposed work

To identify information that can assist countries, especially developing countries, in conducting food composition analyses of foods derived from recombinant-DNA plants to facilitate food safety assessments. This work, to be developed as an Annex to the existing *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants,* will identify key nutrients, anti-nutrients, toxicants, and other substances that are critical to the safety assessment of foods derived from recombinant-DNA plants for staple foods derived from recombinant-DNA plants in developing countries.

2. Its relevance and timeliness

This work is intended to supplement the Codex *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* (CAC/GL 45-2003; the plant guideline) to provide countries with guidance on addressing comparative food composition analyses as part of the safety assessment for staple foods derived from recombinant-DNA plants. Research is progressing in several countries to produce food derived from recombinant-DNA plants. For example, modern biotechnology is being used to develop new varieties of staple crops such as cassava, plantain, sweet potato. Countries will need to conduct food safety assessments for foods derived from these crops prior to commercial distribution. Food composition analyses are an important element of the safety assessment and are specific to each crop. Guidance from Codex would benefit countries that conduct food safety assessments for staple foods derived from modern biotechnology.

3. The main aspects to be covered

a) Identify staple food crops in developing countries in which new varieties are under development using modern biotechnology.
b) Identify and compile information on such substances as key nutrients, anti-nutrients, toxicants for each crop, including data on the range of concentration reported for each component in food.
c) Develop an annex to the plant Guidelines to provide information to countries on food composition analyses

4. An assessment against the *criteria applicable to general subjects* as contained in the *Criteria for the Establishment of Work Priorities*

a) *Consumer protection from the point of view of health and fraudulent practices:* This new work proposal is consistent with this criterion as it provides additional scientific data with which to undertake scientific safety assessments of food derived from modern biotechnology, thus helping to ensure consumer protection.
b) *Diversification of national legislations and apparent resultant or potential impediments to international trade:* This new work proposal is consistent with this criterion as it will provide scientific data which countries may utilize to establish their own individual standards or guidance, and which, when applied internationally may assist in providing an harmonized approach that can facilitate trade.
c) *Scope of work and establishment of priorities between the various section of work:* This new work proposal meets this criterion as it has a clearly defined and achievable scope of work and provides a clear and understandable sequence of what needs to carried-out.

d) *Work already undertaken by other organizations in this field:* This new work proposal meets this criterion as it supplements, but does not duplicate, work undertaken by other international organizations.

5. Relevance to Codex Strategic Objectives

This new work proposal is consistent with:

a) Promoting sound regulatory frameworks.
b) Promoting widest and consistent application of scientific principles and risk analysis.

6. Information on the relation between the proposal and other existing Codex documents.

This proposal would support but not duplicate the Codex *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* (CAC/GL 45-2003).

7. Identification of any requirement for and availability of expert scientific advice.

None identified, though the Task Force will need data and information on recombinant-DNA plants under development in developing countries and data and information on key components for foods derived from such crops.

8. Identification of any need for technical input to the standard from external bodies so that this can be planned for.

None identified.

9. The proposed timeline for completion of the new work, including the start date, the proposed date for adoption at Step 5 and the proposed date for adoption by the Commission; the timeframe for developing a standard should not normally exceed 5 years.

If agreed to by the Task Force at its first meeting, a draft would be presented to the Task Force at its second meeting (2006) for consideration at Step 3. It is expected that the work can be completed within the four-year timeframe for the Task Force.

Annex 5

PROJECT DOCUMENT

Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology: United States Proposal for New Work: Low-level presence in food of plant material derived from recombinant-DNA plants.

Prepared by: The United States of America

1. Purpose and scope of the proposed work

To identify food safety issues in Codex *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* (CAC/GL 45-2003) related to the presence in foods of low levels of material derived from recombinant-DNA plants. The scope of this proposed work would be limited to recombinant-DNA plants developed for food use.

2. Its relevance and timeliness

The focus of this work would be the examination of the existing safety assessment approach in the Codex *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* (CAC/GL 45-2003) to determine which issues in this guideline are appropriate to establish the food safety of low levels of material derived from recombinant-DNA plants. This work is intended to supplement CAC/GL 45-2003 and to provide countries with guidance on addressing food safety issues that pertain to low level presence in foods of material derived from recombinant-DNA plants. This work could be considered as an annex to the Plant Guideline.

Countries will likely be increasingly faced with different circumstances in which they will need to assess the food safety of low levels of recombinant-DNA plant material in food. At various stages in a plant variety's development and production cycle material from that plant variety might be present in the food supply at very low levels. Increasing numbers of new varieties of recombinant-DNA plants are in the research and development stage and are being tested in the field in a growing number of countries. Additionally, as new recombinant-DNA plant varieties leave research and development and enter commerce, older varieties are coming off the market. Even though a plant variety is no longer used commercially, material from it will continue to be present in the food supply, albeit at low levels. Using the existing Codex Guideline on recombinant-DNA plants for identifying the relevant food safety considerations pertaining to such low level presence of recombinant-DNA plant material will aid in the determination of the safety of food in these situations. National governments would use this guidance within the context of their own regulatory frameworks. The document could help guide appropriate risk assessment and risk management decisions made within the contexts of those frameworks.

3. The main aspects to be covered

Develop an annex to the plant Guidelines to identify food safety issues associated with low level presence of recombinant-DNA plant material in food.

4. An assessment against the *criteria applicable to general subjects* as contained in the *Criteria for the Establishment of Work Priorities*

a. *Consumer protection from the point of view of health and fraudulent practices:* This new work proposal is consistent with this criterion as it provides additional guidance with which to undertake scientific safety assessments of food derived from modern biotechnology, thus helping to ensure consumer protection.

b. *Diversification of national legislations and apparent resultant or potential impediments to international trade:* This new work proposal is consistent with this criterion as it will provide scientific guidance which countries may utilize to establish their own individual standards or guidance.

c. *Scope of work and establishment of priorities between the various section of work:* While the precise scope of this work proposal will need to be defined by the Task Force, this proposal provides sufficient guidance to indicate the general scope and nature of the intended work to permit the Task Force to discuss and determine the final scope of the project.
d. *Work already undertaken by other organizations in this field:* This new work proposal meets this criterion as it does not duplicate work undertaken by other international organizations.

5. Relevance to Codex Strategic Objectives
This new work proposal is consistent with:

a) Promoting sound regulatory frameworks.
b) Promoting widest and consistent application of scientific principles and risk analysis.

6. Information on the relation between the proposal and other existing Codex documents.
This proposal would support but not duplicate the Codex *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* (CAC/GL 45-2003).

7. Identification of any requirement for and availability of expert scientific advice.
None identified.

8. Identification of any need for technical input to the standard from external bodies so that this can be planned for.
None identified.

9. The proposed timeline for completion of the new work, including the start date, the proposed date for adoption at Step 5 and the proposed date for adoption by the Commission; the timeframe for developing a standard should not normally exceed 5 years.
If agreed to by the Task Force at its first meeting, a draft would be presented to the Task Force at its second meeting (2006) for consideration at Step 3. It is expected that the work can be completed within the four-year timeframe for the Task Force.

Annex 6

PROJECT DOCUMENT

Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology: Consumers International Proposal for New Work: Food safety guidelines for food derived from recombinant-DNA animals.

Prepared by: Consumers International

1. Purpose and scope of the proposed work

To develop a guideline for the conduct of food safety assessment of foods derived from Recombinant-DNA animals. The guideline would take as a model, the Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003), taking into account differences between plants and animals.

However an extremely important difference between plants and animals is the greater relevance of "other legitimate factors" to animals. Therefore more attention must be given to this area, and guidance should be developed on assessing and integrating other legitimate factors, including environmental impact on public health, animal welfare, and religious and ethical concerns, into the food safety assessment.

2. Its relevance and timeliness

This work would fulfill the recommendation of the first session of the Task Force of March 2000 (ALINORM 01/34, para. 28) that a guideline be developed on safety of foods of animal origin derived from biotechnology, as a third priority after guidelines on "foods of plant origin, followed by micro-organisms used directly in foods." Genetically engineered/genetically modified (recombinant-DNA) animals are being developed in a number of countries around the world and having international guidelines developed would greatly aid countries in assessing the safety of foods derived from such animals.

3. The main aspects to be covered

Using a step-wise approach, develop a guideline for food safety assessment of foods derived from recombinant-DNA animals, taking into account the comparative approach and other concepts from the Principles for Risk Analysis for Foods Derived from Modern Biotechnology and from the Guidelines adopted by Codex for foods derived recombinant-DNA plants and microorganisms.

The guideline should also be developed taking into account the WHO/FAO Expert Consultation on the Safety Assessment of Foods Derived from Genetically Modified Animals, including Fish, held in Rome, Italy on 17-21 November, 2003.

Integration of consideration of "other legitimate factors" should be explicitly addressed.

4. An assessment against the criteria applicable to general subjects as contained in the Criteria for the Establishment of Work Priorities

a. Consumer protection from the point of view of health and fraudulent practices: This new work proposal will provide additional guidance with which to undertake scientific safety assessments of food derived from modern biotechnology, thus helping to ensure consumer protection. The safety assessment, by considering environmental and ethical aspects that can affect food safety would help to ensure consumer protection and also ensure fair and non-fraudulent practices in the food trade. For

example, GM animals could potentially enter the food supply via the environment by escape. Thus, escaped GM fish and shellfish, or their descendants, could be harvested without being detected and subsequently eaten by people. Similar mechanisms could apply for poultry such as ducks and quail that are subject to sport or subsistence harvest. The live transport and sale of GM fish and poultry poses another route for escape of GM animals and their entry into the environment. In all such cases, theses escaped GM animals and their descendents could be eaten by people.

b. Diversification of national legislations and apparent resultant or potential impediments to international trade: This new work proposal will provide scientific guidance which countries may utilize to establish their own individual standards or guidance, and which, when applied internationally, may assist in providing a harmonized approach that can facilitate fair practices in food trade.

c. Scope of work and establishment of priorities between the various section of work: See (1.) above.

d. Work already undertaken by other organizations in this field: This new work does not duplicate work undertaken by other international organizations.

5. Relevance to Codex Strategic Objectives

This new work proposal is consistent with promoting sound regulatory frameworks.

6. Information on the relation between the proposal and other existing Codex documents.

This new work proposal would be consistent with the Principles for the Risk Analysis of Food Derived from Modern Biotechnology (CAC/GL 44-2003) and would complement the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003) and the Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms (CAC/GL 46-2003).

7. Identification of any requirement for and availability of expert scientific advice.

This new work proposal would need expert scientific advice on the proper elements of a safety assessment of GE/GM animal-derived foods. FAO and WHO held an Expert Consultation on the Safety Assessment of Foods Derived from Genetically Modified Animals, including Fish, held in Rome, Italy on 17-21 November, 2003, which should be used in preparation of this new document.

8. Identification of any need for technical input to the standard from external bodies so that this can be planned for.

Technical input already exists. See answer to 7.

9. The proposed timeline for the completion of the new work, including the start date, the proposed date for adoption at Step 5 and the proposed date for adoption by the Commission; the timeframe for developing a standard should not normally exceed 5 years.

If agreed to by the Task Force at its first meeting, a draft would be presented to the Task Force at its second meeting in 2006 for consideration at Step 3. It is expected that the work can be completed within the four-year timeframe for the Task Force.

codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 4 **CX/FBT 05/5/4-Add.1**

June 2005

E/F/S

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

CONSIDERATION OF THE ELABORATION OF STANDARDS, GUIDELINES OR OTHER TEXTS FOR FOODS DERIVED FROM BIOTECHNOLOGY

EUROPEAN COMMUNITY COMMENTS TO CIRCULAR LETTER 2005/2-FBT[1]

OBSERVATIONS DE LA COMMUNAUTÉ EUROPÉENNE CONCERNANT LA LETTRE CIRCULAIRE CL 2005/2-FBT[2]

OBSERVACIONES DE LA COMUNIDAD EUROPEA SOBRE LA CIRCULAR CL 2005/2-FBT[3]

REQUEST FOR PROPOSALS FOR NEW WORK TO BE UNDERTAKEN BY THE CODEX AD HOC INTERGOVERNMENTAL TASK FORCE ON FOODS DERIVED FROM BIOTECHNOLOGY

The European Community and its 25 Member States (hereinafter referred to as the EC) appreciate the opportunity to address the Codex Alimentarius Commission's request for comments on proposals for new work to be undertaken by the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology (CL 2005/2-FBT).

The EC would like to refer to its former comments to CL 2004/7-FBT, in which it thanked the delegation of Japan for its willingness to host a new Task Force on Foods Derived from Biotechnology and supported work in the areas already identified by Codex members and international organisations.

With regard to the specific new work to be covered by the taskforce, the EC would like to propose the following subjects in a <u>decreasing priority order</u>:

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[1] English version is from page 1 to 12.
[2] French version is from page 13 to 24.
[3] Spanish version is from page 25 to 36.

(1) Low level presence of unauthorized genetically modified material in food. As stated before, an agreement, based on science, on this issue would help alleviate or prevent potential trade disputes caused by low levels of GMOs in food through adventitious contamination of non-GM products during production, transport or storage. It would thus serve one of the fundamental objectives of Codex Alimentarius, i.e. to promote fair practices in food trade. The corresponding project proposal is attached (Project document 1).

(2) Food safety assessment of genetically modified animals (including fish) and derived food products. Work on this topic should be in line with the Principles for the Risk Analysis of Foods derived from modern Biotechnology (CAC/GL 44-2003) and based on the outcome of the joint FAO/WHO Expert Consultation on the Safety Assessment of Foods derived from Genetically Modified Animals, including Fish, held at the Headquarters of the Food and Agriculture Organization of the United Nations (FAO) in Rome from 17 to 21 November 2003. Due consideration should be given to environmental and ethical aspects in relation with this question. In order to assist to the development of the proposed Terms of Reference, the EC has developed a project proposal for food produced from GM animals (Project document 2).

(3) Genetically modified plants expressing pharmaceutical or other non-food substances ("bioactive substances"). The EC is of the view that a wider perspective of the area, including all parts of the risk analysis concept, is required. Research and developments in the scientific area has opened the field for commercial developments to use plants in agriculture to produce bioactive substances instead of food, feed and fibre. There is the possibility to grow genetically modified food plants producing significantly enhanced levels of bioactive constituents claimed to have health promoting effects and sold as foods with particular health claims. Finding an appropriate balance between scientific progress and creating consumer trust in the food supply, based on a sound scientific platform, is indeed a challenge for the Task Force to which the EC is fully committed. The corresponding Project proposal (Project document 3) is attached to the present document.

(4) Food safety assessment of food derived from multiple recombinant-DNA plants (stacked genes). More and more recombinant-DNA plants are developed by conventional crossing of other recombinant-DNA plants thus resulting in plants containing multiple recombinant-DNA inserts. The Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003) described the recommended approach to carry out safety assessment of food derived from recombinant-DNA plants. The focus of this work would be the examination of the existing safety assessment to determine which issues in this guideline are appropriate to establish the food safety of food derived from staked gene plants. The corresponding project proposal is attached (Project document 4).

(5) Food Safety Issues Specific to Staple Food Crops for Developing Countries (Food Composition). The EC wishes to support the project proposal on this issue submitted by the United States. The EC agrees with the United Sates that it would be useful for the Task Force to identify information that can assist countries, in particular Developing Countries, in conducting food safety assessments on staple crops that are important to them.

(6) Food produced from cloned animals and their offspring. As cloned animals are ready to be produced commercially and food derived from such animals might be available to consumers in the near future, the EC believes that there is merit to develop guidance for the conduct of food safety assessment of foods derived from such animals. The corresponding Project proposal is attached to the present document (Project document 5).

PROJECT DOCUMENT 1

Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology: European Community proposal for the adventitious presence in food of low level of plant material derived from recombinant-DNA plants.

Prepared by the European Community

1. Purpose and scope of the proposed work

The purpose is to identify food safety issues related to the adventitious presence in foods of level of material derived from recombinant-DNA plants and provide as far as possible guidance as to how such food safety issues ought to be assessed.

2. Relevance and timeliness

More and more new recombinant-DNA plants are developed every year and enter commerce at different paces in different countries. This results in an asymmetric authorisation pattern, where certain products are authorised in one country but not in another. At the same time, older varieties become obsolete and come off the market. These varieties can still remain adventitiously present at low but still detectable level during several years. As a result, more and more countries will be increasingly faced with the issue of adventitious presence of low level of not yet approved (or no longer approved) recombinant-DNA plant in food.

The Codex *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* (CAC/GL 45-2003) described the recommended approach to carry out safety assessment of food derived from recombinant-DNA plants. However, the approach identified in the Guideline may not be appropriate to establish food safety of the adventitious presence of low level of recombinant-DNA plant.

The focus of this work would be the examination of the existing safety assessment approach in the Codex *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* (CAC/GL 45-2003) to determine which issues in this guideline are appropriate to establish the food safety of low levels of material derived from recombinant-DNA plants.

This work is intended to supplement CAC/GL 45-2003 and to provide countries with guidance on addressing food safety issues that pertain to low level adventitious presence in foods of material derived from recombinant-DNA plants. This work could be considered as an annex to the Plant Guideline.

3. The main aspects to be covered

Develop an annex to the plant Guidelines to identify food safety issues associated with the adventitious presence of low level of unapproved_recombinant-DNA plant material developed for food use in food and provide guidance for the food safety assessment. In a second step, criteria could be developed which if fulfilled could lead to a tolerance level for recombinant DNA-plants with an asymmetric authorisation pattern.

4. Assessment against the criteria applicable to general subject as contained in the *Criteria for the establishment of work priorities.*

Consumer protection from the point of view of health and fraudulent practices: This new work proposal is consistent with this criterion as it provides additional guidance with which to undertake scientific safety assessments of food derived form modern biotechnology, thus helping to ensure consumer protection.

Diversification of national legislations and apparent resultant or potential impediments to international trade: This new work proposal is consistent with this criterion as it will provide scientific guidance which countries may utilize to establish their own individual standards or guidance.

Scope of work and establishment of priorities between the various section of work: While the precise scope of this work proposal will need to be defined by the Task Force, this proposal provides sufficient guidance indicate the general scope and nature of the intended work to permit the Task Force to discuss and determine the final scope of the project.

Work already undertaken by other organizations in this field: This new work proposal meets this criterion as it does not duplicate work undertaken by other international organizations.

5. Relevance to Codex Strategic Objectives

This work is consistent with Codex objectives in particular:

- Protection of consumer,
- Facilitation of trade of food,
- Promotion of the application of scientific principles and risk analysis.

6. Information on the relation between the proposal and other existing Codex documents.

The proposal would support but not duplicate the Codex *Guideline for the conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* (CAC/GL 45-2003).

7. Identification of any need for technical inputs for scientific advice.

None identified

8. Identification of any need for technical input to the standard from external bodies that this can be planned for.

None identified.

9. The proposed timeline for completion of the new work, including the start date, the proposed date for adoption at Step 5 and the proposed date for adoption by the Commission; the timeframe for developing a standard should not normally exceed 5 years.

If agreed, to by the Task Force at its first meeting, a draft would be presented to the Task Force at its second meeting (2006) for consideration at Step 3. It is expected that the work can be completed within the four-year timeframe for the Task Force.

PROJECT DOCUMENT 2

Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology: European Community proposal for food produced from GM animals.

Prepared by the European Community

1. Purpose and scope of the proposed work

The purpose is to develop a guideline for the conduct of food safety assessment of foods derived from GM animals. The guideline would take as a model the Codex Guideline for the conduct of food safety assessment of food derived from Recombinant-DNA plants (CAC/GL45-2003), taking into account the differences between plants and animals. In particular specific attention should be paid to ethical and animal welfare issues (in cooperation with OIE).

2. Relevance and timeliness

This work would be in line with the recommendations of the first session of the Task Force on foods derived from biotechnology of July 2001 (ALINORM 01/34) which identified the development of guidelines on safety of foods produced from recombinant-DNA animals as a third priority after the development of guidelines on foods of recombinant-DNA plants and recombinant-DNA micro-organisms. The development of this third guideline is timely because recombinant-DNA animals are in development in many countries and could be placed on the market in a near future. The availability of Codex guidelines would help individual countries to develop their own safety standards and regulatory framework.

3. The main aspects to be covered

The guidelines will be developed from the experience of the plant guideline (CAC/GL45-2003). The guideline could be tested on case study for the assessment of food derived from recombinant-DNA animals that are at an advanced stage of development.

4. Assessment against the criteria applicable to general subject as contained in the *Criteria for the establishment of work priorities.*

a. *Consumer protection from the point of view of health and fraudulent practices:* this new work will contribute to enhance consumer protection by providing guidance as to how to perform safety assessment of food derived recombinant-DNA animals.

b. *Diversification of national legislations and apparent resultant or potential impediments to international trade:* This new work will provide scientific guidance which countries will be able to use to develop their own safety standards and regulatory framework.

c. Scope of work and establishment of priorities between the various sections of work: The precise scope of the proposal would have to be refined by the Task Force, in particular to identify the most suitable case studies to test the guideline.

d. *Work already undertaken by other organizations in this field:* This new work does not duplicate other work undertaken by other international organisations

5. Relevance to Codex Strategic Objectives

This work is consistent with Codex objectives in particular:

- Promotion of consumer protection,
- Promotion of the application of scientific principles and risk analysis,
- Facilitation of trade of food.

6. Information on the relation of between the proposal and other existing Codex documents

This proposal will not duplicate any existing Codex document. It will build on the experience gained from the development of the plant and the micro-organism guidelines. It will draw experience from the WHO/FAO experts group on transgenic animals. It could complement the proposal to develop food safety guideline for food derived cloned animals and their offspring.

7. Identification of any need for technical inputs for scientific advice.

Advices may need to be sought from experts on for assessing specific risks related to the development of recombinant-DNA animals, silence gene activation, vectors used in the development of recombinant-DNA animals, etc.

8. Identification of any need for technical input to the standard from external bodies that this can be planned for.

None identified.

9. The proposed timeline for completion of the new work, including the start date, the proposed date for adoption at Step 5 and the proposed date for adoption by the Commission; the timeframe for developing a standard should not normally exceed 5 years.

If agreed by the Task Force at his first meeting, a draft would be presented to the Task Force at its second meeting in 2006 for consideration at Step 3. It is expected that the work can be completed within the four-year timeframe for the Task Force.

PROJECT DOCUMENT 3

Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology: European Community proposal for genetically modified plants expressing pharmaceutical or other non-food substances.

Prepared by the European Community

1. Purpose and scope of the proposed work

The purpose is to develop a framework for genetically modified plants expressing pharmaceutical or other non-food substances in the general context of food products.

The scope of the work would be limited to possible implications to food products in line with the purposes of the Codex Alimentarius Commission.

2. Relevance and timeliness

The familiarity, breeding, agronomy and processing of cultivated food plants to obtain large quantities of useful material may give economic incitement to develop products that may be useful for the general public. Plants that have been genetically engineered to express novel traits producing medically or technically interesting bioactive substances, may be grown as crops and harvested for the newly expressed molecules (biofarming or plant molecular farming). There is also the possibility to grow genetically modified food plants producing significantly enhanced levels of bioactive constituents claimed to have health promoting effects and sold as foods with particular health claims.

In some of these cases it might be wished that the hereditary material determining the traits in question is not allowed to disseminate into the gene pool of plant varieties that are used for food production or, possibly, into plants in the environment.

Thus, issues related to the cultivation methodology and confinement to prevent physical mixing with food crops becomes an important issue. Even agreements on which types of plant that may be allowed to be modified in this way might be required.

3. The main aspects to be covered

It will be necessary to identify what type of substances could be allowed in crops used for food, to provide guidance on how suitable crops could be contained and how safety assessment with regard to food safety should be carried out and also to identify possible actions in the case of accidental contamination of the food supply.

4. Assessment against the criteria applicable to general subject as contained in the *Criteria for the establishment of work priorities.*

Consumer protection from the point of view of health and fraudulent practices: This new work proposal is consistent with this criterion as it provides additional guidance with which to undertake scientific safety assessments of food derived form modern biotechnology, thus helping to ensure consumer protection.

Diversification of national legislations and apparent resultant or potential impediments to international trade: This new work proposal is consistent with this criterion as it will provide scientific guidance which countries may utilize to establish their own individual standards or guidance.

Scope of work and establishment of priorities between the various section of work: While the precise scope of this work proposal will need to be defined by the Task Force, this proposal provides sufficient guidance indicate the general scope and nature of the intended work to permit the Task Force to discuss and determine the final scope of the project.

Work already undertaken by other organizations in this field: This new work proposal meets this criterion as it does not duplicate work undertaken by other international organizations.

5. Relevance to Codex Strategic Objectives

This work is consistent with Codex objectives in particular:

- Protection of consumer,
- Facilitation of trade of food,
- Promotion of the application of scientific principles and risk analysis.

6. Information on the relation between the proposal and other existing Codex documents.

The proposal would support but not duplicate the Codex *Guideline for the conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* (CAC/GL 45-2003).

7. Identification of any need for technical inputs for scientific advice.

None identified

8. Identification of any need for technical input to the standard from external bodies that this can be planned for.

None identified.

9. The proposed timeline for completion of the new work, including the start date, the proposed date for adoption at Step 5 and the proposed date for adoption by the Commission; the timeframe for developing a standard should not normally exceed 5 years.

If agreed, to by the Task Force at its first meeting, a draft would be presented to the Task Force at its second meeting (2006) for consideration at Step 3. It is expected that the work can be completed within the four-year timeframe for the Task Force.

PROJECT DOCUMENT 4

Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology: European Community proposal for the conduct of food safety assessment of food derived from multiple recombinant-DNA plants (stacked genes).

Prepared by the European Community

1. Purpose and scope of the proposed work

The purpose is to identify specific food safety issues related to food derived from plants from plants (hereafter referred to as stacked gene plants) containing multiple recombinant-DNA inserts and obtained by conventional crossing of recombinant-DNA plants

The scope of the work would be limited to food derived from so-called stacked gene plants.

2. Relevance and timeliness

More and more recombinant-DNA plants are developed by conventional crossing of other recombinant-DNA plants thus resulting in plants containing multiple recombinant-DNA inserts. The Codex *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* (CAC/GL 45-2003) described the recommended approach to carry out safety assessment of food derived from recombinant-DNA plants. However, the Guideline does not address specifically the case of food derived from plants obtained by conventional crossing of recombinant-DNA parental plants.

The focus of this work would be the examination of the existing safety assessment approach in the Codex *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* (CAC/GL 45-2003) to determine which issues in this guideline are appropriate to establish the food safety of food derived from staked gene plants. This work is intended to supplement CAC/GL 45-2003 and to provide countries with guidance on addressing safety assessment of food derived from staked gene plants. This work could be considered as an annex to the Plant Guideline CAC/GL 45-2003.

3. The main aspects to be covered

Develop an annex to the Plant Guidelines to identify specific food safety issues associated with the conventional crossing of recombinant-DNA plants and provide guidance as to how to assess and manage these issues.

4. Assessment against the criteria applicable to general subject as contained in the *Criteria for the establishment of work priorities.*

Consumer protection from the point of view of health and fraudulent practices: This new work proposal is consistent with this criterion as it provides additional guidance with which to undertake scientific safety assessments of food derived form modern biotechnology, thus helping to ensure consumer protection.

Diversification of national legislations and apparent resultant or potential impediments to international trade: This new work proposal is consistent with this criterion as it will provide additional scientific guidance to carry out safety assessment which countries may utilize to establish their own individual standards or guidance.

Scope of work and establishment of priorities between the various sections of work: This proposal is a direct and logical follow-up of the Plant Guideline CAC/GL 45-2003.

Work already undertaken by other organizations in this field: This new work proposal meets this criterion as it does not duplicate work undertaken by other international organizations.

5. Relevance to Codex Strategic Objectives

This work is consistent with Codex objectives in particular:

- Promotion of consumer protection,
- Promotion of the application of scientific principles and risk analysis,
- Facilitation of trade of food.

6. Information on the relation between the proposal and other existing Codex documents.

The proposal would support but not duplicate the Codex *Guideline for the conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* (CAC/GL 45-2003).

7. Identification of any need for technical inputs for scientific advice.

None identified.

8. Identification of any need for technical input to the standard from external bodies that this can be planned for.

None identified.

9. The proposed timeline for completion of the new work, including the start date, the proposed date for adoption at Step 5 and the proposed date for adoption by the Commission; the timeframe for developing a standard should not normally exceed 5 years.

If agreed, to by the Task Force at its first meeting, a draft would be presented to the Task Force at its second meeting (2006) for consideration at Step 3. It is expected that the work can be completed within the four-year timeframe for the Task Force.

PROJECT DOCUMENT 5

Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology: European Community proposal for food produced from cloned animals and their offspring.

Prepared by the European Community

1. Purpose and scope of the proposed work

The purpose is to develop a guideline for the conduct of food safety assessment of foods derived from cloned animals and their offspring. Cloning is here used with reference to the production of individuals with (almost) identical genetic material by asexual reproduction with somatic cell nuclear transfer (known also as somatic cell transfer).

The scope will cover safety assessment of food derived from cloned animals and their offspring. Specific attention should also be paid to ethical and animal welfare issues (in cooperation with OIE).

2. Relevance and timeliness

In 1997, a sheep was produced by somatic cell nuclear transfer. Since that, a number of cloned animals have been produced for a large number of animal species, in particular farm animal species. Cloned animals are now about to be produced commercially, and food derived from such animals or there offspring may be available on the market in the near future. It is also understood that cloning would in many cases, be used in combination with recombinant-DNA animals many of which are also at an advanced stage of development, to produce food.

3. The main aspects to be covered

The Task Force would have to identify the safety issues relating to food produced from cloned animal and their offspring. It would also have to develop the methodology to assess and manage those issues.

As a first step, the Task Force would first have to identify the safety issues relating to animal cloning. In this respect, the creation of a FAO/WHO expert consultation may be considered.

The second step would be to develop guidance to carry out safety assessment of food from cloned animal and their offspring.

4. Assessment against the criteria applicable to general subject as contained in the *Criteria for the establishment of work priorities.*

e. *Consumer protection from the point of view of health and fraudulent practices:* this new work will contribute to enhance consumer protection by providing guidance as to how perform safety assessment of food derived from cloned animals and their offspring.

f. *Diversification of national legislations and apparent resultant or potential impediments to international trade:* This new work will provide scientific guidance which countries will be able to use to develop their own safety standards and regulatory framework.

g. *Scope of work and establishment of priorities between the various sections of work:* The precise scope of the proposal would have to be refined by the Task Force, in particular to clarify which groups of animal species ought to be covered. However, the proposal provides sufficient guidance to indicate the nature of the general scope and of the intended work.

h. *Work already undertaken by other organizations in this field:* This new work does not duplicate other work undertaken by other international organisations

5. Relevance to Codex Strategic Objectives

This work is consistent with Codex objectives in particular:

- Promotion of consumer protection,
- Promotion of the application of scientific principles and risk analysis,
- Facilitation of trade of food.

6. Information on the relation of between the proposal and other existing Codex documents

This proposal will not duplicate any existing Codex document. It would complement the proposal to develop food safety guideline for food derived from recombinant-DNA animals.

7. Identification of any need for technical inputs for scientific advice.

Advices may need to be sought from experts on scientific issues such epigenetic effects, silence gene activation, etc.

8. Identification of any need for technical input to the standard from external bodies that this can be planned for.

The creation of a FAO/WHO expert consultation on the safety assessment of food derived from cloned animals and their offspring, may need to be considered.

9. The proposed timeline for completion of the new work, including the start date, the proposed date for adoption at Step 5 and the proposed date for adoption by the Commission; the timeframe for developing a standard should not normally exceed 5 years.

In order to complete this work, and should the Task Force agree the initial step would be to create a joint FAO/WHO expert group.