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

ALINORM 06/29/34

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Twenty-ninth Session

Geneva, Switzerland, 3- 8 July 2006

REPORT OF THE FIFTH SESSION OF THE CODEX *AD HOC* INTERGOVERNMENTAL TASK FORCE ON FOODS DERIVED FROM BIOTECHNOLOGY

Chiba, Japan, 19-23 September 2005

Note: This document incorporates Codex Circular Letter CL 2005/46-FBT

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4/80.2 **CL 2005/46- FBT**
October 2005

To: Codex Contact Points
Interested International Organizations

From: Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Viale delle Terme di Caracalla, 00100 Rome, Italy

Subject: **Distribution of the Report of the Fifth Session of the Codex *Ad Hoc* Intergovernmental Task Force on Foods Derived from Biotechnology (ALINORM 06/29/34) and Request for comments on Food Safety Assessment of Food Derived from Recombinant-DNA Plants Modified for Nutritional or Health Benefits**

The Report of the Fifth Session of the Codex Ad Hoc Intergovernmental Task Force on Foods derived from Biotechnology is attached. It will be considered by the Twenty-ninth Session of the Codex Alimentarius Commission (Geneva, Switzerland, 3-8 July 2006).

REQUESTS FOR COMMENTS

The Task Force agreed to initiate new work on development of an annex to the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants: Food Safety Assessment of Food Derived from Recombinant-DNA Plants Modified for Nutritional or Health Benefits. An electronic Working group, led by Canada, was established to develop a proposed draft annex (scoping document) to be considered in the next Task Force.

It was agreed that a Circular Letter be sent to request further comments on this work, on the basis of which the electronic working group should initiate its work. (para. 38 of this report).

Therefore, governments and interested international organizations wishing to submit their comments should do so, preferably by E-mail, to the Canadian Codex Contact Point (E-mail:codex_canada@hc-sc.gc.ca; Fax +1 613 941 3537), with a copy to the Secretary, Codex Alimentarius Commission (E-mail:codex@fao.org; Fax +39 06 570 54593) **no later than 15 December 2005**.

SUMMARY AND CONCLUSIONS

The Fifth Session of the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology reached the following conclusions:

MATTERS FOR CONSIDERATION BY THE CODEX ALIMENTARIUS COMMISSION

Approval of new work

The Task Force agreed, subject to the approval by the 29th Session of the Codex Alimentarius Commission, to initiate new work on the elaboration of the following texts:

- A guideline for the conduct of food safety assessment of foods derived from recombinant-DNA animals (paras. 19 and 23);

- An annex to the Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003) regarding food safety assessment of foods derived from recombinant-DNA plants modified for nutritional or health benefits (paras. 32 and 36).

OTHER MATTERS OF INTEREST TO COMMISSION

The Task Force decided to establish the following two Working Groups:

- A physical Working Group to prepare a Proposed Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals, co-chaired by Australia and Japan (para. 25).

- An electronic working group led by Canada to formulate a Proposed Draft Annex (scoping document) to the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants: Food Safety Assessment of Food Derived from Recombinant-DNA Plants Modified for Nutritional or Health Benefits (para. 37).

The Task Force agreed whether or not further scientific advice was needed regarding the Proposed Draft Guideline for recombinant-DNA animals would be considered during the elaboration of the draft guideline. In this context, the Task Force agreed on the initial list of questions for which scientific advice might be sought from an FAO/WHO expert consultation at a later stage (para. 27).

TABLE OF CONTENTS

LIST OF APPENDICES

ALINORM 06/29/34

REPORT OF THE FIFTH SESSION OF THE CODEX *AD HOC* INTERGOVERNMENTAL TASK FORCE ON FOODS DERIVED FROM BIOTECHNOLOGY

Chiba, Japan, 19-23 September 2005

INTRODUCTION

1. The Codex Intergovernmental Task Force on Foods Derived from Biotechnology held its fifth Session in Chiba, Japan, from 19 to 23 September 2005, by courtesy of the Government of Japan. The Session was presided over by Dr. Hiroshi Yoshikura, Adviser, Department of Food Safety, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare. The Session was attended by 152 delegates representing 50 members of the Commission and 4 international intergovernmental and 15 non-governmental observer organizations. A complete list of participants is included as Appendix I to this report.

OPENING OF THE SESSION

2. The Session was opened by Mr. Toshikazu Togari, Vice-Minster of Health, Labour and Welfare, who welcomed the participants to Chiba, Japan. He stressed the importance of developing international guidance on issues related to the safety of the foods derived from biotechnology based on sound scientific evidence and principles. He expressed the wish that this session would agree on new areas of work to be undertaken and that the Task Force would accomplish its work within the agreed timeframe.

3. In welcoming the delegates on behalf of FAO, Mr. Ezzeddine Boutrif, Chief, Food Quality and Standards Service, highlighted the role that biotechnology can play in meeting the needs of an expanding and increasingly urbanized world population. However, for certain applications of biotechnology, expected benefits must be weighed against potential risks, both to human and animal health and to the environment, using a solid scientific framework. The Representative suggested that in defining its work programme, the Task Force should give consideration to those issues that would bring the maximum benefit to consumers' health and enhance food security and nutrition wellbeing of low-income communities, taking due account of work undertaken by other national authorities and relevant organizations. The Representative suggested that in the future an international expert body could be set up to assist in reviewing safety assessments undertaken by different parties with a view to assessing their conformity with Codex guidelines. The Representative also emphasized the need to assist developing countries to build their capacity in the safety assessment of foods derived from biotechnology. The Representative reiterated FAO's readiness to support, jointly with WHO, the work of the Task Force by providing the necessary scientific advice.

4. On behalf of the World Health Organization (WHO), Dr Jørgen Schlundt, Director, Department of Food Safety, Zoonoses and Food borne Diseases, expressed appreciation to the Government of Japan for the continued hosting of the Task Force and attributed the success of the first four-year period of the Task Force to the efficient management of the process from the Japanese Government and a collaborative spirit between participating Member States. The Representative recalled that a resolution of the 53rd World Health Assembly requested WHO to support Member States in providing the scientific basis for health-related decisions regarding genetically modified foods. More recently, the 109th Executive Board of WHO in January 2002 endorsed the Food Safety Strategy which states that WHO will promote a holistic approach to the production and safe use of foods derived from new methods of production, including genetic engineering. The WHO Representative also referred to a new International Food Safety Authorities Network (INFOSAN) which WHO had initiated recently in collaboration with FAO. Finally the Representative re-affirmed WHO's commitment to provide scientific advice necessary for further work of the Task Force.

ADOPTION OF THE AGENDA (Agenda Item 1)[1]

5. The Task Force agreed to the proposal of Kenya to discuss on the issue of foods derived from animals exposed to protection against disease through gene therapy or recombinant-DNA vaccines under Item 5 (Other Business) if time was available.

6. The Task Force adopted the Provisional Agenda as the Agenda of this Session.

7. The Task Force noted that the division of competence between the European Community and its Member States, is presented by the Delegation of the European Community in CRD 3.

MATTERS REFERRED TO THE TASK FORCE BY THE COMMISSION AND THE OTHER CODEX COMMITTEES (Agenda Item 2)[2]

8. The Task Force noted the information presented in document CX/FBT 05/5/2 concerning the matters referred to the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology by the Codex Alimentarius Commission and the other Codex Committees, in particular, the decision by the 27th Session of the Commission to re-establish the Task Force and the recent activities undertaken by the Codex Committees on Methods of Analysis and Sampling and on Food Labelling.

REVIEW OF THE WORK BY INTERNATIONAL ORGANIZATIONS ON THE EVALUATION OF THE SAFETY AND NUTRITION ASPECTS OF FOODS DERIVED FROM BIOTECHNOLOGY (Agenda Item 3)[3]

9. The Task Force noted the information presented in documents CX/FBT 05/5/3 and CX/FBT 05/5/3 Add.1 submitted by several international intergovernmental organizations concerning the work on the evaluation of the safety and nutrition aspects of foods derived from biotechnology.

10. The Representative of the Convention on Biological Diversity (CBD) informed the Task Force that the third session of the Conference of the Parties serving as the meeting of the Parties to Cartagena Protocol on Biosafety (COP-MOP) would be held in March 2006. A Technical Expert Group on Risk Assessment established by the COP-MOP, to be held in November 2005, would discuss the existing approaches to risk assessment, identifying gaps and capacity building needs, and forward recommendations to COP-MOP 3. A document would be also prepared on the needs and modalities of standards with respect to the paragraph 3 of the Article 18 of the Protocol, including identification, handling, packaging and transport practices for Living Modified Organisms.

11. The Representative of the Organisation for Economic Cooperation and Development (OECD) informed the Task Force of the recent activities by the OECD Task Force on Novel Foods and Feeds, especially elaboration of a series of Consensus Documents on food and feed safety which provided information on the major nutrients, toxicants, anti-toxicants and allergens of specific crops. In this respect, new work had started to elaborate consensus documents on the crops of particular interests for developing countries such as papaya and cassava. Attention was also drawn to the fact that additional work was being undertaken by the OECD Task Force in areas such as molecular characterization of transgenic plants and considerations for the safety of animal feeds derived from genetically modified plants, the latter not being covered by the Codex Task Force.

12. The Representative of FAO referred to the work of the Inter-Departmental Working Group on Biotechnology in Food and Agriculture which coordinates the work of the different units related to biotechnology and in particular to FAO's 2004 publication "The State of Food and Agriculture" which included a paper entitled "Agricultural Biotechnology: meeting the needs of the poor?". The Representative

1 CX/FBT 05/5/1; CRD 1 (Comments of Kenya)
2 CX/FBT 05/5/2
3 CX/FBT 05/5/3, CX/FBT 05/5/3 Add.1

also informed the Task Force of the work of the FAO working Group on Biosafety and of its plan to conduct an Expert Consultation on Biosafety and of a Workshop of Safety Assessment on Food Derived from Biotechnology, later this year. He indicated that work was in progress on the development of training materials on the safety assessment of GM foods, in cooperation with WHO, OECD and the Canadian authorities. This material would be based on Codex adopted guidelines, and include practical and concrete examples of how such assessment was carried out.

13. The WHO Representative drew the attention of the Task Force to a recent WHO report "Modern Food Biotechnology, Human Health and Development: an evidence-based study, as the outcome of a three-year study". The report suggests that the development of GM Foods can contribute to enhancing human health and economic development, only if properly assessed before marketing, through broad, coherent, evidence-based evaluation. This assessment should include human health and environmental assessment, but also assessments of potential benefits and social and ethical concerns. The report also stated that GM foods available on the market have passed food safety risk assessment and are not likely to present risks for human health. Finally the report referred to Codex principles and guidelines as the appropriate international basis for food safety risk assessment.

14. The Task Force also noted the information provided by the International Centre for Genetic Engineering and Biotechnology (ICGEB) and the World Organisation for Animal Health (OIE). Especially, attention was drawn to the report on the state of application of genetic engineering for livestock and the recently adopted resolution by the OIE International Committee.

CONSIDERATION OF THE ELABORATION OF STANDARDS, GUIDELINES OR OTHER TEXTS FOR FOODS DERIVED FROM BIOTECHNOLOGY (Agenda Item 4)[4]

15. In order to facilitate discussion under this Agenda item and to provide members and observers with an opportunity to freely express opinions, the Task Force agreed to have a general exchange of views on the whole range of possible areas for new work before examining each of the subjects one-by-one. The Task Force noted that there was a diversity of views among delegations and observers, including the priorities they assigned to different areas of work. The Task Force also noted the particular situations of developing countries in relation to the prevalence of malnutrition and nutrient deficiency diseases as well as their needs for capacity building on the safety assessment of food derived from biotechnology. The Task Force then proceeded with further discussion, item-by-item, as follows.

Recombinant-DNA Animals

16. The Task Force considered the proposal, put forward by several members and observers, to develop a guideline for food safety assessment of foods derived from recombinant-DNA animals including fish. Many delegations supported this work as new work to be undertaken as high priority in view of the possible commercialization of recombinant-DNA animals, especially fish, in a foreseeable future and the availability of the scientific advice already provided by the Joint FAO/WHO Expert Consultation on Safety Assessment of Foods Derived from Genetically Modified Animals, including Fish (Rome, November 2003). Other delegations ranked this work as low priority due to higher priority given by these delegations to the proposed

[4] CL 2005/2-FBT, CX/FBT 05/5/4 (Comments of Argentina, Australia, Brazil, Canada, Iran, Japan, Mexico, New Zealand, United States of America, Venezuela, 49P, BIO, CI); CX/FBT 03/4 Add.1 (Comments of European Community); CRD 1 (Comments of Kenya), CRD 2 (Comments of Chile), CRD 4 (Comments of the Philippines), CRD 5 (Comments of South Africa), CRD 6 (Comments of Canada), CRD 7 (Comments of India), CRD 8 (Comments of the United States of America), CRD 9 (Comments of Republic of Korea), CRD 10 (Comments of Indonesia), CRD 11 (Comments of Mexico), CRD 12 (Comments of Uganda), CRD 13 (Comments of Costa Rica), CRD 14 (Project Document prepared during the session), CED15 (Questions for expert consultations, prepared by Australia during the session), CRD 16 (Project Document prepared by Canada during the Session), CRD 16 Revised (Project Document revised by Canada during the session), CRD 17 (Comments on plants with stacked gene, prepared by Japan during the session), CRD 18 (Comments on plants with stacked genes, prepared by European Community during the session), CRD 19 (Comments on plant with stacked genes, prepared by Iran during the session)

new work related to recombinant-DNA plants and due to insufficient experience at the national level in this area.

17. Some delegations proposed new work for the food safety assessment of animals produced using somatic cell nuclear transfer (SCNT) cloning techniques, either as a separate work item or as part of the new work on recombinant-DNA animals, recognizing that animal cloning was often used complementary to the production of recombinant-DNA animals. Other delegations considered that this work was out of the scope of the Task Force. The Task Force agreed that no new work would be commenced, at this stage, to address the food safety of cloned animals as such, while noting that the issue could be considered, if appropriate and to the extent necessary, during the process of developing a draft guideline for the food safety assessment of recombinant-DNA animals. The Delegation of European Community further stated that the decision not to start new work on cloned animals might lead to diversification of national legislations.

18. Several delegations and observers proposed that the issues relating to ethics, environmental effects, animal welfare be included in the scope of the draft Guideline for recombinant-DNA animals. These delegations and observers stated that these issues constituted "other legitimate factors" as they may have impact on human health and on food trade and that a holistic approach should be taken to appropriately address the concerns of consumers, especially in the context of recombinant-DNA animals. An observer pointed out that the objectives of the Task Force referred to "having regard, where appropriate, to other legitimate factors relevant to the health of consumers and the promotion of fair practices in the food trade". Several delegations, while recognizing that these were important issues, expressed the view that ethical and other issues should not be addressed by Codex, which had no expertise to handle them, but by other appropriate international organizations such as OIE, which had started work on animal welfare, and UNESCO, working on ethics in food and biotechnology. The Task Force noted that the existing work by the Council for International Organization of Medical Sciences (CIOMS) could also be relevant. It was also pointed out that the future guideline should provide safety assessment guidance under the risk analysis framework set out by the Principle for the Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003, hereafter referred as "Principle") and that paragraph 7 of the Principles excluded ethical and other factors from the scope.

19. After an extensive exchange of views, the Task Force agreed to start new work on the food safety assessment of foods derived from recombinant-DNA animals, with the understanding that the initial work would be focused on developing a guideline for recombinant-DNA animals in general, which could be complemented by an annex dealing with issues specific to the food safety assessment of recombinant-DNA fish, if appropriate.

20. In finalizing a Project Document, the Task Force had a lengthy debate on whether or not "ethical or other considerations" should explicitly be included in the purposes and scope of the new work in the Project Document. As a compromise solution, the Task Force decided that the project document referred to the Statement of Principle Concerning the Role of Science in the Codex Decision Making Process and the Extent to Which Other Factors are Taken into Account[5].

21. The Delegation of European Community regretted that no explicit reference to ethical, environmental and animal welfare considerations were included in the project document. This position was supported by several delegations and observers. The Delegation of Iran reserved its position as to the decision by the Task Force. The Delegation of Egypt and the Delegation of Iran stressed that religion should be mentioned as part of ethical considerations. The Delegation of Canada stated that each country could take into account other legitimate factors before making final risk management decisions but the work of the Task Force should be based solely on scientific considerations as relate to food safety assessment. The latter position was supported by the Delegations of Argentina and Brazil.

[5] Codex Alimentarius, Procedural Manual

22. The Representative of FAO, speaking on behalf of both FAO and WHO, stated that given the importance of ethical and other considerations in regard to the international trade of foods derived from recombinant-DNA animals, a workshop could be convened to address these issues, back-to-back with a future session of the Task Force. The Representative of WHO stressed the importance of identifying all problems relevant to the concern of consumers, as part of effective risk communication.

23. The Task Force decided to forward the Project Document, as agreed, to the 58th Session of the Executive Committee for critical review and to the 29th Session of the Codex Alimentarius Commission for approval as new work (Appendix II).

24. The Delegation of Brazil reserved its position by pointing out that the proposed new work on recombinant-DNA animals did not meet the criterion "Diversification of national legislation and apparent resultant or potential impediments to international trade" in the Criteria for the Establishment of Work Priorities in the Procedural Manual.

25. With respect to the advancement of work prior to the next session, the Task Force agreed to establish a physical working group which would prepare a Proposed Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals, co-chaired by Australia and Japan. The working group would meet sometime between February and April 2006 in Japan, using English as working language, with other languages possibly being added if possible. The following members and observers expressed their interest in participating in this working group: Argentina, Brazil, Canada, European Community, France, Germany, Italy, Iran, Kenya, the Netherlands, New Zealand, Norway, Switzerland, Thailand, Turkey, the United States of America, 49th Parallel, BIO, CI, IACFO, ICGMA, FAO and WHO. The proposed draft document would then be circulated for comments at Step 3, prior to consideration by the 6th Session of the Task Force at Step 4.

26. In deciding on the establishment of the working group, the Task Force noted that drafting work would start before the formal approval of new work could be given by the Commission at Step 1, earliest in July 2006. The Task Force therefore agreed to draw the attention of the Executive Committee to the need for a degree of flexibility in the efforts not to delay the standards development by the Codex subsidiary bodies, especially ad hoc Task Forces operating within limited timeframes.

27. While noting that the drafting of the guideline could start, without delay, on the basis of the report of the FAO/WHO Expert Consultation Safety Assessment of Foods Derived from Genetically Modified Animals, including Fish, the Task Force agreed on the following initial list of questions for which scientific advice might be sought from an FAO/WHO expert consultation at a later stage. The Task Force agreed that whether or not further scientific advice was needed would be considered during the elaboration of the draft guideline.

- In relation to the potential risks to human health from the consumption of foods derived from recombinant-DNA animals, what critical information is necessary to assess the safety of viral and other vectors used to generate recombinant-DNA animals?

- Recognizing that animal health assessment will be an important element of overall food safety assessment of foods derived from recombinant-DNA animals, what animal health parameters are important to consider and how should the appropriate comparators be selected for different classes of animals and why?

- Recognizing that targeted compositional analysis is an important element in the overall food safety assessment of food derived from recombinant-DNA plants, how can this approach be practically applied to the safety assessment of food derived from recombinant-DNA animals and how should the appropriate comparators be selected?

Recombinant-DNA plants modified for nutritional or health benefits

28. Several delegations stated that the current trend on development of nutritionally enhanced crops might have significant impact on the health of consumers, especially in developing countries, and suggested that

the Task Force start new work to provide further guidance regarding the safety assessment of these new crops. Attention was drawn to the need to improve capacities of developing countries for conducting safety assessment of these plants and to the potential of these plants to solve problems on malnutrition and nutrient deficiency diseases. These delegations stated that paragraphs 48-53 of the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003, hereafter referred as "Plant Guideline") related to nutritional aspects as part of the food safety assessment did not provide detailed guidance and that the Task Force should produce a comprehensive text as an annex to the existing Plant Guideline.

29. Several other delegations, while recognizing special needs of developing countries, pointed out that safety assessment of nutritionally enhanced plants was sufficiently addressed by the current Plant Guideline and that there was no need to start new work. It was also pointed out that nutritionally enhanced plants had also been developed using conventional breeding and that there was no justification to apply additional safety assessment to recombinant-DNA plants only.

30. Some delegations expressed concerns that nutritionally enhanced staple crops might lead to excessive intake of enhanced nutrients in certain populations and that risk management measures might become necessary for the protection of consumers' health. An observer expressed its view that food and nutrient intake study might be necessary in order to monitor health effects where nutritionally enhanced plants were used because the availability and perceived benefits of such plants could change food consumption patterns of the population.

31. The Delegation of the European Community, supported by some other delegations and observers, stated that considerations on post marketing monitoring systems should be an essential element of the work on this item because consumptions of nutritionally enhanced plants may cause significant changes in dietary intake patterns, in accordance with paragraph 20 of the Principle for the Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003).

32. After some discussion, the Task Force decided to initiate new work in the form of an annex to the Plant Guideline (CAC/GL 45-2003) and proceeded with further scoping of the work on the basis of the draft project documents (CRD 16 and CRD 16 Revised) prepared by Canada.

33. The Task Force agreed that the project title and section 3 of the project document should refer to "plants modified for nutritional or health benefits" rather than to "nutritionally enhanced plants", to include those plants in which certain compositional elements were intentionally reduced. The final title of the project document was "Food Safety Assessment of Foods Derived from Recombinant-DNA Plants Modified for Nutritional or Health Benefits".

34. The Task Force also agreed that the new work should ensure consistency and links with the existing Codex texts dealing with nutrition and health labelling and claims, and avoid duplication of work with the Codex Committee on Nutrition and Foods for Special Dietary Uses.

35. The Representatives of FAO and WHO suggested that the new work on this item should make full use of the report of the Joint FAO/WHO Nutrient Risk Assessment Workshop (Geneva, 2-6 May 2005) and other relevant texts, where appropriate, noting that if scientific advice was required FAO and WHO would consider convening a small-scale expert group meeting to consider specified topics, including exposure assessment, in relation to nutritionally enhanced plants.

36. The Task Force agreed to forward the project document, amended as above, to the 58th Session of the Executive Committee for critical review and to the 29th Session of the Commission for approval as new work (Appendix III).

37. The Task Force further agreed to establish an electronic working group led by Canada to formulate a proposed draft document (scoping document) to be presented to the next session of the Task Force. The following members and observers expressed their interests in participating in the working group: Argentina, Australia, Austria, Belgium, Brazil, China, Costa Rica, Cuba, Denmark, European Community, Egypt,

Finland, France, Germany, Indonesia, Italy, Iran, Kenya, Japan, Madagascar, Mexico, Mongolia, the Netherlands, Nepal, New Zealand, Norway, Pakistan, the Philippines, Republic of Korea, South Africa, Switzerland, Spain, Sweden, Thailand, Turkey, Uganda, the United Kingdom, the United States of America, BIO,CI, Croplife International, ETA, ICGMA and Europabio.

38. It was also agreed that a Circular Letter be sent to request further comments on this work, on the basis of which the electronic working group should initiate its work. The working language of the working group would be English in principle, while members and observers would be allowed to contribute to the work in French and Spanish, if necessary.

Comparative composition analysis

39. Several delegations proposed to give high priority to the proposed work on comparative composition analysis of recombinant-DNA plants including staple crops of particular importance for developing countries.

40. Other delegations pointed out that some international organizations had already undertaken relevant work in this area. Particular reference was made to the development of Consensus Documents by OECD which aimed at assisting in the conduct of comparative compositional analysis by national authorities.

41. The Representatives of FAO and WHO informed the Task Force of their current activities related to capacity building of countries in the safety assessment of foods derived from biotechnology, in particular, a document under development which would provide useful guidance for conducting safety assessments of recombinant-DNA plants and strengthening national infrastructure and expertise in developing countries.

42. The Task Force noted that there was a need to further clarify the scope for new additional work on top of the existing guidance in the Plant Guideline (CAC/GL-45-2003) and agreed that it was premature to consider new work on this subject.

43. The Delegation of India, referring to its written comment, proposed that the Task Force should start, in the future, new work on comprehensive analysis of nutrients, anti-nutrients as well as methods of toxicity studies because quantitative and qualitative analytical methods would be necessary tools to conduct safety assessment of recombinant-DNA plants.

44. The Task Force agreed to invite India to submit a discussion paper on this subject for further consideration by the next session of the Task Force. In this respect, the Task Force noted that the work undertaken by the Codex Committee on Methods of Analysis and Sampling and other relevant international organizations should be fully taken into account when assessing the need for future work, if any.

Plants with Stacked Genes

45. The Task Force discussed whether or not new work should be initiated on the issue of plants with stacked genes. The Delegation of Japan proposed the definition of the plants with staked genes as the first generation of plants obtained through conventional crossing of two parent recombinant-DNA plants whose safety had been already evaluated. The delegation further suggested development of an Annex to the Plant Guideline (CAC/GL 45-2003) in order to provide guidance to governments as to when and how the safety assessment for this type of plants should be conducted in accordance with the Plant Guideline.

46. The Task Force noted that the term “stacked genes” was understood in different ways and recognized the necessity to have a clear, common understanding of “plants with stacked genes” before deciding on the need for new work. Some delegations pointed out that the definition presented by Japan was not sufficient and suggested further elaboration.

47. Several delegations stressed the importance of initiating new work in this area in view of the increasing development of recombinant-DNA plants by crossing between recombinant-DNA plants and the diversification of national legislations applied to these products. Other delegations pointed out that this issue needed to be addressed on a case by case basis, which made it difficult to develop general guidance.

Attention was also drawn to the fact that many plant varieties had been produced through conventional crossing without adverse health effects and that traditional plant breeding had a long history of safe use.

48. After a lengthy discussion, the Delegation of Japan, supported by the Delegation of the United States, expressed the view that although the existing plant guideline did not specifically address plant varieties with two or more recombinant-DNA traits obtained through conventional crossing, many of which had already been developed and commercialised, the guideline provided sufficient guidance for the conduct of safety assessment and that a safety assessment might be needed on a case by case basis for this type of hybrid where each parental recombinant-DNA plant had individually been assessed, and the extent of safety assessment might vary depending on the potential interactions between inserted sequences in the hybrids.

49. The Delegation of European Community, supported by Norway, expressed the view that whilst a pre-market safety assessment was always necessary, in accordance with paragraph 11 of the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology, the extent of the safety assessment might vary on a case by case basis depending on the potential interactions between inserted sequences in the case of plants with stacked genes.

50. After an exchange of views on this subject, the Task Force acknowledged that there was a diversity of opinions among members and therefore decided not to take a decision to initiate new work. The Delegation of Iran, while not objecting to this decision, emphasized that in addition to the safety assessment of parental recombinant-DNA plants, a case by case safety assessment of plants with stacked genes was required at various levels, taking into account the potential interaction between inserted sequences in the hybrids, and stressed that the development of an annex to the Plant Guideline was necessary.

Low Level (Adventitious) Presence of Unauthorized Recombinant-DNA Plant Materials

51. The Task Force noted that some delegations had proposed this work item as high priority. Several delegations and one observer expressed the view that this was a very important issue for the Task Force to consider and supported initiation of new work in this area.

52. The Delegation of the United States stated that development of a new guidance document, as an Annex to the Plant Guideline, would assist member countries in conducting safety assessments of low level adventitious presence of recombinant-DNA plant materials originating from new varieties in the development or field testing stage or from older varieties coming off the market. The delegation believed that many countries would increasingly be faced with these situations where the safety of food needed to be determined.

53. The Delegation of the European Community stated that a low level (adventitious) presence of unauthorized recombinant-DNA plants was often attributable to differences in the approval status of recombinant-DNA plants among countries. An annex to the Plant Guideline could be developed to provide guidance on how to deal with the adventitious presence of unapproved recombinant-DNA plants developed for food use, resulting from asymmetrical approvals.

54. Accordingly, the Delegation of the European Community emphasized the need for establishing an international data sharing system through which member governments could obtain data regarding safety assessments of recombinant-DNA plants conducted in other countries. Such a data sharing system could be developed building on the existing OECD database on the approved events in member countries. In response to this proposal, the Representative of OECD clarified that the current data system operated in close cooperation with the CBD had a specific purpose and that an eventual enlargement of the scope of the database to cover other purposes needed to be carefully examined, in consultation with other organizations such as CBD, FAO and WHO, taking into account feasibility and cost implications.

55. Some delegations pointed out that the term such as “low level” or “unauthorized” as well as the scope of this work required further clarification before new work would be started. Several delegations stated that this issue belonged to risk management and would not fit in the context of the Plant Guideline where the scope was confined to safety assessment based on scientific considerations. Several observers expressed their

opposition to the proposal for new work since no recombinant-DNA plants should be allowed on the market without approval by the national authority.

56. After an exchange of views, the Task Force realized there still remained among delegations different views in the scope of the proposed work and therefore decided not to start new work at the current session.

57. The Delegation of the United States indicated that the delegation would wish to further study this issue to decide whether to revisit the subject at a future session of the Task Force. The Delegation of the European Community expressed its willingness to continue discussion on this item and requested that information on existing databases on recombinant-DNA plants and possible development of a more comprehensive database of recombinant-DNA events be provided by relevant international organizations at the next session of the Task Force.

Plants producing pharmaceutical or bioactive substances

58. Several delegations and observers pointed out that the issues related to plants producing pharmaceutical or bioactive substances were beyond the mandate of Codex. Some delegations suggested that the term of "bioactive substance" should be clearly defined for judging whether or not plants producing such substances could be considered as foods and be addressed by the Task Force.

59. The Delegation of Norway expressed its opinion that issues on contamination of food supply with plants producing pharmaceutical substances could be addressed by the Task Force with a view to assuring food safety and protecting consumers' health, if there was a slightest possibility for the plants to reach to food chain.

60. The Task Force noted that there was no consensus on this matter and agreed not to start new work on this subject.

Post market surveillance

61. The Delegation of Mexico, referring to its written comment, proposed to start new work on post market surveillance with the aim of obtaining scientific information which could support and complement risk assessment of foods derived from biotechnology.

62. Due to the late availability of the written proposal, the Task Force agreed that Mexico submit a discussion paper to the next session of the Task Force with respect to the sanitary surveillance after placing on the market of foods derived from biotechnology.

OTHER BUSINESS, FUTURE WORK AND DATE AND PLACE OF THE NEXT SESSION (Agenda Item 5[6])

63. The Delegation of Kenya, referring to its written comments, proposed that the Task Force should consider, as possible future work, safety assessment of foods derived from animals exposed to protection against disease through gene therapy or recombinant-DNA vaccines.

64. The Task Force noted that the World Organisation for Animal Health (OIE) and other international organizations had ongoing work on the application of these techniques in food animals and that duplication of work with these organizations should be avoided. The Task Force further noted that its terms of reference did not include issues relating to animals that were not modified as such but were fed with genetically modified feeds or treated with recombinant-DNA vaccines.

65. The Task Force however recognized that there might be a potential food safety issue associated with foods derived from animals treated with recombinant-DNA vaccines or gene therapy and that there was a merit in following up the issue in the light of the work being undertaken by other organizations, namely OIE.

[6] CRD 1 (Comment of Kenya)

66. The Task Force therefore invited Kenya to submit a discussion paper to the next session of the Task Force to further elaborate the matter.

67. The Task Force also agreed that Pakistan submit a discussion paper to the next session of the Task Force with regard to the safety assessment of composite foods containing ingredients derived from recombinant-DNA organisms so that the Task Force could evaluate the need for new work.

Future Work

68. The Task Force noted that the following items would be considered at its next session:

- Proposed Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals (led by Australia and Japan);
- Proposed Draft Annex (scoping document) to the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants: Food Safety Assessment of Food Derived from Recombinant-DNA Plants Modified for Nutritional or Health Benefits (led by Canada);
- Discussion paper on Comparative Food Composition Analysis of Staple Foods (prepared by India);
- Discussion paper on Sanitary Surveillance after Placing on the Market of Foods Derived from Biotechnology (prepared by Mexico); and
- Discussion paper on Safety Assessment of Foods Derived from Animals Exposed to Protection against Disease through Gene Therapy or Recombinant-DNA Vaccines (prepared by Kenya).

Date and Place of the Next Session of the Task Force

69. The 6th Session of the Task Force was tentatively scheduled to take place from 27 November to 1 December 2006 in Chiba, Japan, subject to further confirmation by the host government in consultation with the Codex Secretariat.

SUMMARY STATUS OF WORK

Subject	Step	Action by	Document Reference (ALINORM 06/29/34)
Proposed Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals	1/2/3	Governments Working Group 29th CAC	para. 19
Proposed Draft Annex to the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants: Food Safety Assessment of Food Derived from Recombinant-DNA Plants Modified for Nutritional or Health Benefits	1/2/3	Governments Working Group 29th CAC	para. 32
Discussion paper on Comparative Food Composition Analysis of Staple Foods		India 6th Session of the Task Force	para. 44
Discussion paper on Sanitary Surveillance after Placing on the Market of Foods Derived from Biotechnology		Mexico 6th Session of the Task Force	Para. 62
Discussion paper on Safety Assessment of Foods Derived from Animals Exposed to Protection against Disease through Gene Therapy or Recombinant-DNA Vaccines		Kenya 6th Session of the Task Force	para. 66

APPENDIX I

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Heads of Delegation are listed first, followed by alternates and advisors listed in alphabetical order.

Les chefs de délégation figurent en tête et les suppléants et conseillers sont énumérés en ordre alphabétique.

Figuran en primar lugar los Jefes de las delegaciones, los Suplentes y Asesores aparecen por orden alfabético.

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APPENDIX II

PROJECT DOCUMENT

Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals

1. Purposes and scope of the proposed work

To develop a guideline for the conduct of food safety assessment of foods derived from recombinant-DNA animals, taking into account the *Statement of Principle Concerning the Role of Science in the Codex Decision Making Process and the Extent to Which Other Factors are Taken into Account*.[1] 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/GL 45-2003), taking into account the differences between plants and animals.

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 March 2000 (ALINORM 01/34, para 28) which identified the development of guidelines on safety of foods produced from recombinant-DNA animals as a third priority. 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 the 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 form a framework for assessing the safety of food from recombinant-DNA animals, using the plant guideline (CAC/GL 45-2003) as a model.

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

General Criterion

Consumer protection from the point of view of health, food safety, ensuring fair trade practices in the food trade and taking into account the identified needs of developing countries: this new work will contribute to enhancement of consumer protection by providing guidance as to how to perform safety assessment of food derived from recombinant-DNA animals.

Criteria applicable to general subjects

a. *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 assessment methodology, safety standards and regulatory framework, and which, when applied internationally, may assist in providing a harmonized approach.

b. *Scope of work and establishment of priorities between the various sections of work:* See section 1, above.

c. *Work already undertaken by other organizations in this field and/or suggested by the relevant international intergovernmemtal body(ies):* This new work does not duplicate work undertaken by other international organizations and builds on work undertaken by the FAO/WHO Expert Consultation on the Safety Assessment of Foods Derived from Genetically Modified Animals, including Fish (2003).

[1] Codex Alimentarius, Procedural Manual

5. Relevance to Codex Strategic Objectives

The new work contributes to protecting the health of consumers and ensuring fair practices in the trade of foods derived from modern biotechnology by satisfying the following 'Strategic Objectives and Priorities' (CAC Strategic framework 2003-07):

Objective 1: Promoting sound regulatory frameworks
Objective 2: Promoting widest and consistent application of scientific principles and risk analysis
Objective 4: Enhance 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 proposed document will not duplicate existing Codex documents and, in particular, will be consistent with the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius[2] and the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003). It will 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

FAO and WHO held an Expert Consultation on the Safety Assessment of Foods Derived from Genetically Modified Animals, including Fish, in Rome, Italy on 17-21 November 2003, whose outcome should be used, as applicable, in the preparation of this new document. The need for further scientific advice will be considered during the elaboration process of the texts.

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

Coordination with the OIE may be required, as appropriate.

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.

It is expected that the document can be completed within the four-year life span of the Task Force.

[2] Codex Alimentarius, Procedural Manual

APPENDIX III

PROJECT DOCUMENT

Food Safety Assessment of Foods Derived from Recombinant-DNA Plants Modified for Nutritional or Health Benefits

1. Purposes and scope of the proposed work

To provide further guidance, in the form of an annex to the Guidelines for the Conduct of Food Safety Assessment of Foods Derived From Recombinant-DNA Plants (CAC/GL 44-2003), with respect to any additional safety and nutritional considerations related to the assessment of foods derived from nutritionally-enhanced recombinant DNA plants. The scope of this work would not cover plants expressing pharmaceuticals or other non-food related substances as the primary purpose of these plants is not food use but rather for use as factories to produce industrial or pharmaceutical compounds.

2. Relevance and timeliness

There is currently extensive research and development in the area of "second generation" recombinant-DNA plants, including those intentionally modified to enhance the nutritional attributes of foods derived from these plants. It is expected that these products will be ready for commercialization in the very near future.

The Codex *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* (CAC/GL 45-2003) describes the recommended approach to carry out safety assessment of food derived from recombinant-DNA plants. It also provides general guidance with respect to intentional nutritional modification (paragraphs 48-53). In particular, it is stated that "*foods derived from recombinant-DNA plants that have undergone modification to intentionally alter nutritional quality or functionality should be subjected to additional nutritional assessment [beyond that conducted when modifications are for other purposes] to assess the consequences of the changes and whether the nutrient intakes are likely to be altered by the introduction of such foods into the food supply*."

There would be significant value for the Task Force to undertake work aimed to provide further guidance relating to additional safety and nutritional considerations that the assessment of these nutritionally-enhanced foods may require.

3. The main aspects to be covered

Additional safety and nutritional considerations for the assessment of foods derived from recombinant-DNA plants modified for nutritional or health benefits include such aspects as bioavailability and physiological function of the intended modification. Particular focus will be given to staple crops of interest to populations in developing countries

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

This proposal is consistent with:

General Criterion: *Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries.*

Criteria applicable to general subjects:

(a) *Diversification of national legislations and apparent resultant or potential impediment to international trade*: This new work will provide scientific guidance which countries will be able to use to develop their own safety assessment approach, and when applied internationally, may assist in providing a harmonized approach.

(c) *Work already undertaking by other international organizations in this field and/or suggested by relevant international intergovernmental body(ies)*: There is no other international organization that has undertaken international standard setting activities for foods derived from nutritionally enhanced recombinant-DNA plants.

5. Relevance to Codex Strategic Objectives

The proposal meets the following objectives:

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.

This proposed approach to complementing the existing plant guidelines for nutritionally enhanced products is consistent with that taken by the Task Force to provide detailed guidance on the assessment of potential allergenicity of newly expressed protein(s).

The proposal supports but not duplicate the Codex *Principles for the Risk Analysis of Foods derived from Modern Biotechnology* (CAC/GL 44-2003) and the Codex *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* (CAC/GL 45-2003).

There may be a need to ensure consistency and links, as appropriate, between the draft annex and the existing Codex texts dealing with health and nutrition labelling and claims.

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

There may be a need to consult other relevant Codex Committees (e.g., Codex Committee on Nutrition and Foods For Special Dietary Uses).

The following document may be taken into account:
Joint WHO/FAO Nutrient Risk Assessment Workshop: A model for establishing upper levels of intake for nutrients and related substances, 2-5 May 2005, Geneva, Switzerland.

The need for further scientific advice may be considered during the elaboration process of the draft annex.

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

The following documents may be taken into account:

Report of the OECD Workshop on the Nutritional Assessment of Novel Foods and Feeds (Ottawa, Canada, 2001)
Nutritional and Safety Assessments of Foods and Feeds Nutritionally Improved through Biotechnology – Prepared by the Task Force of the ILSI International Food Biotechnology Committee as published in IFT's Comprehensive Reviews in Food Science and Food Safety (2004).

The need for further scientific advice may be considered during the elaboration process of the draft annex.

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.

It is expected that the document can be completed within the 4 year life-span of the Task Force.