

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

PAPER FOR POSTAL CONSIDERATION

CODEX INTERGOVERNMENTAL TASK FORCE ON FOODS DERIVED FROM BIOTECHNOLOGY

This paper invites Members' comments on topics proposed for inclusion in the work programme of this recently re-formed Codex Task Force

Background

1. Codex Alimentarius is the body established by the WHO and FAO to establish international standards for food. The detailed work of Codex is carried out through a series of standing committees that cover discrete areas such as Food Additives, Food Labelling, Fruit Juices etc. In the case of GM foods, Codex previously established an *ad hoc* Task Force with the general objective of elaborating standards, guidelines, or other principles for foods derived from biotechnology.
2. The Task Force met on 4 occasions during 2000-2003 and, based on its recommendations, the following documents were adopted by Codex in 2003:
 - 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.
3. These documents are highly regarded and have been taken fully in account by the European Food Safety Authority in developing its specific approach to safety evaluation of GM foods.
4. In 2004, Codex Alimentarius decided to re-form the Task Force and sought suggestions for potential areas of work.
5. Further comments were sought in February 2005 (Codex letter CL 2005/2-FBT, Annex 1). The Task Force Secretariat has not yet distributed a digest of the responses it has received, but the co-ordinated response from the European Commission is attached (Annex 2). The Task Force will run for four years, until 2009. This Task Force is hosted by Japan and the first meeting will take place in Japan during 19-23 September. It is expected that the discussion will focus on agreement of the Work Programme.

Proposed work programme

6. The European Commission has replied to the February 2005 letter on behalf of the 25 EU member states (Annex 2) and proposed six items for inclusion in the Task Force's work programme during 2005-2009. These are listed below, with comments from the ACNFP Secretariat.

1) Low level presence of unauthorised GM material in food

This project would provide guidance on a risk-based approach to handling the low level presence of unauthorised GM material in foods traded between nations, recognising the asymmetric rate of authorisation in different countries and regions.

2) Food safety assessment of GM animals and derived products

The output from this project would be a third set of guidelines on safety evaluation, to complement existing Codex guidelines dealing with GM plants and GM microorganisms.

3) GM plants expressing pharmaceutical or other bioactive substances

This project would provide guidance on "biopharming" – the large-scale production of bioactive compounds through cultivation – in order to minimise the risk to consumers from accidental contamination of the food supply.

4) Safety assessment of food derived from multiple rDNA plants (stacked genes)

Existing Codex guidelines for the safety assessment of food derived from GM plants does not specifically address varieties obtained by conventional crosses between different GM lines. This issue has been discussed recently by the ACNFP in the context of applications made in the EU (e.g. MON863 x MON810 maize) and EFSA has recently published opinions on 3 such GM hybrids.

5) Food safety issues specific to staple food crops for developing countries

This proposal was originally made by the United States, recognising that genetic modification of staple crops may present different issues for developing countries, where a individual crop may represent the major source of nutrition for many people

6) Food produced from cloned animals and their offspring

Cloning does not fall within the EU definition of "genetic modification" but is often regarded as a comparable technology. It is also possible that cloning could be applied commercially to propagate genetic modifications in animals for food production. This project would develop guidelines for the safety assessment of food from cloned animals (including fish).

Committee Action Required

7. Committee Members are invited to consider on the proposals listed above in paragraphs 5 and 6. It will be particularly useful at this stage to have any comments on the relative importance of the various issues and on and significant uncertainties in the science that might limit the success of these projects within the allotted 4-year timescale.

**Secretariat
August 2005**

Annexes attached:

Annex 1 – Codex letter CL 2005/2-FBT

Annex 2 – European Community comments to Circular Letter 2005/2-FBT

ACNFP/73P/1B Annex 1

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

Codex letter CL 2005/2-FBT.

**Secretariat
August 2005**

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



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CX 4/80.1

CL 2005/2- FBT
February 2005

TO: Codex Contact Points
Interested International Organizations

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

SUBJECT: **Request for proposals for new work to be undertaken by the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology**

DEADLINE: **30 April 2005**

COMMENTS: **To:** Dr. MATSUMOTO Yoshiyuki
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BACKGROUND

1. The 26th Session of the Codex Alimentarius Commission considered the proposal to establish a new Task Force on Foods Derived from Biotechnology and requested Japan to submit a proposal on the new Task Force. The 53rd Session of the Executive Committee agreed that Japan would prepare a project document in the form of draft terms of reference for a new Ad Hoc Task Force with a list of potential areas of work.

2. In accordance with this decision, the Circular Letter appended with Draft Terms of Reference and Project Document: Proposal for New Work on Foods Derived from Biotechnology (CL2004/7-FBT) was issued. In response to this Circular Letter, comments on the potential areas for work were received from Argentina, Australia, Canada, Hungary, Indonesia, Iran, Mexico, New Zealand, United States of America, Venezuela, European Community, Biotechnology Industry Organization, Croplife International, 49th Parallel Biotechnology Consortium and Greenpeace International (CAC/27 LIM.9 & LIM.11).

The comments received covered areas as follows :

- 1) Foods derived from animals
 - Transgenic animals, including fish
 - Cloned animals
- 2) Foods derived from plants
 - Plants expressing bioactive substances or nutritionally-enhanced plants

- Plants with “stacked” genes (i.e. several genes conferring different traits in the same plant)
 - Biopharming
 - Plants expressing pharmaceutical or other non-food substance
- 3) Low level presence of unauthorized genetically engineered foods in authorized foods
 - 4) Comparative food composition analysis

3. The 27th Session of the Codex Alimentarius Commission agreed to establish a new Ad Hoc Intergovernmental Task Force on Foods derived from Biotechnology with 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). The Commission noted the willingness of the delegation of Japan to host the new Task Force subject to confirmation of availability of funds (ALINORM04/27/41, para. 90).

4. 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 and noted that the issues concerning potential areas for future work including “cloned animals” and “bioactive substances” would be clarified and discussed in the new Task Force (ALINORM 04/27/41, paras 89 and 91).

In accordance with the decisions of the Commission, the present Circular Letter is hereby distributed to solicit specific proposals for new work to be addressed by the Task Force.

REQUEST FOR COMMENTS

5. Governments and international organizations are requested to make comments on the issues to be addressed by the Task Force (particularly from among, but not limited to the list of areas shown in paragraph 2) with;

- 1) Sufficient clarification on the suggested issues, including
 - the rationale,
 - the scope,
 - the need for additional scientific advice,
 - any questions to be answered by experts concerning the proposed issues,
 - information on the relation between the suggested issues and other existing Codex and other pertinent documents, and
 - the expected outcome, such as guideline, annex to any of the existing or forthcoming CTFBT documents, etc.,

with supplementary explanation on technical terms where necessary;

- 2) Priorities to be set among the proposals;
- 3) Any other considerations.

Where appropriate, comments may incorporate project document(s) (see Elaboration Procedures, Part 2 Critical Review, in the Procedural Manual, 14th Edition) for issues proposed.

6. Governments and international organizations wishing to submit comments should do so in writing, preferably by email to the above address **before 30 April 2005**. The comments received will be compiled and distributed as a working document of the forthcoming session of the Task Force.

Note: For information, the Terms of reference of the Task Force agreed in the 27th Session of the Codex Alimentarius Commission (ALINORM 04/27/41 Appendix VIII), the contents of the “Principles for the Risk Analysis of Foods derived from Modern Biotechnology (CAC/GL 44-2003)” and the “Guideline for the Conduct of Food Safety Assessment of the Foods derived from Recombinant-DNA Plants (CAC/GL 45-2003)” developed by the previous Task Force, and the “Questions for a Joint FAO/WHO Expert Consultation” addressed in the first meeting of the previous Task Force are reproduced in Annex, which may assist in the above consideration.

A. THE TERMS OF REFERENCE OF THE AD HOC INTERGOVERNMENTAL TASK FORCE ON FOODS DERIVED FROM BIOTECHNOLOGY (ALINORM 04/27/41 APPENDIX VIII)

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.

B. THE CONTENTS OF THE PRINCIPLES AND GUIDELINES DEVELOPED BY THE PREVIOUS AD HOC INTERGOVERNMENTAL TASK FORCE ON FOODS DERIVED FROM BIOTECHNOLOGY

PRINCIPLES FOR THE RISK ANALYSIS OF FOODS DERIVED FROM MODERN BIOTECHNOLOGY (CAC/GL 44-2003)

1. Introduction
2. Scope and Definitions
3. Principles
 - Risk Assessment
 - Risk Management
 - Risk Communication
 - Consistency
 - Capacity Building and Information Exchange
 - Review Processes

GUIDELINE FOR THE CONDUCT OF FOOD SAFETY ASSESSMENT OF FOODS DERIVED FROM RECOMBINANT-DNA PLANTS (CAC/GL 45-2003)

1. Scope
2. Definitions
3. Introduction to Food Safety Assessment
 - Unintended Effects
 - Framework of Food Safety Assessment
4. General Considerations
 - Description of the Recombinant-DNA Plant
 - Description of the Host Plant and its Use as Food

Description of the Donor Organism(s)
Description of the Genetic Modification(s)
Characterization of the Genetic Modification(s)
Safety Assessment
 Expressed Substances (non-nucleic acid substances)
 Assessment of possible toxicity
 Assessment of possible allergenicity (protein)
 Compositional Analyses of Key Components
 Evaluation of Metabolites
 Food Processing
 Nutritional Modification
5. Other considerations
 Potential Accumulation of Substances Significant to Human Health
 Use of Antibiotic Resistance Marker Genes
 Review of Safety Assessments

ANNEX TO “GUIDELINE FOR THE CONDUCT OF FOOD SAFETY ASSESSMENT OF FOODS DERIVED FROM RECOMBINANT-DNA PLANTS (CAC/GL 45-2003)”:

ASSESSMENT OF POSSIBLE ALLERGENICITY

1. Introduction
2. Assessment Strategy
3. Initial Assessment
 - 3-1. Source of the Protein
 - 3-2. Amino acid Sequence Homology
 - 3-3. Pepsin Resistance
4. Specific Serum Screening
5. Other Considerations

C. THE QUESTIONS FOR AN EXPERT CONSULTATION RAISED BY THE PREVIOUS AD HOC INTERGOVERNMENTAL TASK FORCE ON FOODS DERIVED FROM BIOTECHNOLOGY AT ITS FIRST SESSION (2000)

QUESTIONS FOR A JOINT FAO/WHO EXPERT CONSULTATION (ALINORM 01/34, Appendix III)

1. What over-arching scientific principles should be applied to safety and nutritional assessment?
2. What is the role and limitation of substantial equivalence in safety and nutrition assessment? Are there alternative strategies that should be used for safety and nutrition assessment?
3. What scientific approach can be used to monitor and assess possible long term health effects or unintended/unexpected adverse effects?
4. What scientific approach can be used to assess potential allergenicity?
5. What scientific approach can be used to assess the possible risks arising from the use of antibiotic resistance marker genes in plants and micro-organisms?

ACNFP/73P/1B Annex 2

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

European Community comments to Circular Letter 2005/2-FBT.

**Secretariat
August 2005**

European Community comments to Circular Letter 2005/2-FBT

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 decreasing priority order:

(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 stacked 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 States 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 from 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, silencing 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 from 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 their 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.