codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX AD HOC INTERGOVERNMENTAL TASK FORCE ON FOODS DERIVED FROM BIOTECHNOLOGY

Fifth Session

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

PROJECT DOCUMENT 1

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

Prepared by the European Community

1. Purpose and scope of the proposed work

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

2. Relevance and timeliness

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

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

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

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

3. The main aspects to be covered

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

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

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

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

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

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

5. Relevance to Codex Strategic Objectives

This work is consistent with Codex objectives in particular:

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

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

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

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

None identified

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

None identified.

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

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

PROJECT DOCUMENT 2

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

Prepared by the European Community

1. Purpose and scope of the proposed work

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

2. Relevance and timeliness

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

3. The main aspects to be covered

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

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

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

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

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

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

5. Relevance to Codex Strategic Objectives

This work is consistent with Codex objectives in particular:

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

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

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

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

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

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

None identified.

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

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

PROJECT DOCUMENT 3

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

Prepared by the European Community

1. Purpose and scope of the proposed work

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

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

2. Relevance and timeliness

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

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

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

3. The main aspects to be covered

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

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

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

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

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

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

5. Relevance to Codex Strategic Objectives

This work is consistent with Codex objectives in particular:

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

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

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

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

None identified

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

None identified.

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

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

PROJECT DOCUMENT 4

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

Prepared by the European Community

1. Purpose and scope of the proposed work

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

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

2. Relevance and timeliness

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

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

3. The main aspects to be covered

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

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

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

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

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

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

5. Relevance to Codex Strategic Objectives

This work is consistent with Codex objectives in particular:

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

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

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

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

None identified.

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

None identified.

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

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

PROJECT DOCUMENT 5

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

Prepared by the European Community

1. Purpose and scope of the proposed work

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

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

2. Relevance and timeliness

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

3. The main aspects to be covered

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

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

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

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

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

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

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

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

5. Relevance to Codex Strategic Objectives

This work is consistent with Codex objectives in particular:

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

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

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

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

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

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

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

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

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