codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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

Agenda Item 4 **CX/FBT 05/5/4**

May 2005

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX AD HOC INTERGOVERNMENTAL TASK FORCE ON FOODS DERIVED FROM BIOTECHNOLOGY

Fifth Session

Chiba, Japan, 19-23 September 2005

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

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

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

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

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

ARGENTINA

General Comments

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

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

Specific Comments

A. Priority assignments. Preliminary Comments and modifications

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

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

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

Sub-header 1: Foods derived from animals

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

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

Sub-header 2: Foods derived from plants

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

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

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

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

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

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

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

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

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

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

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

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

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

Sub-header 4: Comparative food composition analysis

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

Sub-header 5:

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

C. Comments on the proposed priorities.

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

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

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

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

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

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

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

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

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

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

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

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

AUSTRALIA

GENERAL COMMENTS

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

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

SPECIFIC COMMENTS

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

A. High Priority Areas for New Work

(i) Foods derived from transgenic animals

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

Scope and issued to be addressed

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(ii) Foods derived from cloned animals

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

Scope and issues to be addressed

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

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

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

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

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

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

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

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

(iii) Comparative food composition analysis

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

(iv) Plants expressing bioactive substances or nutritionally enhanced plants

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

NUTRITIONALLY ENHANCED PLANTS

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

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

PLANTS EXPRESSING BIOACTIVE SUBSTANCES

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

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

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

B. Areas of work with lower priority

(i) Plants with "stacked" genes

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

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

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

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

(i) Biopharming

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

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

BRAZIL

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

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

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

1. Plants with "stacked genes"; and

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

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

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

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

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

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

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

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

CANADA

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

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

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

1) Novel foods derived from animal origin

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

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

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

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

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

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

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

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

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

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

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

General Considerations

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

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

IRAN

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

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

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

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

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

JAPAN

General Comments

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

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

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

Specific Comments

Japan suggests three items with priority order given below.

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

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

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

1. The purpose

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

2. The rationale

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

3. The scope

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

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

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

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

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

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

6. Any other considerations

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

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

1. The purpose

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

2. The rationale

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

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

3. The scope

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

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

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

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

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

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

6. Any other considerations

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

(III) FOODS DERIVED FROM FISH (TRANSGENIC FISH)

1. The purpose

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

2. The rational

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

3. The scope

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

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

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

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

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

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

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

6. Any other considerations

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

MEXICO

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

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

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

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

NEW ZEALAND

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

Rationale

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

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

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

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

Scope

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

Need for additional scientific work

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

Relationship between the suggested issue and other existing Codex documents

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

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

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

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

Expected outcome

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

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

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

UNITED STATES OF AMERICA

COMMENTS

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

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

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

United States Proposed Projects

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

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

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

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

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

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

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

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

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

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

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

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

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

VENEZUELA

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

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

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

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

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

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

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

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

49th PARALLEL BIOTECHNOLOGY CONSORTIUM

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

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

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

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

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

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

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

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

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

BIOTECHNOLOGY INDUSTRY ORGANIZATION (BIO)

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

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

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

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

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

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

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

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

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

CONSUMERS INTERNATIONAL

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

Foods derived from animals

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

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

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

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

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

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

Foods derived from plants

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

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

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

Annex 1

PROJECT DOCUMENT

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

Prepared by: Japan

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

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

2. Its relevance and timeliness.

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

3. The main aspects to be covered.

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

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

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

This proposal is consistent with:

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

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

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

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

5. Relevance to the Codex strategic objectives.

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

Objective 1: Promoting sound regulatory frameworks

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

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

Objective 6: promoting maximum application of Codex standards

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

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

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

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

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

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

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

Necessary, if available.

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

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

Annex 2

PROJECT DOCUMENT

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

Prepared by: Japan

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

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

2. Its relevance and timeliness.

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

3. The main aspects to be covered.

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

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

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

This proposal is consistent with:

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

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

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

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

5. Relevance to the Codex strategic objectives.

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

Objective 1: Promoting sound regulatory frameworks

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

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

Objective 6: promoting maximum application of Codex standards

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

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

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

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

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

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

Necessary, if available.

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

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

Annex 3

PROJECT DOCUMENT

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

Prepared by: Japan

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

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

2. Its relevance and timeliness.

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

3. The main aspects to be covered.

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

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

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

This proposal is consistent with:

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

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

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

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

5. Relevance to the Codex strategic objectives.

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

Objective 1: Promoting sound regulatory frameworks

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

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

Objective 6: promoting maximum application of Codex standards

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

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

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

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

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

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

Necessary, if available.

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

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

Annex 4

PROJECT DOCUMENT

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

Prepared by : The United States of America

1. Purpose and scope of the proposed work

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

2. Its relevance and timeliness

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

3. The main aspects to be covered

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

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

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

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

5. Relevance to Codex Strategic Objectives

This new work proposal is consistent with:

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

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

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

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

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

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

None identified.

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

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

Annex 5

PROJECT DOCUMENT

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

Prepared by: The United States of America

1. Purpose and scope of the proposed work

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

2. Its relevance and timeliness

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

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

3. The main aspects to be covered

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

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

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

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

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

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

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

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

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

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

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

Annex 6

PROJECT DOCUMENT

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

Prepared by: Consumers International

1. Purpose and scope of the proposed work

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

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

2. Its relevance and timeliness

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

3. The main aspects to be covered

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

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

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

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

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

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

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

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

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

5. Relevance to Codex Strategic Objectives

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

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

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

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

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

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

Technical input already exists. See answer to 7.

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

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