codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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

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.

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[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.