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.

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[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.

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[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.