codex alimentarius commission

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WORLD HEALTH ORGANIZATION

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CX 4/80.2

CL 2007/18-FBT
June 2007

TO: Codex Contact Points
Interested International Organizations

FROM: Secretary, Codex Alimentarius Commission
Joint FAO/WHO Food Standards Programme
Viale delle Terme di Caracalla, 00153 Rome, Italy

SUBJECT: Proposed draft Annex to the Codex Guideline for the Conduct of Food Safety Assessment of Foods derived from Recombinant-DNA Plants: Food Safety Assessment of Foods Derived from Recombinant-DNA Plants modified for Nutritional or Health Benefit

DEADLINE: **31 July 2007**

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The Codex *ad hoc* Intergovernmental Task Force on Foods Derived from Biotechnology, at its Sixth Session, agreed to return the captioned proposed draft Annex to Step 2 for further drafting by a physical working group led by Canada, co-chaired by Argentina and New Zealand, and open to all the members and observers (ALINORM 07/30/34 para.59).

This Circular Letter incorporates the report of the physical working group which met on 7 - 9 May 2007 in Ottawa, Canada. The report includes the proposed draft Annex prepared by the working group as presented in the Attachment 1. Attachcment 2, which is not part of the proposed draft Annex, is also included to provide examples to illustrate what is meant by a certain term used therein.

Governments and international organizations wishing to provide comments on the proposed draft Annex at Step 3, prior to consideration by the Seventh Session of the Task Force at Step 4 (Chiba, Japan, 24 - 28 September 2007), should do so in writing, preferably by email, to the above addresses **by 31 July 2007.**

REPORT OF THE WORKING GROUP ON THE PROPOSED DRAFT ANNEX TO THE CODEX *GUIDELINE FOR THE CONDUCT OF FOOD SAFETY ASSESSMENT OF FOODS DERIVED FROM RECOMBINANT –DNA PLANTS:* FOOD SAFETY ASSESSMENT OF FOODS DERIVED FROM RECOMBINANT-DNA PLANTS MODIFIED FOR NUTRITIONAL OR HEALTH BENEFITS

BACKGROUND

1. At the Sixth Session (2006), the Codex *ad hoc* Intergovernmental Task Force on Food Derived from Biotechnology (Task Force) was invited to discuss the Proposed Draft Annex (Scoping Document) to the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants: Food Safety Assessment of Foods Derived From Recombinant-DNA Plants Modified for Nutritional or Health Benefits[1] and comments on this document, at Step 3, were received by the Task Force by October 1st, 2006[2].

2. At the Sixth Session (2006), the Task Force agreed to return the proposed draft Annex to Step 2 for further drafting by a physical working group to be chaired by Canada and co-chaired by New Zealand and Argentina. The Task Force agreed that the Working Group would prepare the proposed draft Annex to the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants on the basis of the outputs of the previous electronic Working Group and the comments received at Step 3 contained in CX/FBT 06/6/5 and CX/FBT 06/6/5-Add.1, as well as comments provided during the Sixth Session of the Task Force.

3. The Working Group met in Ottawa, Ontario, Canada., on May 7-9, 2007. Attachment 3 lists the Working Group participants. The Working Group developed a proposed draft Annex to the Codex Plant Guideline, which is presented in Attachment 1.

4. The key points brought forward in the discussion of the Working Group include the following.

Scope and Structure of the Annex

5. The Working Group agreed with the overall approach taken by the co-chairs in drafting the proposed draft annex using the structure of a risk assessment, as described in the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius[3]. However, it was stressed that the proposed draft was intended to support existing safety assessment guidance rather than extending to guidance on risk assessment.

6. The Working Group agreed that the scope of the document would be limited to the food safety assessment of foods derived from plants modified for nutritional or health benefits and that risk management measures were outside this scope. Extensive discussion was held on whether specific examples of risk management measures should be included in the text, but the Working Group agreed that this was not required.

7. The Working Group agreed that the assessment of the benefits of foods derived from plants modified for nutritional or health benefit was outside the scope of the document. However, the delegation of the European Community and the delegations of its three Member States attending the meeting, in line with the common position already expressed by the European Community and delegates, were of the view that the positive work started by the Working Group on Food Safety Assessment of Foods derived from recombinant-DNA Plants modified for Nutritional or Health benefit needs to be completed by further Codex work on the specific characterization of the benefits related to the food derived from recombinant-DNA Plants modified for nutritional or health benefit. In particular the delegations referred to above were of the view that risks and benefits should be expressed in a way they can be weighed up.

8. The Working Group agreed that taking into account the agreed scope the annex, it should not repeat or revise the safety assessment approach taken in the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants and instead agreed it should focus specifically on those areas which are specific to the assessment foods derived from plants modified for nutritional or health benefit.

[1] CX/FBT 06/6/5
[2] CX/FBT 06/6/5-Add. 1
[3] Codex Alimentarius Commission Procedural Manual, 16th edition.

9. The Working Group discussed whether there would be a need to revisit the formatting and the structure of the draft annex attached to this report. Some delegations suggested that, for the sake of clarity, it would be advantageous to revisit the sequential order of the paragraphs in section three during Seventh Session of the Task Force meeting to be held in September 2007.

Assessment of Food Safety Considerations

10. Some discussion occurred in the Working Group around the need to include examples at certain points in the text. In particular the Working Group discussed whether examples of the term "undesirable substances" would be need in paragraph 1b of Attachment 1. One delegation indicated a preference to include the examples of "toxins, allergens and anti-nutritional factors". The group could not agree on the addition of these examples to the text and due to time limitations the group agreed that these examples would be left out of the draft Annex.

11. The Working Group had some very useful discussions on the need to include definitions for the text, which terms would require definition and the correct definition of those terms. After several lengthy discussions on the subject the Working Group agreed that the only definition that would be included in the Annex was that for "nutrient". The group agreed that definitions for "related substances", "bioavailability", "undesirable substances" and "upper levels" were not to be included in the text, either because an established definition existed in other codex publications or because the Working Group felt that other Codex Committees were better qualified to define those terms.

12. Text was proposed by the European Community specifically proposing a general principle to be taken into account during the exposure assessment, regarding that these foods should not be nutritionally disadvantageous to the consumer compared with the foods intended to be replaced. Argentina and other delegations expressed that this text was likely outside the scope of the document since it encompasses the consideration of benefits and besides it refers to decisions to be taken during risk management, and for these reasons it should not be included in the draft Annex. Mexico also noted that the text was presented on the third day of the meeting and due to time constraints it could not fully considered by the delegates or even discussed. Therefore, it was agreed that this text would be placed in the draft annex in square brackets (in paragraph 14 of Attachment 1) to be further discussed at the Task Force meeting.

13. Additional text, regarding the proper design of feeding studies, was also proposed by the European Community. Again this text was introduced on the final day of the meeting and so could not be fully discussed by the delegates. It was agreed to the insertion of the text in square brackets (in paragraph 12 of Attachment 1) so that it could be fully discussed at the Task Force meeting

14. The Working Group noted that the term "multiple chemical forms" was ambiguous, so it was placed in square brackets (in paragraph 9 of Attachment 1) so that it could be clarified. New Zealand, as one of the co-chairs, offered to provide examples to illustrate what was meant by the term. These examples are included in Attachment 2.

15. The Task Force is invited to consider the proposed draft Annex to the Codex Plant Guideline on *Food Safety Assessment of Foods Derived from Recombinant-DNA Plants Modified for Nutritional of Health Benefits* with a view towards its further progression in the Codex Step Procedure.

Attachment 1

PROPOSED DRAFT ANNEX: Food Safety Assessment of Foods Derived from Recombinant-DNA Plants Modified for Nutritional or Health Benefits

Section 1 – Introduction

1. General guidance for the safety assessment of foods derived from recombinant-DNA plants is provided in the Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (*CAC/GL 45-2003*) (Codex Plant Guideline). This annex provides additional considerations that are specific to foods modified for nutritional or health benefits. The document does not extend beyond a safety assessment and therefore, it does not cover assessment of the benefits themselves or any corresponding health claims, or risk-management measures[4].

2. The following factors determine whether a recombinant-DNA plant is a recombinant-DNA Plant Modified for Nutritional or Health Benefits, and as such within the scope of this Annex:

   (a) the recombinant-DNA plant exhibits a particular trait in portion(s) of the plant intended for food use, and;

   (b) The trait is a result of either i) alteration of either the quantity or bioavailability of a nutrient(s) or related substance(s), ii) removal or reduction of undesirable substance(s), or iii) alteration of the interaction(s) of nutritional relevance of these substances.

Section 2 - Definition:

The definition below applies to this Annex:

Nutrient[5] - means any substance normally consumed as a constituent of food:

(a) which provides energy; or

(b) which is needed for growth and development and maintenance of healthy life; or

(c) a deficit of which will cause characteristic biochemical or physiological changes to occur.

Section 3 – Food Safety Assessment

3. The Codex General Principles for the Addition of Essential Nutrients to Foods (*CAC/GL 09-1987* (amended 1989, 1991) (Codex Essential Nutrient Principles) are generally applicable to the assessment of food derived from a plant which is modified by increasing the amount of a nutrient(s) or related substance(s) available for absorption and metabolism. The Food Safety Framework outlined within the Codex Plant Guideline[6] applies to the overall safety assessment of a food derived from a recombinant-DNA plant modified for nutritional or health benefits. This annex presents additional considerations regarding the food safety assessment of those foods.

4. Foods derived from recombinant-DNA plants modified for nutritional or health benefits may benefit certain populations/sub populations, while other populations/sub populations may be at risk from the same food[7].

5. Rather than trying to identify every hazard associated with a particular food, the intention of a safety assessment of food derived from recombinant-DNA plants is the identification of new or altered hazards relative to the conventional counterpart. Since recombinant-DNA plants modified for nutritional or health benefits result in food products with a composition that may be significantly different from their conventional counterparts, the choice of an appropriate comparator is of great importance for the safety assessment addressed in this annex (Codex Plant Guideline paragraph 4 and 51). Those alterations identified in a plant modified to obtain nutritional or health benefits are the subject of this safety assessment.

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[4] Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (*CAC/GL 44-2003*, paragraph 19)
[5] General Principles for the addition of essential Nutrients to Foods - *CAC/GL 09-1987* (amended 1989, 1991)
[6] Paragraphs 18-21 (Safety Framework) and 48-53 (Nutrition Modification)
[7] Further guidance for susceptible and high-risk population groups is provided in paragraph 49 of CAC/GL 45-2003 - Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants.

6. Upper levels of intake for many nutrients have been set out by some national, regional and international bodies[8] may be considered, as appropriate.

7. The safety assessment of related substances should follow a case-by-case approach taking into account upper levels as well as other values, e.g. Acceptable Daily Intake (ADI), where appropriate.

8. Although it is preferable to use a scientifically-determined upper level of intake of a specific nutrient or related substance, when no such value has been determined, consideration may be given to an established history of safe use for nutrients or related substances that are consumed in the diet if the resulting exposure would be consistent with those historical safe levels.

9. With conventional fortification of food, typically the [chemical form] of a nutrient is characterised and added at controlled concentrations. Concentration levels of plant nutrients or related substances may vary in both conventionally bred and recombinant-DNA plants due to growing conditions. In addition, [multiple chemical forms/analogues] of the nutrient that may not be characterized from a nutrition perspective might be expressed in the food as a result of the modification. Where appropriate, information may be needed on the [multiple chemical forms/ analogues] of the nutrient(s) or related substance(s) expressed in the portion of the plant intended for food use, their respective levels and their combined bioavailability in the food.

10. Bioavailability of the nutrient(s), related substance(s), or undesirable substance(s) in the food that were the subject of the modification in the recombinant-DNA plant should be established, where appropriate.

11. Bioavailability will vary for different nutrients, and testing regimes should be relevant to the nutrient, and the food containing the nutrient, as well as the health, nutritional status and dietary practices of the specific populations consuming the food. *In vitro*, and *in vivo* bioavailability methods exist, the latter conducted in animals and in humans. *In vitro* methods can provide information to assess extent of release of a substance from plant tissues during the digestive process. *In vivo* studies, in particular, human studies may provide more relevant information about whether and to what extent the nutrient or related substance is bioavailable.

12. [In the case animal studies are performed to assess the nutritional value and the bioavailability of the newly expressed substance(s), the animal species (strain/sex) should be sensitive enough to the nutrient(s), or substance(s) in question. The control diets need to be formulated in such a way that the key measured endpoints are responsive to a difference in the quantity and/or bioavailability of the enhanced nutrient(s), substance(s), or decreased undesirable substance(s). In the case of a new, or increased level of a nutrient(s) or related substance(s), the choices for control diets may be made on a case-by-case basis and the appropriate comparator(s) with and without external fortification may be necessary.]

13. Guidance on dietary exposure assessment of foods derived from recombinant-DNA plants with nutritional modifications is provided in paragraph 49 of the Codex Plant Guideline. In the context of this Annex, dietary exposure assessment is the estimation of the concentration of the nutrient(s) or related substance(s) in a food, the usual consumption of that food, and any known factors that impact bioavailability. Exposure to a nutrient(s) or related substance(s) should be evaluated in the context of the total diet and the assessment should be carried out based on the customary dietary consumption, by the relevant population(s), of the corresponding food that is likely to be displaced. Most, if not all, aspects of exposure assessment are not unique to recombinant-DNA plants modified for nutritional or health benefits.

14. [When evaluating the exposure, it is appropriate to take into account that the consumption of the modified food should not be nutritionally disadvantageous to the consumer compared with the food that it intends to replace. Possible exceptions to this consideration related to differences in regional consumption patterns could be assessed on a case-by-case basis.]

15. The first step of an exposure assessment is determining the level(s) of the substance(s) in question in the portion of the plant intended for food use. Guidance on determining changes in levels of these substances is provided in the Plant Guideline.[9]

[8] Where such guidance is not provided by Codex, information provided by the FAO/WHO may be preferably considered.

16. Consumption patterns will vary from country to country depending on the importance of the food in the diet(s) of a given population(s). Therefore, it is recommended that consumption estimates are based on national or regional food consumption data when available, using existing guidance[10] on estimation of exposure in a given population(s). When national or regional data is unavailable, FAO diet data may provide a useful resource. Data on staple food products may also be supplemented by information from FAO Food Balance Sheets.

17. To assess the safety of a food derived from a recombinant-DNA plant modified for a nutritional or health benefit, the estimated intake of the nutrient or related substance in the population(s) is compared with the nutritional or toxicological reference values, such as upper levels of intake, ADIs for that nutrient or related substance, where these values exist. This may involve assessments of different consumption scenarios against the relevant nutritional reference value, taking into account possible changes in bioavailability, or extend to probabilistic methods that characterise the distribution of exposures within the relevant population(s).

[9] CAC/GL 45-2003. Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants, paragraphs 44 and 45.

[10] A Model for Establishing Upper Levels of Intake for Nutrients and Related Substances. Report of a Joint FAO/WHO Technical Workshop on Nutrient Risk Assessment. WHO Headquarters, Geneva, Switzerland, 2-6 May 2005

Attachment 2

Examples of different chemical forms of nutrients[11]

Nutrient	Forms
Iron	Porphyrin-bound iron in hemoglobin and myoglobin from meat, poultry, and fish is more readily absorbed than nonheme iron found in foods of plant and animal origin.
Selenium	Main food sources of selenium are the organic forms, selenocysteine and selenomethionine, which tend to be better absorbed than selenite, the inorganic form
Zinc	Organic zinc complexes (e.g., from oysters) are more readily absorbed than inorganic zinc salts
Folate	Polyglutamates (mainly 5-methyl tetrahydrofolate [5MeTHF] in fresh food) are less well absorbed than synthetic monoglutamate form (i.e., folic acid)
Vitamin B6	Free pyridoxine, pyridoxamine (plus phosphorylated forms) in plants and pyridoxal (plus phosphorylated forms in animal foods) are better absorbed than pyridoxine β-D-glucoside in heat-processed milk products
Niacin	Niacin in mature maize, present as nicotinic acid esterified to polysaccharides, which is unavailable for absorption

[11] Table adapted from Gibson RS (2007) The role of diet- and host-related factors in nutrient bioavailability and thus in nutrient-based dietary requirement estimates. *Food and Nutrition Bulletin* vol. 28, no. 1 (supplement), 77-100.

Attachment 3

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