codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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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 Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants on Low-level Presence of Recombinant-DNA Plant Materials**

DEADLINE: **20 July 2007**

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This Circular Letter CL 2007/17-FBT rev. is to send the revised report of the working group distributed in May 2007. Please note that the added texts in the report are underlined in paragraphs 19 and 20 and that there are no changes made in the Attachments of the report.

The Codex *ad hoc* Intergovernmental Task Force on Foods Derived from Biotechnology, at its Sixth Session, agreed to start new work to elaborate a Proposed Draft Annex to the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants on Low-level Presence of Recombinant-DNA Plant Materials. The Task Force also agreed to establish a physical working group, chaired by the United States and co-chaired by Germany and Thailand, for preparing the proposed draft annex (ALINORM 07/30/34, para.78).

This Circular Letter incorporates the report of the physical working group which met on 13-15 March 2007. The report is accompanied by the proposed draft Annex to the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants. As indicated in the report, the physical working group provided the proposed draft Annex in two different formats, as presented in Attachments 1 and 2 (see paras 21-25 below).

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 20 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*: ASSESSMENT OF FOOD SAFETY CONSIDERATIONS ARISING FROM LOW-LEVEL PRESENCE OF RECOMBINANT-DNA PLANT MATERIAL IN FOOD

BACKGROUND

1. The Fifth Session (2005) of the Codex *ad hoc* Intergovernmental Task Force on Food Derived from Biotechnology (Task Force) considered a proposal by the United States to undertake new work on the low-level presence of unauthorized recombinant-DNA plant material[1]. Although, the Task Force did not accept the proposal for new work at that time, it indicated that the United States may wish to further study the issue to decide whether to revisit the subject at a future session of the Task Force. The Delegation of the European Community expressed its willingness to continue discussion on the item with a particular focus on information on existing databases on recombinant-DNA plants and possible development of a more comprehensive database of recombinant-DNA events.

2. At the Sixth Session (2006) of the Task Force, the United States again proposed work on the subject but with a different focus[2]. The United States proposed that the Task Force develop guidance on carrying out an assessment of food safety considerations in situations of low-level presence in which the r-DNA plant has already been found to be safe and authorized for commercialization for food by one or more countries through an assessment performed according to the Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (Codex Plant Guideline), but the importing country has not determined its food safety. It was further proposed that the guidance be developed as an Annex to the Codex Plant Guideline.

3. After extensive discussion, including an in-session Working Group to help develop a Terms of Reference for the project and a draft project proposal, the Task Force agreed to undertake this new work. The Task Force developed a project proposal[3] with two objectives:

- To identify and incorporate into a draft annex of the Plant Guideline, the relevant sections of the Plant Guideline essential to the safety assessment in situations of low-level presence; and,
- To identify information-sharing mechanisms to facilitate utilization of the Annex and to determine whether it should apply, and the data necessary to conduct an assessment of food safety in the importing country.

4. The Task Force also agreed on what the project would not do. This project would not:

- Address risk management measures; national authorities will determine when a recombinant-DNA plant material is present at a level low enough for this Annex to be appropriate.
- Preclude national authorities from conducting a full risk assessment; countries can decide when and how to use the Annex within the context of their regulatory systems.
- Eliminate the responsibility of industries, exporters and, when applicable, national competent authorities to continue to meet countries' relevant import requirements, including in relation to unapproved recombinant-DNA material.

[1] ALINORM 06/29/34, paragraphs 51-57.
[2] ALINORM 07/30/34, paragraphs 72-80.
[3] ALINORM 07/30/34, Appendix IV

5. The Task Force agreed to establish a physical Working Group[4] to undertake development of the Annex and accepted the willingness of the United States to Chair the Working Group and the willingness of Germany and Thailand to Co-Chair the Working Group.

6. The Task Force agreed that the proposed draft annex to be elaborated by the Working Group at Step 2 would be circulated for comments at Step 3, prior to consideration by the Seventh Session of the Task Force at Step 4.

MEETING OF THE WORKING GROUP

7. The Working Group met in Washington, D.C., U.S.A., on March 13-15, 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 two versions in Attachments 1 and 2. The proposed draft Annex of Attachment 1 contains all relevant paragraphs from the Codex Plant Guideline, with modification as warranted. It also includes two additional paragraphs (paragraphs 7 and 8), which list the paragraphs of the Codex Plant Guideline that have been modified and explain how and why they have been modified. The proposed draft Annex of Attachment 2 lists the numbers of all the relevant paragraphs from the Codex Plant Guideline, but contains text only of those paragraphs that have been altered.

8. The key points brought forward in the discussion of the Working Group included the following.

Assessment of Food Safety Considerations

9. The Working Group agreed that low level presence could pose different exposure issues depending on whether the low level presence was of a commodity product like grains, beans and oils seeds, or an unprocessed whole food ordinarily eaten in undiluted form, such as many fruits and vegetables.

10. The Working Group agreed that all components of the Codex Plant Guideline that related to safety of any new proteins produced in the plant as a result of the genetic modification would be relevant to both situations of low level presence and should be included in the Annex.

11. The Working Group agreed that, with some modification relating to nutritional composition, the following Codex Plant Guideline sections should be included in the Annex:

- description of the recombinant-DNA plant;
- description of host plant and its use as food;
- description of the donor organism(s);
- description of the genetic modification(s);
- characterization of the genetic modification(s);
- assessment of possible toxicity of expressed (non-nucleic acid) substances; and
- assessment of possible allergenicity of newly expressed proteins.

12. The Working Group agreed, in accordance with the terms of reference agreed by the Task Force, that it would be up to importing countries to decide when recombinant-DNA plant material unauthorized in the importing country was at a level low enough to be subject to the Annex, but that as a general matter, it would have to be at least low enough that the importing country could be confident that the material would not have nutritional significance for its population. Therefore, it was agreed that components of the Codex Plant Guideline relating to nutritional modification (paragraphs 48 – 53 of the Codex Plant Guideline) or changes in levels of nutrients or antinutrients would not be relevant to the Annex.

13. Similarly, it was agreed that changes in levels of endogenous toxicants would likely be relevant to low level presence of recombinant-DNA plant material primarily in the case of unprocessed whole foods that ordinarily are eaten in undiluted form, such as many fruits and vegetables. Paragraphs 44 – 47 and 54 were modified accordingly.

[4] The following members and observers expressed their interest in taking part in the Working Group: Argentina, Australia, Austria, Belgium, Brazil, Canada, Chile, China, Costa Rica, Czech Republic, Denmark, European Community, Finland, France, Greece, Germany, India, Iran, Ireland, Italy, Japan, Kenya, Mexico, Mali, Norway, Paraguay, Philippines, South Africa, Sweden, Switzerland, Thailand, the United States of America, ETA, CropLife International, CI, BIO, 49P, EUROPABIO, IICA.

14. The Working Group recognized that using the term "food safety assessment" in the Annex could cause confusion with a food safety assessment for unrestricted food use conducted according to the Codex Plant Guideline. The Working Group therefore agreed to use the phrase "assessment of food safety considerations" instead of "food safety assessment" or "safety assessment" when referring to the assessment carried out according to the Annex, noting that the use of the new phrase did not indicate any deviation from the comparative approach outlined in the Codex Plant Guideline.

Data and Information Sharing

15. The Working Group agreed on a set of information that would be made available in an agreed format via a publicly-accessible website. The agreed set of information would facilitate rapid access by importing Codex Member countries to additional information from the authorizing Codex Member country and the product applicant relevant to the assessment in accordance with the Annex. Further, it would increase transparency while enabling the website to be set up relatively quickly and maintained relatively easily because it would contain a limited set of data and information.

16. The Working Group agreed that upon request the authorizing Codex Member shall make available to other Codex Members additional complementary information on the outcome of its safety assessment in accordance with the Codex Plant Guideline, in conformity with its regulatory/legal framework, and as appropriate, new scientific information relevant to the conclusions of the food safety assessment conducted in accordance with the Codex Plant Guideline.

17. The Working Group agreed that the product applicant shall make all reasonable efforts to provide further information and clarification as necessary to allow the assessment according to the Annex to proceed, as well as a validated protocol and non-viable reference materials.

18. Norway stated for the record that it preferred that the website also contain validated detection methods and all the information necessary to conduct an assessment of food safety considerations arising from low level presence of recombinant DNA plant material in food.

19. The Working Group agreed that it would be best if an international organization, such as FAO, could host and maintain the website, but that the website should not duplicate existing websites. The website AGBIOS Biotech crop database, which is maintained by a private party in Canada, was mentioned as a useful existing website that should also be considered. It was noted that the electronic Biosafety Clearing-House (BCH) maintained by the Secretariat of the Convention on Biological Diversity (CBD) as part of the Cartagena Protocol on Biosafety might also contain relevant information on national decisions on recombinant-DNA plants and could be applied to avoid duplication of work.

20. It was agreed that the Co-Chairs and representatives of the biotechnology industry would meet with international organizations, such as FAO, to discuss how the website might be maintained and whether FAO or another group (e.g., AGBIOS, CBD Secretariat) might set it up and maintain it. The results of that meeting are to be reported to the Task Force in Chiba in September, 2007. The representatives also agreed to provide more detail on industry's commitment to supply to countries the information and data described in the Annex.

Structure of the Annex

21. The Working Group discussed whether the Annex should reproduce the relevant paragraphs from the Codex Plant Guideline or only refer to them and only reproduce those that had been modified from the Codex Plant Guideline.

22. The advantage of reproducing all the relevant paragraphs was that the document could stand alone and would be easier to use. The advantage of reproducing only the modified paragraphs was that it would result in a shorter document more typical of an annex and would highlight the differences from the Codex Plant Guideline.

23. There were a variety of views by delegations, none strongly held, but more favoured the shorter approach than the stand-alone approach. It was decided that the Co-Chairs would circulate the shorter version (Attachment 2) to the participants of the Working Group via electronic means for review before finalizing the report of the working group meeting, although the possibility was raised that the Co-Chairs might circulate both the shorter version and the longer version (Attachment 1) to allow better comparison.

24. The Co-Chairs electronically circulated both versions of the Annex to the Working Group participants. Few delegations expressed a preference in response, although of those that did, more preferred the longer version. The Co-Chairs therefore decided that both versions should be provided to the Task Force, so that it could decide which to progress.

RECOMMENDATION

25. The working group recommends that:

- the Task Force, at its Seventh Session, should consider the proposed draft Annex to the Codex Plant Guideline on Assessment of Food Safety Considerations Arising from Low Level Presence of Recombinant-DNA Plant Material in Food with a view towards its further progression in the Codex Step Procedure.
- as part of that consideration, the Task Force should decide which of the two versions of the Annex to pursue.

Attachment 1

PROPOSED DRAFT ANNEX TO THE CODEX *GUIDELINE FOR THE CONDUCT OF FOOD SAFETY ASSESSMENT OF FOODS DERIVED FROM RECOMBINANT-DNA PLANTS* (CAC/GL 45-2003): ASSESSMENT OF FOOD SAFETY CONSIDERATIONS ARISING FROM LOW-LEVEL PRESENCE OF RECOMBINANT-DNA PLANT MATERIAL IN FOOD

SECTION 1 – PREAMBLE

1. An increasing number of recombinant–DNA plants are being authorized for commercialization. However, they are authorized at different rates in different countries. As a consequence of these asymmetric authorizations, low levels of recombinant DNA plant materials that have passed a food safety assessment according to the Codex Guideline for the conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (Codex Plant Guideline) in one or more countries may on occasion be present in food in importing countries in which the food safety of the relevant recombinant-DNA plants has not been determined.

2. This Annex describes the recommended approach to making assessments of the food safety considerations in such situations of low-level presence of recombinant-DNA plant material or in advance preparation for such potential circumstances[5].

3. This annex also describes data and information sharing mechanisms to facilitate utilization of the Annex and to determine whether it should apply.

4. This Annex can be applied in two different dietary exposure situations:

   A. That involving commodities, such as grains, beans or oil seeds, in which exposure to food from a variety not authorized in the importing country would likely be to dilute low level amounts at any one time. This would likely be the more common situation of low-level presence of recombinant-DNA plant material. Because any food serving of grains, beans or oil seeds would almost necessarily come from multiple plants, and because of how these types of commodities generally are sourced from multiple farms, are commingled in grain elevators, are further commingled in export shipments, at import and when used in processed foods, any inadvertently commingled material derived from recombinant-DNA plant varieties would be present only at a low level in any individual serving of food.

   B. That involving foods that are commonly consumed whole and undiluted, such as some fruits and vegetables like potatoes, tomatoes, and papaya, in which exposure would be rare but could be to an undiluted form of the unauthorized recombinant-DNA plant material. While the likelihood of consuming material from such an unauthorized variety would be low and the likelihood of repeated consumption would be much lower, any such consumption might be of an entire unauthorized fruit or vegetable.

5. In both cases, the dietary exposure will be significantly lower than would be considered in a food safety assessment of the recombinant-DNA plant according to the Codex Plant Guideline. As a result, only certain elements of the Codex Plant Guideline will be relevant and therefore are included in this Annex.

6. This Annex does not:

   - Address risk management measures; national authorities will determine when a recombinant-DNA plant material is present at a level low enough for this Annex to be appropriate;
   - preclude national authorities from conducting a safety assessment according to the Codex Plant Guideline[6]; countries can decide when and how to use the Annex within the context of their regulatory systems; or

[5] This guidance is not intended for a recombinant-DNA plant that was not authorized in an importing country as a result of that country's food safety assessment.

[6] The Terms of Reference states that the annex would not preclude national authorities from conducting a "full risk assessment." However, the Working Group noted that in the context of an annex to the Codex Plant Guideline, it would be better to state that the annex would not preclude national authorities from conducting a "safety assessment according to the Codex Plant Guideline."

- eliminate the responsibility of industries, exporters and, when applicable, national competent authorities to continue to meet countries' relevant import requirements, including in relation to unauthorized recombinant-DNA plant material.

SECTION 2 – SECTIONS OF THE CODEX PLANT GUIDELINE APPLICABLE TO THE ASSESSMENT OF FOOD SAFETY CONSIDERATIONS ARISING FROM LOW-LEVEL PRESENCE OF RECOMBINANT-DNA PLANT MATERIAL IN FOOD

7. The assessment of the food safety considerations arising from low-level presence of recombinant-DNA plant material in food follows a stepwise process, almost exactly as described in the Codex Plant Guideline. The principal difference between the recommendations in this Annex and those in the Codex Plant Guideline is that this Annex does not contain recommendations for evaluating changes in nutritional content, and except for foods ordinarily consumed whole and in undiluted form, does not contain recommendations for evaluating changes in levels of endogenous toxicants or allergens. This difference is because it is unlikely that such changes would be relevant to food safety in a situation of low level presence of recombinant-DNA plant material.

8. For convenience, below the Annex reproduces or modifies the sections and paragraphs of the Codex Plant Guideline that apply to the assessment of the food safety considerations arising from low-level presence of recombinant-DNA plant material in food, beginning at Paragraph 22. Paragraphs 22, 35 and 46, and the Section heading above paragraph 35, have had the phrase "safety assessment" changed to "assessment of food safety considerations," to avoid confusion with a food safety assessment conducted according to the Codex Plant Guideline. Paragraphs 26, 32D, 35, 36, 38, 44, 45, 46, 47, and 54 have been modified[7], and paragraphs 34, 48 – 53, and 59 have been omitted[8], to reflect the differences described in the preceding paragraph regarding the relevance of nutritional composition and levels of endogenous toxicants and allergens. Paragraph 41 was modified to clarify reference to the annex on allergenicity.

(Sections and Paragraphs Below Are Adapted From and Numbered According to the Codex Plant Guideline.)

SECTION 4 - GENERAL CONSIDERATIONS

DESCRIPTION OF THE RECOMBINANT-DNA PLANT

22. A description of the recombinant-DNA plant being presented for assessment of food safety considerations should be provided. This description should identify the crop, the transformation event(s) to be reviewed and the type and purpose of the modification. This description should be sufficient to aid in understanding the nature of the food being submitted for assessment of food safety considerations.

DESCRIPTION OF THE HOST PLANT AND ITS USE AS A FOOD

23. A comprehensive description of the host plant should be provided. The necessary data and information should include, but need not be restricted to:

    A) common or usual name; scientific name; and, taxonomic classification;

[7] Paragraphs 26, 36 and 38 no longer refer to antinutrients and paragraph 47 no longer refers to bioavailability of nutrients; paragraph 32D is modified to focus on edible portions of the plant; Paragraph 35 is modified to remove consideration of possible effects on population sub-groups, because one would not expect such effects from low level presence; paragraph 44 is modified to focus on key toxins and allergens (rather than key components) in foods ordinarily consumed whole and in undiluted form; paragraph 46 and paragraph 54 are modified to focus on foods ordinarily consumed whole and in undiluted form.

[8] Paragraph 34 was omitted because it contains only general information of little relevance to materials at low level presence; paragraphs 48-53 were omitted because they refer to nutritional modifications; and paragraph 59 was omitted because it refers to information relevant to the safety assessment under the Codex Plant Guideline, but paragraph 14 of Section 3 is adapted from it.

B) history of cultivation and development through breeding, in particular identifying traits that may adversely impact on human health ;

C) information on the host plant's genotype and phenotype relevant to its safety, including any known toxicity or allergenicity; and

D) history of safe use for consumption as food.

24. Relevant phenotypic information should be provided not only for the host plant, but also for related species and for plants that have made or may make a significant contribution to the genetic background of the host plant.

25. The history of use may include information on how the plant is typically cultivated, transported and stored, whether special processing is required to make the plant safe to eat, and the plant's normal role in the diet (e.g. which part of the plant is used as a food source, whether its consumption is important in particular subgroups of the population, what important macro- or micro-nutrients it contributes to the diet).

DESCRIPTION OF THE DONOR ORGANISM(S)

26. Information should be provided on the donor organism(s) and, when appropriate, on other related species. It is particularly important to determine if the donor organism(s) or other closely related members of the family naturally exhibit characteristics of pathogenicity or toxin production, or have other traits that affect human health. The description of the donor organism(s) should include:

A. its usual or common name;

B. scientific name;

C. taxonomic classification;

D. information about the natural history as concerns food safety;

E. information on naturally occurring toxins and allergens; for microorganisms, additional information on pathogenicity and the relationship to known pathogens; and,

F. information on past and present use, if any, in the food supply and exposure route(s) other than intended food use (e.g., possible presence as contaminants).

DESCRIPTION OF THE GENETIC MODIFICATION(S)

27. Sufficient information should be provided on the genetic modification to allow for the identification of all genetic material potentially delivered to the host plant and to provide the necessary information for the analysis of the data supporting the characterization of the DNA inserted in the plant.

28. The description of the transformation process should include:

A) information on the specific method used for the transformation (e.g. *Agrobacterium*-mediated transformation);

B) information, if applicable, on the DNA used to modify the plant (e.g. helper plasmids), including the source (e.g. plant, microbial, viral , synthetic), identity and expected function in the plant; and

C) intermediate host organisms including the organisms (e.g. bacteria) used to produce or process DNA for transformation of the host organism;

29. Information should be provided on the DNA to be introduced, including:

A) the characterization of all the genetic components including marker genes, regulatory and other elements affecting the function of the DNA;

B) the size and identity;

C) the location and orientation of the sequence in the final vector/construct; and

D) the function.

CHARACTERIZATION OF THE GENETIC MODIFICATION(S)

30. In order to provide clear understanding of the impact on the composition and safety of foods derived from recombinant-DNA plants, a comprehensive molecular and biochemical characterization of the genetic modification should be carried out.

31. Information should be provided on the DNA insertions into the plant genome; this should include:

    A) the characterization and description of the inserted genetic materials;

    B) the number of insertion sites;

    C) the organization of the inserted genetic material at each insertion site including copy number and sequence data of the inserted material and of the surrounding region, sufficient to identify any substances expressed as a consequence of the inserted material, or, where more appropriate, other information such as analysis of transcripts or expression products to identify any new substances that may be present in the food; and

    D) identification of any open reading frames within the inserted DNA or created by the insertions with contiguous plant genomic DNA including those that could result in fusion proteins.

32. Information should be provided on any expressed substances in the recombinant-DNA plant; this should include:

    A) the gene product(s) (e.g. a protein or an untranslated RNA);

    B) the gene product(s)' function;

    C) the phenotypic description of the new trait(s);

    D) the level and site of expression in the plant of the expressed gene product(s), and the levels of its metabolites in the edible portions of the plant; and

    E) where possible, the amount of the target gene product(s) if the function of the expressed sequence(s)/gene(s) is to alter the accumulation of a specific endogenous mRNA or protein.

33. In addition, information should be provided:

    A) to demonstrate whether the arrangement of the genetic material used for insertion has been conserved or whether significant rearrangements have occurred upon integration;

    B) to demonstrate whether deliberate modifications made to the amino acid sequence of the expressed protein result in changes in its post-translational modification or affect sites critical for its structure or function;

    C) to demonstrate whether the intended effect of the modification has been achieved and that all expressed traits are expressed and inherited in a manner that is stable through several generations consistent with laws of inheritance. It may be necessary to examine the inheritance of the DNA insert itself or the expression of the corresponding RNA if the phenotypic characteristics cannot be measured directly;

    D) to demonstrate whether the newly expressed trait(s) are expressed as expected in the appropriate tissues in a manner and at levels that are consistent with the associated regulatory sequences driving the expression of the corresponding gene;

    E) to indicate whether there is any evidence to suggest that one or several genes in the host plant has been affected by the transformation process; and

    F) to confirm the identity and expression pattern of any new fusion proteins.

ASSESSMENT OF FOOD SAFETY CONSIDERATIONS

Expressed Substances (non-nucleic acid substances)

Assessment of possible toxicity

35. The assessment of food safety considerations should take into account the chemical nature and function of the newly expressed substance and identify the concentration of the substance in the edible parts of the recombinant-DNA plant, including variations and mean values.

36. 36. Information should be provided to ensure that genes coding for known toxins present in the donor organisms are not transferred to recombinant-DNA plants that do not normally express those toxic characteristics. This assurance is particularly important in cases where a recombinant-DNA plant is processed differently from a donor plant, since conventional food processing techniques associated with the donor organisms may deactivate, degrade or eliminate toxicants.

37. For the reasons described in Section 3, conventional toxicology studies may not be considered necessary where the substance or a closely related substance has, taking into account its function and exposure, been consumed safely in food. In other cases, the use of appropriate conventional toxicology or other studies on the new substance may be necessary.

38. In the case of proteins, the assessment of potential toxicity should focus on amino acid sequence similarity between the protein and known protein toxins as well as stability to heat or processing and to degradation in appropriate representative gastric and intestinal model systems. Appropriate oral toxicity studies[9] may need to be carried out in cases where the protein present in the food is not similar to proteins that have previously been consumed safely in food, and taking into account its biological function in the plant where known.

39. Potential toxicity of non-protein substances that have not been safely consumed in food should be assessed on a case-by-case basis depending on the identity and biological function in the plant of the substance and dietary exposure. The type of studies to be performed may include studies on metabolism, toxicokinetics, sub-chronic toxicity, chronic toxicity/carcinogenicity, reproduction and development toxicity according to the traditional toxicological approach.

40. This may require the isolation of the new substance from the recombinant-DNA plant, or the synthesis or production of the substance from an alternative source, in which case, the material should be shown to be biochemically, structurally, and functionally equivalent to that produced in the recombinant-DNA plant.

Assessment of possible allergenicity (proteins)

41. When the protein(s) resulting from the inserted gene is present in the food, it should be assessed for potential allergenicity in all cases. An integrated, stepwise, case-by-case approach used in the assessment of the potential allergenicity of the newly-expressed protein(s) should rely upon various criteria used in combination (since no single criterion is sufficiently predictive on either allergenicity or non-allergenicity). As noted in paragraph 20, the data should be obtained using sound scientific methods. A detailed presentation of issues to be considered can be found in the annex to the Codex Plant Guideline entitled *Assessment of Possible Allergenicity*.[10]

42. The newly expressed proteins in foods derived from recombinant-DNA plants should be evaluated for any possible role in the elicitation of gluten-sensitive enteropathy, if the introduced genetic material is obtained from wheat, rye, barley, oats, or related cereal grains.

43. The transfer of genes from commonly allergenic foods and from foods known to elicit gluten-sensitive enteropathy in sensitive individuals should be avoided unless it is documented that the transferred gene does not code for an allergen or for a protein involved in gluten-sensitive enteropathy.

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[9] Guidelines for oral toxicity studies have been developed in international fora, for example, the OECD Guidelines for the Testing of Chemicals.

[10] The FAO/WHO expert consultation 2001 report, which includes reference to several decision trees, was used in developing the allergenicity Annex.

Analyses of Key Toxicants and Allergens

44. Analyses of key toxicants[11] and allergens are important in certain cases of foods from recombinant-DNA plants (e.g., those that are commonly consumed whole and undiluted, such as potatoes, tomatoes, and papaya). Analyses of concentrations of key toxicants and allergens of the recombinant-DNA plant typical of the food should be compared with an equivalent analysis of a conventional counterpart grown and harvested under the same conditions. The statistical significance of any observed differences should be assessed in the context of the range of natural variations for that parameter to determine its biological significance. The comparator(s) used in this assessment should ideally be the near isogenic parental line. In practice, this may not be feasible at all times, in which case a line as close as possible should be chosen. The purpose of this comparison is to establish that substances that can affect the safety of the food have not been altered in a manner that would have an adverse impact on human health.

45. The location of trial sites should be representative of the range of environmental conditions under which the plant varieties would be expected to be grown. The number of trial sites should be sufficient to allow accurate assessment of key toxicants and allergens over this range. Similarly, trials should be conducted over a sufficient number of generations to allow adequate exposure to the variety of conditions met in nature. To minimise environmental effects, and to reduce any effect from naturally occurring genotypic variation within a crop variety, each trial site should be replicated. An adequate number of plants should be sampled and the methods of analysis should be sufficiently sensitive and specific to detect variations in key toxicants and allergens.

Evaluation of Metabolites

46. Some recombinant-DNA plants may have been modified in a manner that could result in new or altered levels of various metabolites in the food. In certain cases of foods from recombinant-DNA plants (e.g., those that are commonly consumed whole and undiluted), consideration should be given to the potential for the accumulation of metabolites in the food that would adversely affect human health. Assessment of food safety considerations arising from low level presence of recombinant-DNA material in foods from such plants requires investigation of residue and metabolite levels in the food. Where altered residue or metabolite levels are identified in foods, consideration should be given to the potential impacts on human health using conventional procedures for establishing the safety of such metabolites (e.g. procedures for assessing the human safety of chemicals in foods).

Food Processing

47. The potential effects of food processing, including home preparation, on foods derived from recombinant-DNA plants should also be considered. For example, alterations could occur in the heat stability of an endogenous toxicant. Information should therefore be provided describing the processing conditions used in the production of a food ingredient from the plant. For example, in the case of vegetable oil, information should be provided on the extraction process and any subsequent refining steps.

SECTION 5 - OTHER CONSIDERATIONS
POTENTIAL ACCUMULATION OF SUBSTANCES SIGNIFICANT TO HUMAN HEALTH

54. Some recombinant-DNA plants may exhibit traits (e.g., herbicide tolerance) which may indirectly result in the potential for accumulation of pesticide residues, altered metabolites of such residues, toxic metabolites, contaminants, or other substances which may be relevant to human health. In certain cases of foods from recombinant-DNA plants (e.g., those that are commonly consumed whole and undiluted), the assessment should take this potential for accumulation into account. Conventional procedures for establishing the safety of such compounds (e.g., procedures for assessing the human safety of chemicals) should be applied.

[11] Key toxicants are those toxicologically significant compounds known to be inherently present in the plant, such as those compounds whose toxic potency and level may be significant to health (e.g. solanine in potatoes if the level is increased.

USE OF ANTIBIOTIC RESISTANCE MARKER GENES

55. Alternative transformation technologies that do not result in antibiotic resistance marker genes in foods should be used in the future development of recombinant-DNA plants, where such technologies are available and demonstrated to be safe.

56. Gene transfer from plants and their food products to gut microorganisms or human cells is considered a rare possibility because of the many complex and unlikely events that would need to occur consecutively. Nevertheless, the possibility of such events cannot be completely discounted[12].

57. In assessing safety of foods containing antibiotic resistance marker genes, the following factors should be considered:

    A) the clinical and veterinary use and importance of the antibiotic in question;
    (Certain antibiotics are the only drug available to treat some clinical conditions (e.g. vancomycin for use in treating certain staphylococcal infections). Marker genes encoding resistance to such antibiotics should not be used in recombinant-DNA plants.)

    B) whether the presence in food of the enzyme or protein encoded by the antibiotic resistance marker gene would compromise the therapeutic efficacy of the orally administered antibiotic; and
    (This assessment should provide an estimate of the amount of orally ingested antibiotic that could be degraded by the presence of the enzyme in food, taking into account factors such as dosage of the antibiotic, amount of enzyme likely to remain in food following exposure to digestive conditions, including neutral or alkaline stomach conditions and the need for enzyme cofactors (e.g. ATP) for enzymatic activity and estimated concentration of such factors in food.)

    C) safety of the gene product, as would be the case for any other expressed gene product.

58. If evaluation of the data and information suggests that the presence of the antibiotic resistance marker gene or gene product presents risks to human health, the marker gene or gene product should not be present in the food. Antibiotic resistance genes used in food production that encode resistance to clinically used antibiotics should not be present in foods.

SECTION 3 – DATA AND INFORMATION SHARING

9. In order for Codex Members to use this Annex, it is essential that they have access to requisite data and information.

10. Codex Members shall make available to a central database (to be maintained by...) information on recombinant-DNA plants authorized in accordance with the Codex Plant Guideline This information shall be presented in accordance with the following format:

    a. name of product applicant

    b. summary of application

    c. country of authorization

    d. date of authorization

    e. scope of authorization

    f. unique identifier

    g. summary of safety assessment by competent authority(s), and

    h. contact details of the competent authority(s) responsible for the safety assessment and the product applicant.

[12] In cases where there are high levels of naturally occurring bacteria which are resistant to the antibiotic, the likelihood of such bacteria transferring this resistance to other bacteria will be orders of magnitude higher than the likelihood of transfer between ingested foods and bacteria.

11. This process shall facilitate rapid access by importing Codex Member countries to additional information relevant to the assessment of food safety considerations arising from low-level presence of recombinant DNA plant material in foods in accordance with this Annex.

12. The authorizing Codex Member shall make available complementary information to other Codex Members on the outcome of its safety assessment in accordance with the Codex Plant Guideline, in conformity with its regulatory/legal framework.

13. The product applicant shall make all reasonable efforts to provide further information and clarification as necessary to allow the assessment according to this Annex to proceed, as well as a validated protocol for an event-specific or trait-specific detection method, as specified by the Codex Member, and non-viable reference materials.

14. As appropriate, new scientific information relevant to the conclusions of the food safety assessment conducted in accordance with the Codex Plant Guideline by the authorizing country should be made available.

Attachment 2

PROPOSED DRAFT ANNEX TO THE CODEX *GUIDELINE FOR THE CONDUCT OF FOOD SAFETY ASSESSMENT OF FOODS DERIVED FROM RECOMBINANT-DNA PLANTS* (CAC/GL 45-2003): ASSESSMENT OF FOOD SAFETY CONSIDERATIONS ARISING FROM LOW-LEVEL PRESENCE OF RECOMBINANT-DNA PLANT MATERIAL IN FOOD

SECTION 1 – PREAMBLE

1. An increasing number of recombinant–DNA plants are being authorized for commercialization. However, they are authorized at different rates in different countries. As a consequence of these asymmetric authorizations, low levels of recombinant DNA plant materials that have passed a food safety assessment according to the Codex Guideline for the conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (Codex Plant Guideline) in one or more countries may on occasion be present in food in importing countries in which the food safety of the relevant recombinant-DNA plants has not been determined.

2. This Annex describes the recommended approach to making assessments of the food safety considerations in such situations of low-level presence of recombinant-DNA plant material or in advance preparation for such potential circumstances[13].

3. This annex also describes data and information sharing mechanisms to facilitate utilization of the Annex and to determine whether it should apply.

4. This Annex can be applied in two different dietary exposure situations:

    a. That involving commodities, such as grains, beans or oil seeds, in which exposure to food from a variety not authorized in the importing country would likely be to dilute low level amounts at any one time. This would likely be the more common situation of low-level presence of recombinant-DNA plant material. Because any food serving of grains, beans or oil seeds would almost necessarily come from multiple plants, and because of how these types of commodities generally are sourced from multiple farms, are commingled in grain elevators, are further commingled in export shipments, at import and when used in processed foods, any inadvertently commingled material derived from recombinant-DNA plant varieties would be present only at a low level in any individual serving of food.

    b. That involving foods that are commonly consumed whole and undiluted, such as some fruits and vegetables like potatoes, tomatoes, and papaya, in which exposure would be rare but could be to an undiluted form of the unauthorized recombinant-DNA plant material. While the likelihood of consuming material from such an unauthorized variety would be low and the likelihood of repeated consumption would be much lower, any such consumption might be of an entire unauthorized fruit or vegetable.

5. In both cases, the dietary exposure will be significantly lower than would be considered in a food safety assessment of the recombinant-DNA plant according to the Codex Plant Guideline. As a result, only certain elements of the Codex Plant Guideline will be relevant and therefore are included in this Annex.

6. This Annex does not:

    - Address risk management measures; national authorities will determine when a recombinant-DNA plant material is present at a level low enough for this Annex to be appropriate;

    - preclude national authorities from conducting a safety assessment according to the Codex Plant Guideline[14]; countries can decide when and how to use the Annex within the context of their regulatory systems; or

[13] This guidance is not intended for a recombinant-DNA plant that was not authorized in an importing country as a result of that country's food safety assessment.

[14] The Terms of Reference states that the annex would not preclude national authorities from conducting a "full risk assessment." However, the Working Group noted that in the context of an annex to the Codex Plant Guideline, it would be better to state that the annex would not preclude national authorities from conducting a "safety assessment according to the Codex Plant Guideline."

- eliminate the responsibility of industries, exporters and, when applicable, national competent authorities to continue to meet countries' relevant import requirements, including in relation to unauthorized recombinant-DNA plant material.

SECTION 2 – SECTIONS OF THE CODEX PLANT GUIDELINE APPLICABLE TO THE LOW-LEVEL PRESENCE OF RECOMBINANT-DNA PLANT MATERIAL IN FOOD

7. The following sections of the Codex Plant Guideline apply to the assessment of the food safety considerations arising from low-level presence of recombinant-DNA plant material in food. Paragraphs that apply are specifically indicated. If paragraphs are not listed, they can be omitted from consideration.

GENERAL CONSIDERATIONS

DESCRIPTION OF THE RECOMBINANT-DNA PLANT

Paragraph 22 applies as written:

22. A description of the recombinant-DNA plant being presented for assessment of food safety considerations should be provided. This description should identify the crop, the transformation event(s) to be reviewed and the type and purpose of the modification. This description should be sufficient to aid in understanding the nature of the food being submitted for assessment of food safety considerations.

DESCRIPTION OF THE HOST PLANT AND ITS USE AS A FOOD

Paragraphs 23, 24 and 25 apply.

DESCRIPTION OF THE DONOR ORGANISM(S)

Paragraph 26 applies as written:

26. Information should be provided on the donor organism(s) and, when appropriate, on other related species. It is particularly important to determine if the donor organism(s) or other closely related members of the family naturally exhibit characteristics of pathogenicity or toxin production, or have other traits that affect human health. The description of the donor organism(s) should include:

A. its usual or common name;

B. scientific name;

C. taxonomic classification;

D. information about the natural history as concerns food safety;

E. information on naturally occurring toxins and allergens; for microorganisms, additional information on pathogenicity and the relationship to known pathogens; and,

F. information on past and present use, if any, in the food supply and exposure route(s) other than intended food use (e.g., possible presence as contaminants).

DESCRIPTION OF THE GENETIC MODIFICATION(S)

Paragraphs 27, 28 and 29 apply.

CHARACTERIZATION OF THE GENETIC MODIFICATION(S)

Paragraphs 30, 31, 32 and 33 apply, except that 32 (D) applies as written:

32 (D): the level and site of expression in the plant of the expressed gene product(s), and the levels of its metabolites in the edible portions of the plant; and

ASSESSMENT OF FOOD SAFETY CONSIDERATIONS

Expressed Substances (non-nucleic acid substances)

Assessment of possible toxicity

Paragraphs 35 and 36 apply as written:

35. The assessment of food safety considerations should take into account the chemical nature and function of the newly expressed substance and identify the concentration of the substance in the edible parts of the recombinant-DNA plant, including variations and mean values.

36. Information should be provided to ensure that genes coding for known toxins present in the donor organisms are not transferred to recombinant-DNA plants that do not normally express those toxic characteristics. This assurance is particularly important in cases where a recombinant-DNA plant is processed differently from a donor plant, since conventional food processing techniques associated with the donor organisms may deactivate, degrade or eliminate toxicants.

Paragraph 37 applies.

Paragraph 38 applies as written:

38. In the case of proteins, the assessment of potential toxicity should focus on amino acid sequence similarity between the protein and known protein toxins as well as stability to heat or processing and to degradation in appropriate representative gastric and intestinal model systems. Appropriate oral toxicity studies[15] may need to be carried out in cases where the protein present in the food is not similar to proteins that have previously been consumed safely in food, and taking into account its biological function in the plant where known.

Paragraphs 39 and 40 apply.

Assessment of possible allergenicity (proteins)

Paragraph 41 applies as written:

41. When the protein(s) resulting from the inserted gene is present in the food, it should be assessed for potential allergenicity in all cases. An integrated, stepwise, case-by-case approach used in the assessment of the potential allergenicity of the newly-expressed protein(s) should rely upon various criteria used in combination (since no single criterion is sufficiently predictive on either allergenicity or non-allergenicity). As noted in paragraph 20, the data should be obtained using sound scientific methods. A detailed presentation of issues to be considered can be found in the annex to the Codex Plant Guideline entitled *Assessment of Possible Allergenicity.*[16]

Paragraphs 42 and 43 apply.

Analyses of Key Toxicants and Allergens

Paragraphs 44 and 45 apply as written:

44. Analyses of key toxicants[17] and allergens are important in certain cases of foods from recombinant-DNA plants (e.g., those that are commonly consumed whole and undiluted, such as potatoes, tomatoes, and papaya). Analyses of concentrations of key toxicants and allergens of the recombinant-DNA plant typical of the food should be compared with an equivalent analysis of a conventional counterpart grown and harvested under the same conditions. The statistical significance of any observed differences should be assessed in the context of the range of natural variations for that parameter to determine its biological significance. The

[15] Guidelines for oral toxicity studies have been developed in international fora, for example, the OECD Guidelines for the Testing of Chemicals.

[16] The FAO/WHO expert consultation 2001 report, which includes reference to several decision trees, was used in developing the allergenicity Annex.

[17] Key toxicants are those toxicologically significant compounds known to be inherently present in the plant, such as those compounds whose toxic potency and level may be significant to health (e.g. solanine in potatoes if the level is increased).

comparator(s) used in this assessment should ideally be the near isogenic parental line. In practice, this may not be feasible at all times, in which case a line as close as possible should be chosen. The purpose of this comparison is to establish that substances that can affect the safety of the food have not been altered in a manner that would have an adverse impact on human health.

45. The location of trial sites should be representative of the range of environmental conditions under which the plant varieties would be expected to be grown. The number of trial sites should be sufficient to allow accurate assessment of key toxicants and allergens over this range. Similarly, trials should be conducted over a sufficient number of generations to allow adequate exposure to the variety of conditions met in nature. To minimize environmental effects, and to reduce any effect from naturally occurring genotypic variation within a crop variety, each trial site should be replicated. An adequate number of plants should be sampled and the methods of analysis should be sufficiently sensitive and specific to detect variations in key toxicants and allergens.

Evaluation of Metabolites

Paragraph 46 applies as written:

46. Some recombinant-DNA plants may have been modified in a manner that could result in new or altered levels of various metabolites in the food. In certain cases of foods from recombinant-DNA plants (e.g., those that are commonly consumed whole and undiluted), consideration should be given to the potential for the accumulation of metabolites in the food that would adversely affect human health. Assessment of food safety considerations arising from low level presence of recombinant-DNA material in foods from such plants requires investigation of residue and metabolite levels in the food. Where altered residue or metabolite levels are identified in foods, consideration should be given to the potential impacts on human health using conventional procedures for establishing the safety of such metabolites (e.g. procedures for assessing the human safety of chemicals in foods).

Food Processing

Paragraph 47 applies as written:

47. The potential effects of food processing, including home preparation, on foods derived from recombinant-DNA plants should also be considered. For example, alterations could occur in the heat stability of an endogenous toxicant. Information should therefore be provided describing the processing conditions used in the production of a food ingredient from the plant. For example, in the case of vegetable oil, information should be provided on the extraction process and any subsequent refining steps.

OTHER CONSIDERATIONS

POTENTIAL ACCUMULATION OF SUBSTANCES SIGNIFICANT TO HUMAN HEALTH

Paragraph 54 applies as written:

54. Some recombinant-DNA plants may exhibit traits (e.g., herbicide tolerance) which may indirectly result in the potential for accumulation of pesticide residues, altered metabolites of such residues, toxic metabolites, contaminants, or other substances which may be relevant to human health. In certain cases of foods from recombinant-DNA plants (e.g., those that are commonly consumed whole and undiluted), the risk assessment should take this potential for accumulation into account. Conventional procedures for establishing the safety of such compounds (e.g., procedures for assessing the human safety of chemicals) should be applied.

USE OF ANTIBIOTIC RESISTANCE MARKER GENES

Paragraphs 55, 56, 57 and 58 apply.

SECTION 3 – GUIDANCE ON DATA AND INFORMATION SHARING

8. In order for Codex Members to use this Annex, it is essential that they have access to requisite data and information.

9. Codex Members shall make available to a central database (to be maintained by...) information on recombinant-DNA plants authorized in accordance with the Codex Plant Guideline This information shall be presented in accordance with the following format:

    a. name of product applicant

    b. summary of application

    c. country of authorization

    d. date of authorization

    e. scope of authorization

    f. unique identifier

    g. summary of safety assessment by competent authority(s), and

    h. contact details of the competent authority(s) responsible for the safety assessment and the product applicant.

10. This process shall facilitate rapid access by importing Codex Member countries to additional information relevant to the assessment of food safety considerations arising from low-level presence of recombinant-DNA plant material in foods in accordance with this Annex.

11. The authorizing Codex Member shall make available complementary information to other Codex Members on the outcome of its safety assessment in accordance with the Codex Plant Guideline, in conformity with its regulatory/legal framework.

12. The product applicant shall make all reasonable efforts to provide further information and clarification as necessary to allow the assessment according to this Annex to proceed, as well as a validated protocol for an event-specific or trait-specific detection method, as specified by the Codex Member, and non-viable reference materials.

13. As appropriate, new scientific information relevant to the conclusions of the food safety assessment conducted in accordance with the Codex Plant Guideline by the authorizing country should be made available

Attachment 3

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