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FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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ALINORM 08/31/34

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

31st Session

Geneva, Switzerland, 30 June – 5 July 2008

REPORT OF THE SEVENTH SESSION OF THE CODEX *AD HOC* INTERGOVERNMENTAL TASK FORCE ON FOODS DERIVED FROM BIOTECHNOLOGY

Chiba, Japan, 24-28, September 2007

NOTE: This report contains Codex Circular Letter CL 2007/39-FBT

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CX 4/80.2 **CL 2007/39-FBT**
October 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: **Distribution of the Report of the Seventh Session of the Codex *ad hoc* Intergovernmental Task Force on Foods Derived from Biotechnology (ALINORM 08/31/34)**

The report of the Seventh Session of the Codex *ad hoc* Intergovernmental Task Force on Foods Derived from Biotechnology will be considered by the 31st Session of the Codex Alimentarius Commission (Geneva, Switzerland, 30 June-5 July 2008).

MATTERS FOR ADOPTION BY THE 31ST SESSION OF THE CODEX ALIMENTARIUS COMMISSION

1. **Proposed Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals, at Step 5/8** (para. 33 and Appendix II)

2. **Proposed Draft Annex on Food Safety Assessment of Foods Derived from Recombinant-DNA Plants Modified for Nutritional or Health Benefits, at Step 5/8** (paras 73 and 74 and Appendix III)

3. **Proposed Draft Annex on Food Safety Assessment in Situations of Low-level Presence of Recombinant-DNA Plant Material in Food, at Step 5/8** (para. 106 and Appendix IV)

Governments and international organizations wishing to submit comments on the above texts should do so in writing, preferably by e-mail, to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy (e-mail: codex@fao.org, telefax : +39 06 57054593) **no later than 15 March 2008.**

SUMMARY AND CONCLUSIONS

The Seventh Session of the Codex *ad hoc* Intergovernmental Task Force on Foods Derived from Biotechnology reached the following conclusions:

Matters for Adoption by the Commission

The Task Force agreed to forward to the 31st Session of the Commission for adoption at Step 5/8:

- Proposed Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals (para. 33 and Appendix II);
- Proposed Draft Annex: Food Safety Assessment of Foods Derived from Recombinant-DNA Plants Modified for Nutritional or Health Benefits (paras 73 and Appendix III); and
- Proposed Draft Annex: Food Safety Assessment in Situations of Low-level Presence of Recombinant-DNA Plant Material in Food (para. 106 and Appendix IV).

Matters Referred to Codex Committees and Task Forces

Committee on Methods of Analysis and Sampling (CCMAS)

- The Task Force noted that that the work underway in the CCMAS on the detection and identification of foods derived from biotechnology was complementary to the work of the Task Force and agreed to encourage this committee to proceed with its work with urgency (para. 8).

Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU)

- Recognizing that the proposed draft annex contained references to certain concepts related to nutrition, the Task Force agreed to invite the 29th Session of the CCNFSDU to review the document and provide comments if necessary. In this regard, the Task Force noted the priority this work should be given by the CCNFSDU, given the time constraints of the Task Force (para. 74).

Other Matters

The Task Force:

- welcomed the recommendations from the 2007 FAO/WHO Expert Consultation on the Safety of Foods Derived from Recombinant-DNA Animals, especially those addressed to FAO, WHO and OIE, with the understanding that these agencies would further discuss priorities and concrete modalities for conducting joint activities (para. 16); and
- agreed to request FAO to provide update on the database for data and information sharing at the 31st Session of the Commission (para. 106).

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LIST OF APPENDICES

INTRODUCTION

1. The Codex *ad hoc* Intergovernmental Task Force on Foods Derived from Biotechnology held its Seventh Session in Chiba, Japan, from 24 to 28 September 2007, by courtesy of the Government of Japan. The Session was presided over by Dr Hiroshi Yoshikura, Adviser, Department of Food Safety, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare. The Session was attended by 198 delegates representing 52 members of the Commission and 4 international intergovernmental and 13 non-governmental observer organizations. A complete list of participants is included as Appendix I to this report.

OPENING OF THE SESSION

2. The Session was opened by Mr Takeshi Erikawa, Vice-Minister of Health, Labour and Welfare. He welcomed the participants to Chiba and, referring to the importance of building international consensus in the area of food safety in light of the globalizing trade in foods derived from biotechnology, encouraged sincere and dedicated discussions by the Task Force.

Division of Competence

3. The Task Force noted the division of competence between the European Community and its Member states, according to paragraph 5, Rule II of the Procedure of the Codex Alimentarius Commission, as presented in CRD 1.

ADOPTION OF THE AGENDA (Agenda Item 1)[1]

4. The Task Force adopted the Provisional Agenda as its Agenda for the Session.

MATTERS REFERRED TO THE TASK FORCE BY THE COMMISSION AND OTHER CODEX COMMITTEES (Agenda Item 2)[2]

5. The Task Force noted the information presented in document CX/FBT 07/7/2 concerning the matters of interest to the Codex *ad hoc* Intergovernmental Task Force on Foods Derived from Biotechnology arising from the 30th Session of the Codex Alimentarius Commission and the recent sessions of the Committees on Methods of Analysis and Sampling and on Food Labelling.

6. The Task Force was informed that the Committee on Residues of Veterinary Drugs in Foods, at its 17th Session, had not provided any advice on the issue of animals treated with recombinant-DNA vaccines in reply to the referral by the Task Force[3], considering that the issue was beyond the mandate of the Committee[4].

7. The Task Force also noted the new work undertaken by the Committee on Nutrition and Foods for Special Dietary Uses to elaborate a proposed draft principle of nutritional risk analysis, addressing nutritional risk assessment and related key concepts. These concepts might be relevant to the discussion of Agenda Item 5.

8. The Task Force noted that that the work underway in the Committee on Methods of Analysis and Sampling on the detection and identification of foods derived from biotechnology was complementary to the work of the Task Force and agreed to encourage this committee to proceed with its work with urgency.

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1 CX/FBT 07/7/1

2 CX/FBT 07/7/2

3 ALINORM 07/30/34, para.71

4 ALINORM 08/31/31, paras 15-16

REVIEW OF THE WORK BY INTERNATIONAL INTERGOVERNMENTAL ORGANIZATIONS RELATED TO FOODS DERIVED FROM BIOTECHNOLOGY (Agenda Item 3)[5]

9. The Task Force noted with appreciation the information presented in document CX/FBT 07/7/3 submitted by several international intergovernmental organizations concerning their work related to foods derived from biotechnology.

10. The Representative of the Organisation for Economic Cooperation and Development (OECD) underlined a few recent developments in the OECD Task Force for the Safety of Novel Foods and Feeds. First, the Representative noted and welcomed increasingly active participation of non-member countries, especially in the development of some OECD Consensus Documents. Second, the Representative informed the Task Force that the OECD Task Force had initiated the update of the Consensus Documents on low erucic acid rapeseed and on soybean. Furthermore, the Representative drew the attention of the Task Force to the work on unique identifiers by the Working Group on Harmonisation of Regulatory Oversight in Biotechnology, which had recently revised the OECD Guidance for the Designation of a Unique Identifier for Transgenic Plants to cover gene-stacked events and had been considering a guidance for unique identifiers for transgenic microorganisms, starting from bacteria.

11. The Representative of the World Organisation for Animal Health (OIE) informed the Task Force of most recent work by the *ad hoc* Group on Biotechnology. The *ad hoc* Group had met a third time in June 2007 and developed two Guidelines, which were forwarded to the Biological Standards Commission of the OIE, meeting in September 2007. The *Guidelines for Somatic Cell Nuclear Transfer in Production Livestock and Horses*, which primarily dealt with identification of animal health risks and their management, as well as risks and prevention measures related with the technology, recommended four steps in risk analysis processes: management of the animal health risks associated with embryo production; management of the animal health risks related to the recipients (surrogate dams); management of the animal health risks of animal clones themselves; and management of the animal health risk of the next generation. The Task Force was informed that the *Guidelines for DNA Vaccines*, which covered vaccines delivering genes encoding relevant immunogen response in the form of bacterial plasmid DNA molecules, were intended to provide guidance to manufactures seeking to develop these vaccines. The Representative indicated that the work of the *ad hoc* Group on Biotechnology was coordinated, as necessary, with the work of the *ad hoc* Groups on Traceability and Animal Identification and on Animal Welfare, as well as the OIE Animal Production Food Safety Working Group.

12. The Representative of FAO, on behalf of both FAO and WHO, expressed the commitment of FAO and WHO to continue to support Codex work in biotechnology, particularly that done by the Task Force. The Representative further explained that FAO's work in the area of biotechnology was coordinated by an internal working group composed of representatives from several departments of the Organization, which had been active in releasing science-based information about biotechnology in the form of newsletters. The Representative also referred to the FAO Glossary of Biotechnology for Food and Agriculture, published in four languages on CD-ROM, and to the training-of-trainers workshop on safety assessment of foods derived from biotechnology held in Ottawa, which had been a pilot test of a training package FAO was preparing for finalization.

13. The Representative of FAO, on behalf of both FAO and WHO, introduced document CX/FBT 07/7/3-Add.1 (summary of the Report of the FAO/WHO Expert Consultation on the Safety of Foods Derived from Recombinant-DNA Animals), which was closely linked to Agenda Item 4 and accordingly considered therein in more detail.

[5] CX/FBT 07/7/3; CX/FBT 07/7/3-Add.1; CX/FBT 07/7/3-Add.2; CRD 5 (Comments of South Africa); CRD 6 (Comments of the Philippines)

14. In response to the request for clarification made by several delegations about the possible further involvement of the OIE in the food safety aspects of foods derived from biotechnology, in particular on the issue of animals treated with recombinant-DNA vaccines, the Representative of the OIE clarified that the organization's main area of concern was animal health, which might have a bearing on food safety, while not excluding the possibility of addressing food safety aspects of recombinant-DNA vaccines in the future if the organization was so requested. In this respect, the Representative of FAO, while generally welcoming the cooperation between FAO and OIE, especially in the provision of scientific advice and technical assistance, noted that the responsibilities of other normative issues on food safety should lie primarily within the Codex Alimentarius Commission and the Task Force.

15. While recalling that the Task Force at its last session had taken a decision not to start new work on the food safety assessment of animals treated with recombinant-DNA vaccines, several delegations requested that to avoid a policy vacuum in the area of food safety assessment of recombinant-DNA vaccines, follow-up actions be taken by FAO, WHO and OIE as appropriate, with particular reference to some of the recommendations of the 2007 FAO/WHO Expert Consultation on the Safety Assessment of Foods Derived from Recombinant-DNA Animals, which, among others, called for a joint FAO/WHO/OIE expert group to consider the animal health and food safety issues raised by recombinant-DNA vaccines.

16. After some discussion, the Task Force welcomed the recommendations from the 2007 FAO/WHO Expert Consultation reproduced in document CX/FBT 07/7/3 Add.1, especially those addressed to FAO, WHO and OIE, with the understanding that these agencies would further discuss priorities and concrete modalities for conducting joint activities.

17. The Task Force expressed appreciation to FAO and WHO for organizing the expert consultation on a prompt manner and encouraged FAO and WHO to continue efforts to follow up on the above recommendations.

PROPOSED DRAFT GUIDELINE FOR THE CONDUCT OF FOOD SAFETY ASSESSMENT OF FOODS DERIVED FROM RECOMBINANT-DNA ANIMALS (Agenda Item 4)[6]

Scientific advice from FAO and WHO

18. The Task Force recalled that its Sixth Session had agreed to forward questions regarding i) marker and reporter genes, and ii) non-heritable applications, to FAO and WHO for scientific advice.[7] The Task Force noted that the reply to these questions from a joint FAO/WHO expert consultation on safety assessment of foods derived from recombinant DNA animals, held on 26 February – 2 March 2007, were reproduced in document CX/FBT 07/7/3-Add.1.

Proposed draft guideline

19. The Task Force recalled that at its Sixth Session it had agreed to return the section on "Use of Antibiotic Resistance Marker Genes" (paragraphs 64 - 67) to Step 3 for comments and retain the remaining sections of the proposed guideline at Step 4, pending certain questions to be answered by a joint FAO/WHO expert consultation.

20. The Task Force, at the current session, agreed to focus its discussion on: i) the section of the "Use of Antibiotic Resistance Marker Genes" taking into account comments submitted to the current session and ii) whether any other amendments were necessary in conjunction with non-heritable applications, fully taking into account the outcome of the FAO/WHO expert consultation.

6 CL 2006/54-FBT, ALINORM 07/30/34, Appendix III; CX/FBT 07/7/4; CX/FBT 07/7/4-Add.1; CRD 2 (Comments of Thailand); CRD 5 (Comments of South Africa); CRD 6 (Comments of the Philippines); CRD 7 (Comments of Indonesia); CRD 8 (Comments of Republic of Korea); CRD 9 (Comments from Consumers International); CRD 10 (Comments of Kenya); CRD 11 (Comments of New Zealand)

7 ALINORM 07/30/34, para.45

21. The discussion held and decision made are summarized below:

(i) Marker and reporter genes

22. Many delegations expressed the view that the current text in this section should remain unchanged since the report of the above expert consultation had not brought any new scientific evidence that would justify the need for additional or different provisions in the section on antibiotic resistance marker gene (paragraph 64-67), compared to the corresponding section in the Codex Plant Guideline (CAC/GL 45-2003).

23. The Delegation of Kenya, supported by some other delegations, proposed to require insertion of introns within the marker genes so as to make them non-functional in gut microflora that may take up the gene. However, the Task Force, noting that gene transfer from animal tissues to human gut microorganisms or human cells was considered a remote possibility and that the proposed technology, involving rather complex procedures and implications regarding other risks, might not be generally applicable and would require further research to determine its relevance, agreed that this proposed amendment was not necessary.

24. The Task Force noted the view expressed by an observer, supported by some delegations, that the current provisions on marker genes in the proposed draft guideline discouraged the use of marker genes encoding resistance to the drugs of clinical and veterinary importance. The observer drew the attention of the Task Force to a conclusion of the expert consultation responding to the question on reliable and safe techniques available to remove specific DNA sequences. As the recommendation encouraged continuing validation and development of gene excision systems that would allow the controlled removal of specific DNA sequences in recombinant-DNA animals, the section on marker and reporter genes in the draft guideline could be revisited in the future, when sufficient data and information on the gene excision technique became available.

25. After some discussion, the Task Force agreed to maintain the section on marker and reporter genes unchanged.

(ii) Non-heritable constructs

26. The Task Force considered the remaining paragraphs of the draft proposed guideline, to determine whether any other amendments were necessary in conjunction with non-heritable applications.

27. The Delegation of the European Community pointed out that the FAO/WHO expert consultation addressed the issues on non-heritable constructs in detail and provided a series of conclusions and recommendations regarding, among others, potential hazards in relation to non-heritable constructs. The Delegation stated that the proposed draft guideline, being developed without specific consideration of non-heritable applications, mainly due to lack of sufficient time to do so, should recognize this fact in its text. The Delegation thus proposed to introduce two amendments, in order to indicate that the issue of non-heritable construct was not addressed by the guideline. Specifically, the Delegation proposed to change the term “trait” to “heritable trait” in paragraph 1 and add a new footnote to paragraph 7 to state that non-heritable constructs would require specific safety considerations that were outlined by the report of the 2007 FAO and WHO expert consultation.

28. One delegation pointed out that the expert consultation had concluded that the difference between recombinant-DNA constructs regarding the nature of the hazards and risks were a function of whether the construct had been integrated into the genome or maintained episomally and did not depend on its heritability. For this delegation, there was no scientific basis for supporting the proposal from the Delegation of the European Community.

29. Some delegations were of the view that, according to the expert consultation’s recommendations, there might arise a need to develop an additional guideline on non-heritable constructs in the future, possibly in the form of an annex and that it was desirable to keep such possibility open in the current document. At the same time, it was also recognized that in most cases, the proposed draft guideline could provide useful guidance for assessing the food safety of non-heritable constructs, and, therefore, that while the proposed draft guideline was primarily intended for heritable constructs, the text could remain silent on non-heritable applications.

30. The Task Force noted a view that the Codex Plant Guideline remained silent as to non-heritable constructs, whereas there were some cases where non-heritable constructs might be introduced in plants.

31. A question was raised as to whether all the animals treated with recombinant-DNA vaccines should be considered as containing non-heritable recombinant-DNA constructs. One delegation stated that certain non-heritable constructs including recombinant-DNA vaccines were intended to remain episomal for some time, according to the report of the expert consultation, and that not all animals treated with recombinant-DNA vaccines should be considered as recombinant DNA animals. The delegation also argued that the application of non-heritable constructs, as such, was not a recombinant-DNA technology, and was therefore out of the scope of the proposed draft guideline.

32. After some discussion, the Task Force agreed to include a footnote to paragraph 1, so as to clarify that the draft proposed guideline had been developed primarily for animals bearing heritable recombinant-DNA constructs. The Task Force also agreed to add a footnote to the last sentence of paragraph 7, indicating possible need for additional specific consideration for the food safety assessment of non-heritable constructs.

Status of the Proposed Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals

33. The Task Force agreed to forward the proposed draft guideline, as amended above and with some editorial changes, for adoption at Steps 5/8 by the 31st Session of the Commission, with the recommendation to omit Steps 6 and 7. The proposed draft guideline is presented in Appendix II to this report.

34. The Task Force also agreed that, upon the final adoption of the proposed draft guideline, a consequential change be made in the existing text in the footnote 6 to paragraph 13 of the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (CAL/GL 44-2003), to add a reference to the title of the proposed draft guideline.

35. The Task Force recognized the intensive work done by delegations during the plenary of the Task Force as well as at the meetings of the physical working groups in the course of elaborating the proposed draft guideline. The recommendation above to omit Steps 6 and 7 was the reflection of all the efforts and contribution of Codex members and observers.

PROPOSED DRAFT ANNEX 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 AND HEALTH BENEFITS (Agenda Item 5)[8]

36. The Task Force recalled that at its Sixth Session, it had agreed to return the proposed draft annex to Step 2 for redrafting by a physical working group led by Canada, co-chaired by Argentina and New Zealand. The revised proposed draft annex, prepared by the Physical Working Group had been circulated for comments at Step 3, prior to consideration at Step 4.

37. The Delegation of Canada, speaking as Chairperson of the Physical Working Group, introduced the report of the Physical Working Group and highlighted that the Working Group had agreed to exclude, from the scope of the proposed draft annex, risk management measures and assessment of benefits. The Delegation indicated that some texts were kept in square brackets as the Working Group had not considered them in detail due to time constraints.

38. The Task Force agreed to consider the proposed draft annex, as contained in the above Circular Letter CL 2007/18-FBT, paragraph by paragraph. The discussion held and decisions made are summarized below. Paragraph numbers indicated in parentheses below correspond to those in the final text, in Appendix III to this report.

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[8] CL 2007/18-FBT; CX/FBT 07/7/5 (Comments of Australia, Brazil, European Community, Kenya, Malaysia, New Zealand, Philippines, BIO and ILSI); CX/FBT 07/7/5-Add.1(Comments of Japan and United States of America); CX/FBT 07/7/5-Add.2 (Comments of Costa Rica); CRD 2 (Comments of Thailand), CRD 4 (Comments of Ghana); CRD 5 (Comments of South Africa); CRD 6 (Comments of the Philippines); CRD 8 (Comments of Republic of Korea); CRD 9 (Comments from CI); CRD 10 (Comments of Kenya); CRD 12 (Prepared by Secretariat)

Section 1 - Introduction

Paragraph 2

39. The Task Force agreed to add the words "introduction of a new nutrient(s) or related substance(s)" in point b of paragraph 2, as new item i), so as to indicate appropriately the scope of the proposed draft annex, which should cover nutrients or related substances newly introduced through recombinant-DNA techniques.

40. The Task Force did not agree to a proposal made by the Delegation of Thailand to add a reference to "related to nutritional benefits" after the words "undesirable substance". Instead, the Task Force agreed to add, in point b, a reference to allergens and toxicants, as examples of undesirable substances.

41. It was agreed to add a reference to "health relevance" to item iii), re-numbered as iv), for consistency with the scope of the annex.

Section 2 - Definition

42. The Task Force agreed to assign a paragraph number "3" to the first sentence under Section 2 and re-numbered the following paragraphs accordingly.

43. The Delegation of the European Community expressed the view that it was important to define certain terms used in the Annex, including those relevant to nutritional risk assessment. This proposal was supported by some other delegations and an observer. The Delegation suggested that definitions of these terms could be developed by the Task Force, using, as a basis, some definitions found in the report of the Joint FAO/WHO Technical Workshop on Nutrient Risk Management, held in 2005.

44. Other delegations were of the opinion that the work to develop definitions related to nutritional safety assessment should be entrusted to the Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU). It was pointed out that new work had already been started by the CCNFSDU to elaborate risk analysis principles including definitions of "bioavailability", "related substances" and "upper level". Therefore, future potential inconsistency of definitions should be avoided between the Task Force and the CCNFSDU, the latter having a primary role on nutrition matters within the Codex system.

45. After some discussion, the Task Force agreed not to develop additional definitions, with a view to avoiding duplication with ongoing work undertaken by the CCNFSDU. Instead, the Task Force agreed to insert a text, as new paragraph 4, indicating that the proposed draft annex draws, where appropriate, on the definitions of key nutritional concepts to be found or to be developed in relevant Codex texts, especially those elaborated by the CCNFSDU.

Section 3 – Food Safety Assessment

Paragraph 4 (new paragraph 6)

46. The Task Force did not agree to a proposal to refer to the case where "populations/sub-populations may be unaffected", to maintain the intent of the text.

Paragraph 5 (new paragraph 7)

47. To improve clarity, it was agreed to separate the reference to "Codex Plant Guideline paragraphs 4 and 51" to footnotes 5 and 6 respectively.

Paragraph 6 (new paragraph 8)

48. With regard to the study on upper levels of nutrient intake, the Delegation of the United States of America, referring to its written comment, pointed out that there were yet limitations in available dose-response and clinical data in identifying risks associated with nutrient substances at high levels of intake , and therefore proposed to add a new text so as to emphasize the need to consider the basis for deriving these upper levels in assessing the public health implication of exceeding intake levels of nutrients. The Task Force concurred with this proposal.

Paragraph 7 (new paragraph 9)

49. The Task Force agreed to delete the reference to "Acceptable Daily Intake (ADI)", recognizing that in Codex standards setting work as well as in risk assessments by JECFA, the concept of ADI was usually used for the assessment of chemicals such as food additives and residues of veterinary drugs, and would not necessarily apply to the safety assessment of nutrition.

Paragraph 8 (new paragraph 10)

50. The Task Force agreed to replace the word "resulting" with "expected or foreseeable", for the sake of clarity.

Paragraph 9 (new paragraph 11)

51. The Task Force had discussion on the terms in square brackets (regarding chemical forms/analogues of nutrients and related substance). The Task Force agreed not to use the terms "multiple" and "analogues" as these were considered ambiguous. The Task Force made some editorial changes for the sake of clarity, and agreed to delete the reference to "combined bioavailability", noting that the concept was captured in the sentence newly added to paragraph 10 (new paragraph 12) (*see* para 55).

52. The Task Force noted that the list of examples of different chemical forms of nutrients presented in Attachment 2 of CL 2007/18-FBT had been prepared only for facilitating discussion and that it was not intended to be incorporated into the proposed draft annex.

Paragraph 10 (new paragraph 12)

53. The Delegation of Thailand questioned whether consideration of bioavailability of undesirable substances was necessary, pointing out that the text read differently between 2(b) and paragraph 10.

54. To this question, it was clarified that requirement in paragraph 10 was describing certain exceptional cases where levels of undesirable substances warranted a study on bioavailability. Therefore, the Task Force agreed to retain the reference to undesirable substances.

55. In relation to an amendment made to paragraph 9, the Task Force agreed to add a new sentence at the end of paragraph 10 to state that "if more than one chemical form of the nutrients or related substances is present, their combined bioavailability should be established, where appropriate".

Paragraph 11 (new paragraph 13) and paragraph 12

56. The Task Force had extensive discussion on paragraph 12 in square brackets.

57. The Delegation of European Community recalled that the text was prepared to provide details on animal studies if such studies were to be performed to assess the nutritional value and the bioavailability of the newly expressed substances. Two observers supported the proposed text pointing out that it provided useful guidance on animal study design.

58. Several delegations expressed the view that paragraph 54 of the Codex Plant Guideline already provided sufficient guidance on animal studies and that detailed description of the design for animal studies was not necessary in this annex and proposed the deletion of the paragraph.

59. Some delegations suggested amending the proposed text to provide more general guidance on animal studies. It was also stated that the text should not over-emphasise the importance of animal studies *vis-à-vis* human studies.

60. After some discussion, recognizing that the elements of paragraph 12 could better be placed in paragraph 11, the Task Force agreed to delete paragraph 12 and to add a new sentence, as the second last sentence of paragraph 11, stating that "*in vivo* studies in animals are of limited value in assessing nutritional value or nutrient bioavailability for humans and would require careful design in order to be relevant."

61. The Task Force also agreed to make some editorial amendments to other sentence in paragraph 11 in relation to testing methods.

Paragraph 13 (new paragraph 14) and paragraph 14

62. The Task Force considered, in detail, paragraph 14 in square brackets, regarding the evaluation of exposure to recombinant-DNA plants with nutritional modification.

63. The Delegation of the European Community expressed the view that the safety assessment should take into account the assessment of the nutritional or health benefits of foods derived from recombinant-DNA plants modified for such purposes. The evaluation of potential benefit of a product in a given population should be made by the respective competent national authorities when such products were placed on the market. This position was supported by two observers.

64. Some delegations pointed out that the assessment of nutritional advantage/disadvantage as stated in the text belonged to risk management measures, and therefore, proposed to delete the paragraph. These delegations stated that the concept of being nutritionally disadvantageous was ill defined and should be replaced by the concept of "nutritional risk" if the paragraph was to be retained. One observer also pointed out that elements of paragraph 14 were already covered by paragraph 13.

65. During the long discussion and exchange of views, several different alternative texts were proposed by delegations, some of which were reproduced in CRD 12.

66. After further discussion, the Task Force agreed to delete paragraph 14 and insert a new sentence as the second last sentence in paragraph 13, which read: "When evaluating the exposure, it is appropriate to consider information on whether consumption of the modified food could lead to adverse nutritional effects as compared to consumption of the food that it is intended to replace."

67. The Task Force also agreed to amendments to other sentences of paragraph 13, to replace "impact" by "influence" and "usual" with "expected or foreseeable", for clarity.

Paragraph 16 (new paragraph 18)

68. The Delegation of the United States of America, referring to its written comment, proposed to delete the last two sentences which contained the reference to the FAO diet data and the FAO Food Balance Sheet. The Delegation pointed out that the report of the FAO/WHO Nutrient Risk Assessment Workshop stated on page 167 that national or regional food-use data such as food balance sheet, regional diet, and sales data provided very limited information for quantitative exposure estimation.

69. Some delegations opposed the deletion of these sentences and suggested to retain them as they were or as a footnote, observing that data from the FAO database were sometimes the only information available in developing countries which often lacked data on food consumption.

70. The Representative of FAO clarified that the Food Balance Sheet did not represent actual consumption data, but indicated the amount of foods available per capita.

71. The Task Force agreed to move the last sentence to a footnote to allow for some flexibility and make some amendments to clarify the remaining sentences.

72. The Delegation of Sudan proposed to add a reference to the "importance of tradition(s) and custom(s) of a given population", since those two factors also influenced food consumption patterns. The Representative of FAO clarified that, from a technical point of view, the proposed two factors influenced food consumption patterns through their impact on diets, which was already recognized in the text. The Task Force decided to keep the text as it was.

Status of the Proposed Draft Annex: Food Safety Assessment of Foods Derived from Recombinant-DNA Plants Modified for Nutritional or Health Benefits

73. The Task Force, recognizing that the substantial progress had been made to the text at the plenary and the working group of the Task Force and that all outstanding issues had been resolved, agreed to forward the proposed draft annex, as amended above and with some editorial changes, for adoption at Steps 5/8 by the 31st Session of the Commission, with the recommendation to omit Steps 6 and 7. The proposed draft annex is presented in Appendix III to this report.

74. Recognizing that the proposed draft annex contained references to certain concepts related to nutrition, the Task Force agreed to invite the 29th Session of the CCNFSDU to review the document and provide comments if necessary. In this regard, the Task Force noted the priority this work should be given by the CCNFSDU, given the time constraints of the Task Force. The Task Force also noted the view of the European Community that the CCNFSDU might wish to review the annex in light of the WHO Global Strategy on Diet, Physical Activity and Health.

75. In view of the relatively short time left prior to the 29th Session of the CCNFSDU (12-16 November 2007), the Task Force agreed to urge the Task Force's delegates to liaise closely with their counterpart delegates to the CCNFSDU, with a view to facilitating review of the proposed draft annex by the CCNFSDU.

76. The Task Force also agreed that, upon the final adoption of the proposed draft guideline, a consequential change be made in paragraph 48 of the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant DNA-Plants (CAL/GL 45-2003); the new sentence to be added at the end of paragraph 48 of the Guideline would read: "A detailed presentation of issues to be considered can be found in Annex 2 to this document". The current Annex on Assessment of Possible Allergenicity would become Annex 1 to the Guideline. Paragraph 41 of the Guideline and its footnote 4 would be amended accordingly.

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 MATERIAL (Agenda Item 6)[9]

77. The Task Force recalled that at its Sixth Session it had agreed on new work on an 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 material, which was subsequently approved by the 30th Session of the Commission. A physical working group on low-level presence of recombinant-DNA plant material had been established, chaired by the United States and co-chaired by Germany and Thailand.[10]

78. The Delegation of the United States of America, speaking as the Chairperson of the Physical Working Group, summarized the discussions and recommendations contained in Circular Letter CL 2007/17-FBT Rev. The Task Force appreciated the work of the Physical Working Group, which had agreed on the proposed draft Annex in its entirety, while leaving two options for the structure of the annex, and noted that the Physical Working Group had agreed that Co-chairs and representatives of the biotechnology industry would meet with international organizations, such as FAO, in order to discuss arrangements for a future database for data and information sharing for the purpose of the annex.

79. The Representative of FAO informed the Task Force that a consultative meeting, which had met at the FAO Headquarters in May 2007 in response to the request by the Physical Working Group, had noted that the OECD BioTrack Product Database had covered most of the information items required for the purpose of the annex and, while expressing its preference for a database hosted by FAO, had recommended that FAO and OECD find a workable cooperation arrangement. The Representative further indicated that FAO and OECD had subsequently reached an agreement to develop a database system housed in FAO, which would draw data from, and export data to, the OECD Database.

80. The Representative of FAO outlined the proposed functionality of the database and procedures for its establishment as follows:

- The database, covering all the information items identified in Section 3 of the proposed draft annex, would be accommodated in the International Portal on Food Safety, Animal and Plant Health (IPFSAPH), a portal site managed by FAO in cooperation with Codex, CBD, IPPC, OIE, WHO and WTO, which provides links to SPS-related regulatory information with powerful search function;
- Initial data entry to the database would be accomplished by the incorporation of relevant data from the OECD Database and manual entry of information items which are not covered by the OECD Database, followed by confirmation by Codex members of the accuracy of the data entered, upon which the database would be made publicly accessible;

[9] CL 2007/17-FBT Rev.; CX/FBT 07/7/6 (Comments of Australia, Brazil, Canada, Japan, Kenya, Malaysia, New Zealand, Philippines and the United States of America); CX/FBT 07/7/6-Add.1 Rev. (Comments of Costa Rica and the European Community); CX/FBT 07/7/3-Add.2 (Review of the Work by International Intergovernmental Organizations Related to Food Derived from Biotechnology – Submission from FAO); CRD 2 (Comments of Thailand); CRD 3 (Comments of Nigeria); CRD 4 (Comments of Ghana); CRD 5 (Comments of South Africa); CRD 6 (Comments of the Philippines); CRD 7 (Comments of Indonesia); CRD 8 (Comments of Republic of Korea); CRD 9 (Comments from CI); CRD 10 (Comments of Malaysia); CRD 13 (Comments of the European Community)

[10] ALINORM 07/30/34, paras 77 and 78

- The database would be kept up to date through new entries upon notification to FAO by Codex members and automated bidirectional data sharing between the FAO and OECD databases.

81. The Task Force commended the work done by FAO in coordination with OECD, which had met the expectation of the Task Force and its Physical Working Group within a short period of time. In response to requests for clarification by some delegations with regard to the sustainability of the arrangement for the database, the Representative of FAO explained that the activities on the IPFSAPH, which was managed within the Regular Budget of FAO, had been accorded high priority by the Organization due to its link with the SPS Agreement and that it would continue to be the case for the foreseeable future. Automated data entry and data sharing with the OECD Database would keep the maintenance cost to a reasonable level.

82. One delegation stressed the need for capacity building activities in the area of food safety assessment and detection of recombinant-DNA plant materials, so that developing countries could cope with the situation of low-level presence in accordance with the Proposed Draft Annex. The Representative of FAO stated that FAO/WHO had implemented a number of capacity building activities, including the strengthening of the regulatory framework for safety assessment of foods derived from biotechnology and enhancement of capacities for the detection of recombinant-DNA material as well as the conduct of safety assessments. While more activities could be envisaged in the future, subject to the availability of extra-budgetary funds.

83. Prior to in-depth consideration of the proposed draft annex, the Delegation of the European Community reiterated its position expressed at the Sixth Session of the Task Force that it had comprehensive regulatory framework for addressing adventitious presence and could agreed with this new work on condition that the annex provided for an effective system for data and information sharing. Subsequently, the Task Force considered the proposed draft annex paragraph by paragraph and considered and agreed on amendments as follows, as well as some other editorial changes.

General Issues

84. The Task Force was reminded that the term "food safety assessment" was a result of long and difficult consultations during the first term of the Task Force and had become a core concept on which the Task Force based its work. The Task Force noted that introducing a new term "assessment of food safety considerations" as proposed by the Physical Working Group might lead to possible confusions and agreed to revert to the term "food safety assessment", originally used throughout the Codex Plant Guideline, and use it consistently in the annex, as it was clear that this term applied in situations of low-level presence in the context of this annex.

85. With regard to the choice between the longer and shorter versions of the proposed draft annex, the Task Force agreed to base its discussion on the shorter one (Attachment 2 of the CL 2007/17-FBT Rev.) because it allowed clear indication of the difference between the provisions of the Codex Plant Guideline and those applicable to the food safety assessment in situations of low-level presence of recombinant-DNA plant material, and because an annex to a Codex document usually did not repeat what was included in the main document.

Section 1

86. The Task Force noted that the footnote to the second bullet point of paragraph 6 had been only for the purpose of reporting discussion by the Physical Working Group and agreed on its deletion.

Section 2

87. The Task Force noted that the applicability of the sections of the Codex Plant Guideline other than Sections 4 and 5 was not clear from the proposed wording in paragraph 7, which simply stated that the paragraphs listed under this section applied to food safety assessment in situations of low-level presence, and amended the first sentence as follows: "For the food safety assessment in situations of low-level presence of recombinant-DNA plant materials in food, Sections 4 and 5 of the Codex Plant Guideline apply as amended as follows."

88. The Task Force noted that paragraphs contained in Section 2 after paragraph 7 should be renumbered in a continuous sequence. The Task Force also noted that paragraphs 22 and 41 of the Codex Plant Guideline did not need to be reproduced in the annex because these paragraphs had become identical to the corresponding paragraphs in the Codex Plant Guideline after the decision of the Task Force not to introduce the new term "assessment of food safety considerations" (*see* para. 84 above).

Section 3[11]

89. The Task Force noted that the modal verb "shall" was used in several places in Section 3 and, with the understanding that all Codex standards and related texts were voluntary in nature, agreed to replace it with "should" throughout the text.

90. The Task Force agreed to amend the chapeau of paragraph 9 to clarify that the database should be "publicly accessible".

91. The Task Force agreed to the proposal one delegation to delete the words "the outcome of" from paragraph 11.

92. The Task Force had intensive discussion on the proposals by the Delegation of the European Community (CRD 13) on the nature and format of information to be submitted to the proposed database as provided in paragraph 9, as well as related provisions in paragraph 12.

Links to information in other databases

93. The Delegation of the European Community proposed to include in the database a reference to a notification(s) to the Biosafety Clearing House (BCH) of the Cartagena Protocol and/or OECD BioTrack Product Database.

94. While some observers supported the proposal, stating that such reference would allow users easy access to the information contained in these two databases, many delegations were against its inclusion because in their view these databases, not being focused on food safety specifically, did not provide useful information for the purpose of this annex. Other delegations were of the view that there should be no reference to the Cartagena Protocol or to the OECD, to which not all the Codex members were party or member. It was also pointed out that the Cartagena Protocol addressed living modified organisms only, while Codex had to address food.

95. The Delegation of Argentina indicated that, considering that some members had concerns on the reference to the BCH and the OECD, a more general reference on information sources could be acceptable, such as "links to the information on the same product in other international databases." One delegation found the proposal too general and preferred to limit the scope to those databases relevant to food safety. Another delegation, noting that such links to other relevant databases might not always exist, proposed to add "as appropriate" at the end of the sentence. With these modifications, many delegations supported the proposal by the Delegation of Argentina.

96. The Delegation of the European Community proposed, as an alternative or additional to the revised reference above, to add a footnote to "f. unique identifier", which read "Unique identifier allows access to complementary information on recombinant-DNA plants notified to the Biosafety Clearing House of the Cartagena Protocol and/or the OECD BioTrack Product Database". However, other delegations did not agree to this proposed footnote, even as a factual statement, for the reasons mentioned above.

97. After some further discussion, the Task Force agreed not to add a footnote to item f but to add the following item, without reference to "food safety relevance", after item f "unique identifier": "Links to the information on the same product in other databases maintained by relevant international organizations, as appropriate". It was understood that in certain cases, the BCH and the OECD BioTrack Product Database could provide important information to regulating authorities.

[11] The paragraph numbers in the following paragraphs refers to those contained in the Attachment 2 of the CL 2007/17-FBT Rev. Paragraphs 8 to 13 correspond to paragraphs 27 to 32 of the Appendix IV to this report.

Summary of the safety assessment

98. The Delegation of the European Community proposed that the summary of the safety assessment should be structured following the headings of the Codex Plant Guideline and be focused on the areas of specific relevance and interest of the risk assessor. The Delegation clarified that this provision would not only ensure that the safety assessment be conducted in accordance with the Codex Plant Guideline but also would allow rapid access to relevant information, which is critical to the food safety assessment in situations of low-level presence.

99. While some delegations expressed support to the proposal by the Delegation of the European Community because they believed that a uniform and standardized presentation of the summary of the food safety assessment would facilitate the review of the food safety assessment, particularly for developing countries, several other delegations were not supportive of the proposal because it would require rearrangement of the existing summaries of food safety assessments when the format for such summaries under their national legislation was different from the structure of the Codex Plant Guideline even though the safety assessment itself was in line with the Codex Plant Guideline. Some delegations also pointed out that it would be practically impossible to determine, in advance, the "areas of specific relevance and interest to the risk assessor" at the time of submission of the information to the database.

100. After some discussion, the Task Force agreed that the summary of the safety assessment "should be consistent with the framework of food safety assessment of the Codex Plant Guideline".

Detection method and reference material

101. The Delegation of the European Community proposed to include "either a validated protocol for an event-specific detection method suitable for low-level situations and appropriate (either viable or non-viable) reference material, or information on where these can be secured", as another information item in the database. The Delegation stressed that access to such information was key to the management of situations of low-level presence, in which competent authorities should urgently assess the actual presence of recombinant-DNA plant materials in the commodity in question.

102. The Delegation of the United States of America, while recognizing the need for and usefulness of such information, proposed that the database contain information only where it could be obtained. The Delegation, supported by an observer, also expressed some concern on the inclusion of "viable" reference material, the provision of which was in most cases impossible due to intellectual property rights.

103. The Task Force, with the understanding that the submission of the viable reference material was optional and would usually not be needed, agreed to include the following information item in the database: "where detection method protocols and appropriate reference material (non-viable, or in certain circumstances, viable) suitable for low-level situations may be obtained", with a footnote indicating that this information might be provided by the product applicant or in some cases by Codex members. The Task Force also agreed to amend the reference to viable/non-viable material in paragraph 12 to make it consistent with the decision taken on paragraph 9.

104. The Task Force noted that while paragraph 12 included provisions similar to those under paragraph 9, the requirements in this paragraph was intended for product applicants, not Codex members, and agreed to retain paragraph 12 (new paragraph 31). The Task force agreed with the proposal by the Delegation of the European Community to clarify that the provision of this paragraph was without prejudice to legitimate concerns to safeguard the confidentiality of commercial and industrial information.

105. In reply to a proposal to delete the reference to trait-specific detection method, several delegations noted that a trait-specific detection method could be sufficient in cases, for example, where the trait in question was not authorized in the importing country.

Status of the Proposed Draft Annex: Food Safety Assessment in Situations of Low-level Presence of Recombinant-DNA Plant Material in Food

106. In view of the progress made and consensus reached, the Task Force agreed to forward the proposed draft annex as amended above for adoption at Steps 5/8 by the 31st Session of the Commission, with the recommendation to omit Steps 6 and 7. The proposed draft annex is presented in Appendix IV to this report. The Task Force also agreed to request FAO to provide update on the database for data and information sharing at the 31st Session of the Commission.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 7)

107. The Observer from the OIE informed the Task Force that as a follow-up to the FAO/WHO Expert Consultation on the Safety Assessment of Foods Derived from Recombinant-DNA animals (26 February – 2 March 2007), the OIE would convene an expert meeting, jointly with FAO and WHO, probably in 2008, to consider the issues related to the animals with non-heritable recombinant-DNA constructs including recombinant-DNA vaccines.

DATE AND PLACE OF THE NEXT SESSION (Agenda Item 8)

108. Given that the three proposed draft documents considered under Items 4, 5 and 6 were advanced to Step 5/8, no further session of the Task Force was foreseen. Should the need for another session of the Task Force arise following the consideration of these proposed drafts by the 31st Session of the Commission in July 2008, the host government would make necessary arrangements in consultation with the Codex Secretariat.

SUMMARY STATUS OF WORK

SUBJECT MATTER	STEP	ACTION BY	DOCUMENT REFERENCE (ALINORM 07/30/34)
Proposed Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals	5/8	31st CAC	Para. 33 Appendix II
Proposed Draft Annex: Food Safety Assessment of Foods Derived from Recombinant-DNA Plants Modified for Nutritional or Health Benefits	5/8	29th Session of the CCNFSDU 31st CAC	Paras 73 and 74 Appendix III
Proposed Draft Annex: Food Safety Assessment in Situations of Low-level Presence of Recombinant-DNA Plant Material in Foods	5/8	31st CAC	Para. 106 Appendix IV

Appendix I

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Appendix II

PROPOSED DRAFT GUIDELINE FOR THE CONDUCT OF FOOD SAFETY ASSESSMENT OF FOODS DERIVED FROM RECOMBINANT-DNA ANIMALS (At Step 5/8 of the Procedure)

SECTION 1 — SCOPE

1. This Guideline supports the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology. It addresses safety and nutritional aspects of foods consisting of, or derived from, animals that have a history of safe use as sources of food, and that have been modified by modern biotechnology to exhibit new or altered expression of traits[1].

2. The development, raising and use of animals for human purposes, and in particular, for use for food, raise a variety of issues beyond food safety. Without prejudice to their legitimacy or importance, or to whether or how the use of recombinant-DNA methods in developing animals for food use might affect those issues, this Guideline addresses only food safety and nutritional issues. It therefore does not address:

- animal welfare;
- ethical, moral and socio-economical aspects;
- environmental risks related to the environmental release of recombinant-DNA animals used in food production;
- the safety of recombinant-DNA animals used as feed, or the safety of animals fed with feed derived from recombinant-DNA animals, plants and microorganisms.

3. The Codex principles of risk analysis, particularly those for risk assessment, are primarily intended to apply to discrete chemical entities such as food additives and pesticide residues, or a specific chemical or microbial contaminant that have identifiable hazards and risks; they are not intended to apply to whole foods as such. Indeed, few foods, whatever their origin, have been assessed scientifically in a manner that would fully characterize all risk associated with the food. Further, many foods contain substances that would likely be found harmful if subjected to conventional approaches to safety testing. Thus, a more focused approach is required where the safety of a whole food is being considered.

4. This approach is based on the principle that the safety of foods derived from new animal lines, including recombinant-DNA animals, is assessed relative to the conventional counterpart having a history of safe use, taking into account both intended and unintended effects. Rather than trying to identify every hazard associated with a particular food, the intention is to identify new or altered hazards relative to the conventional counterpart.

5. This safety assessment approach falls within the risk assessment framework as discussed in Section 3 of the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology. If a new or altered hazard, nutritional or other food safety concern is identified by the safety assessment, the risk associated with it would first be assessed to determine its relevance to human health. Following the safety assessment and, if necessary, further risk assessment, the food would be subjected to risk management considerations in accordance with the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology before it is considered for commercial distribution.

6. Risk management measures such as post-market monitoring of consumer health effects may assist the risk assessment process. These are discussed in paragraph 20 of the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology.

[1] This Guideline was developed primarily for animals bearing heritable recombinant-DNA constructs.

7. The Guideline describes the recommended approach for the food safety assessment of foods derived from recombinant-DNA animals where a conventional counterpart exists, and identifies the data and information that are generally applicable to making such assessments.[2] In assessing the safety of food from recombinant-DNA animals, the approach should take into account all of the following:

A) the nature of the recombinant-DNA construct and its expression product(s), if any;

B) the health status of the recombinant-DNA animal; and

C) the composition of foods produced from recombinant-DNA animals, including key nutrients.

While this Guideline is designed for foods derived from recombinant-DNA animals, the approach described could, in general, be applied to foods derived from animals that have been altered by other techniques[3].

8. A diverse range of animals are used as food or for food production (e.g. mammals, birds, finfish and shellfish) and may be modified using in vitro nucleic acid techniques. Because of the combined impacts of their genetic diversity, husbandry, and conditions under which they are raised or harvested, assessment of food safety must be considered on a case-by-case basis, with due regard to the framework presented in this Guideline.

SECTION 2 — DEFINITIONS

9. The definitions below apply to this Guideline:

"Recombinant-DNA Animal" — an animal in which the genetic material has been changed through *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles.

"Conventional Counterpart" — an animal breed with a known history of safe use as food from which the recombinant-DNA animal line was derived, as well as the breeding partners used in generating the animals ultimately used as food, and/or food derived from such animals[4].

SECTION 3 — INTRODUCTION TO FOOD SAFETY ASSESSMENT

10. Traditionally, food products derived from animals developed through conventional breeding or obtained from wild species have not been systematically subjected to extensive chemical, toxicological, or nutritional evaluation prior to marketing. Thus, although new breeds of animals are often evaluated by breeders for phenotypic characteristics they are not subjected to the rigorous and extensive food safety testing procedures, including validated toxicity studies in test animals, that are typical of chemicals such as food additives or contaminants that may be present in food. Instead, food derived from an animal of known and acceptable health status has generally been considered suitable for human consumption.

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2 The approach to the safety assessment of foods derived from recombinant-DNA animals was first discussed at the 1991 Joint FAO/WHO Consultation on Strategies for Assessing the Safety of Foods Produced by Biotechnology. Further elaboration of the recommended approach was undertaken at the 2003 Joint FAO/WHO Expert Consultation on the Safety Assessment of Foods Derived from Genetically Modified Animals, Including Fish.

3 The food safety assessment of foods derived from animals bearing non-heritable constructs may require additional specific consideration, e.g. regarding hazards identified in the 2007 Joint FAO/WHO Expert Consultation on the Safety Assessment of Foods Derived from Recombinant-DNA Animals.

4 It is recognized that for the foreseeable future, foods derived from modern biotechnology will not be used as conventional counterparts.

11. The use of animal models for assessing toxicological endpoints is a major element in the risk assessment of many compounds, such as pesticides. In most cases, however, the substance to be tested is well characterized, of known purity, of no particular nutritional value, and human exposure to it is generally low. It is therefore relatively straightforward to feed such compounds to test animals at a range of doses some several orders of magnitude greater than the expected human exposure levels, in order to identify any potential adverse health effects of importance to humans. In this way, it is possible in most cases, to estimate levels of exposure at which adverse effects are not observed and to set safe intake levels by the application of appropriate safety factors.

12. Studies using test animals cannot readily be applied to testing the risks associated with whole foods, which are complex mixtures of compounds, and often characterized by a wide variation in composition and nutritional value. Due to their bulk and effect on satiety, they can usually only be fed to test animals at low multiples of the amounts that might be present in the human diet. In addition, a key factor to consider in conducting animal studies on foods is the nutritional value and balance of the diets used, in order to avoid the induction of adverse effects that are not related directly to the material itself. Detecting any potential adverse effects and relating these conclusively to an individual characteristic of the food can therefore be extremely difficult. If the characterization of the food indicates that the available data are insufficient for a thorough safety assessment, properly designed studies using test animals could be requested on the whole food. Another consideration in deciding the need for studies with test animals is whether it is appropriate to subject test animals to such a study if it is unlikely to give rise to meaningful information.

13. Due to the difficulties of applying traditional toxicological testing and risk assessment procedures to whole foods, and based on the experience of assessing the safety of whole foods, a more focused approach is required for the safety assessment of food derived from animals, including recombinant-DNA animals. This has been addressed by the development of a multidisciplinary approach for assessing safety, which takes into account both intended and unintended changes that may occur in the animal or in the food products derived from it, using the concept of substantial equivalence.

14. The concept of substantial equivalence is a key step in the safety assessment process. However, it is not a safety assessment in itself; rather it represents the starting point, which is used to structure the safety assessment of a new food relative to its conventional counterpart. This concept is used to identify similarities and differences between the new food and its conventional counterpart[5]. It aids in the identification of potential food safety and nutritional issues and is considered the most appropriate strategy to date for safety assessment of foods derived from recombinant-DNA animals. The safety assessment carried out in this way does not imply absolute safety of the new product; rather, it focuses on assessing the safety of any identified differences so that the safety of the new product can be considered relative to its conventional counterpart.

UNINTENDED EFFECTS

15. In achieving the objective of conferring a specific trait (intended effect) to an animal by the insertion of defined DNA sequences, additional traits could, in some cases, be acquired or existing traits could be lost or modified (unintended effects). The potential occurrence of unintended effects is not restricted to the use of *in vitro* nucleic acid techniques. Rather, it is an inherent and general phenomenon that can also occur in conventional breeding as well in association with the use of assisted reproductive technologies currently in use. Unintended effects may be deleterious, beneficial, or neutral with respect to the health of the animal or the safety of the foods derived from the animal. Unintended effects in recombinant-DNA animal may also arise through the insertion of DNA sequences and/or they may arise through subsequent conventional breeding of the recombinant-DNA animal. Safety assessment should include data and information to reduce the possibility that a food derived from a recombinant-DNA animal would have an unexpected, adverse effect on human health.

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[5] The concept of substantial equivalence as described in the report of the 2000 joint FAO/WHO expert consultation (Document WHO/SDE/PHE/FOS/00.6, WHO, Geneva, 2000). The concept of substantial equivalence was further considered in the context of comparative safety assessment at the 2003 Joint FAO/WHO Expert Consultation on the Safety Assessment of Foods Derived from Genetically Modified Animals, Including Fish.

16. Unintended effects can result from the random insertion of DNA sequences into the animal genome, which may cause disruption or silencing of existing genes, activation of silent genes, or modifications in the expression of existing genes. Unintended effects may also result in the formation of new or changed patterns of metabolites.

17. Unintended effects due to *in vitro* nucleic acid techniques may be subdivided into two groups: those that are "predictable" and those that are "unexpected". Many unintended effects are largely predictable based on knowledge of the inserted trait and its metabolic connections or of the site of insertion. As knowledge of animal genomes grows, and familiarity with *in vitro* nucleic acid techniques increases, it may become easier to predict unintended effects of a particular modification. For example, homologous recombination, where appropriate, allows precise gene placement and so may reduce the occurrence of unintended effects associated with random integration. Molecular biological and biochemical techniques can also be used to analyse changes that occur at the level of transcription and translation that could lead to unintended effects. These should all be considered on a case-by-case basis.

18. The safety assessment of food derived from recombinant-DNA animals involves methods to identify and detect such unintended effects and procedures to evaluate their biological relevance and potential impact on food safety. A variety of data and information are necessary to assess unintended effects, because no individual test can detect all possible unintended effects or identify, with certainty, those relevant to human health. These data and information, when considered in total, provide assurance that the food is unlikely to have an adverse effect on human health. The assessment of unintended effects takes into account the phenotypic characteristics of the animal that are typically monitored by breeders during animal production stock development and improvement. These assessments provide a first screen for recombinant-DNA animals exhibiting unintended traits. Recombinant-DNA animals that pass this screen are subjected to safety assessment as described in Sections 4 and 5.

FRAMEWORK OF FOOD SAFETY ASSESSMENT

19. The safety assessment follows a stepwise process of addressing relevant factors that include:

A) General description of the recombinant-DNA animal;

B) Description of the recipient animal prior to the modification[6] and its use as food or for food production;

C) Description of the donor organism or other source(s) of the introduced recombinant-DNA;

D) Description of the genetic modification(s) including the construct(s) used to introduce the recombinant-DNA;

E) Description of the methods used to produce the initial recombinant-DNA animal[7] and the processes to produce the recombinant-DNA animal ultimately used as food or for food production;

F) Characterization of the genetic modification(s) in the recombinant-DNA animal ultimately used as food or for food production;

G) Safety assessment:

   a. Health status of the recombinant-DNA animal;

   b. Expressed substances (non-nucleic acid substances);

   c. Compositional analyses of key components;

   d. Food storage and processing; and

   e. Intended nutritional modification;

H) Other considerations.

20. In certain cases, the characteristics of the food may necessitate additional data and information to address issues that are unique to the product under review.

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6 Not to be confused with a surrogate dam.

7 First animal produced as a result of introducing the recombinant-DNA construct. Sometimes referred to as the founder animal

21. Experiments intended to develop data for safety assessment should be designed and conducted in accordance with sound scientific concepts and principles, as well as, where appropriate, Good Laboratory Practice. Primary data should be made available to regulatory authorities at request. Data should be obtained using sound scientific methods and analysed using appropriate statistical techniques. Analytical methods should be documented.[8]

22. The goal of each safety assessment is to provide assurance, in the light of the best available scientific knowledge, that the food does not cause harm when prepared, used and/or eaten according to its intended use. Safety assessments should address the health aspects for the whole population, including immunocompromised individuals, infants, the elderly and individuals with food hypersensitivities. The expected endpoint of such an assessment will be a conclusion regarding whether the new food is as safe as the conventional counterpart taking into account dietary impact of any changes in nutritional content or value. In essence, therefore, the outcome of the safety assessment process is to define the product under consideration in such a way as to enable risk managers to determine whether any measures are needed to protect the health of consumers and if so to make well-informed and appropriate decisions in this regard.

SECTION 4 — GENERAL CONSIDERATIONS

GENERAL DESCRIPTION OF THE RECOMBINANT-DNA ANIMAL

23. A description of the recombinant-DNA animal being presented for safety assessment should be provided. This description should identify the introduced recombinant-DNA, the method by which the recombinant-DNA is introduced to the recipient animal and the recombinant-DNA animal ultimately used as food or for food production, as well as the purpose of the modification. The potential risk of introducing pathogenic elements (e.g. elements responsible for transmissible spongiform encephalopathies and other infectious disease) originating from biological materials used as sources or during the production should be considered. The description should be sufficient to aid in understanding the nature and types of food being submitted for safety assessment.

DESCRIPTION OF THE RECIPIENT ANIMAL PRIOR TO THE MODIFICATION AND ITS USE AS FOOD OR FOR FOOD PRODUCTION

24. A comprehensive description of the recipient animal prior to the modification 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;

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

C) information on the animal's genotype and phenotype relevant to its safety, including any known toxicity or allergenicity, symbiosis with toxin-producing organisms, potential for colonization by human pathogens;

D) information on the effect of feed, exercise and growth environment on food products; and

E) history of safe use as food or for food production.

25. Relevant phenotypic information should be provided not only for the recipient animal prior to the modification, but also for related lines and for animals that have made or may make a significant contribution to the genetic background of the recipient animal prior to the modification, if applicable.

26. The history of use may include information on how the animals breed and grow, how its food products are obtained (e.g. harvest, slaughter, milking), and the conditions under which those food products are made available to the consumer (e.g. storage, transport, processing). The extent to which the food products provide important nutritional components to particular subgroups of the population, and what important macro- or micronutrients it contributes to the diet should also be considered.

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[8] Reference is made to the General Criteria for the Selection of Methods of Analysis in the Codex Alimentarius Procedural Manual.

DESCRIPTION OF THE DONOR ORGANISM OR OTHER SOURCE(S) OF THE INTRODUCED RECOMBINANT-DNA

27. Information should be provided:

A) Whether the recombinant-DNA was synthesized and it is not from a known natural source;

B) If derived from another organism:

i. that organism's usual or common name;

ii. scientific name;

iii. taxonomic classification;

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

v. information on naturally occurring toxins, and allergens;

vi. for microorganisms, additional information on pathogenicity (to humans or the animal) and the relationship to known human or animal pathogens;

vii. for donors of animal or viral origin, information on the source material (e.g. cell culture) that has been used, and its origins; and

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

It is particularly important to determine whether the recombinant-DNA sequences impart pathogenicity or toxin production, or have other traits that affect human health (e.g. allergenicity).

DESCRIPTION OF THE GENETIC MODIFICATION(S) INCLUDING THE CONSTRUCT(S) USED TO INTRODUCE THE RECOMBINANT-DNA

28. Sufficient information should be provided on the genetic modification to allow for the identification of all genetic material potentially delivered to the recipient animal and to provide the necessary information for the analysis of the data supporting the characterization of the DNA inserted into the recombinant-DNA animal ultimately used as food or for food production.

29. The description of the process of introducing and incorporating (if appropriate) the recombinant-DNA into the recipient animal should include:

A) information on the specific methodology used for the transformation;

B) information, if applicable, on the DNA used to modify the animal (e.g. genes coding for proteins used for packaging vectors), including the source, identity and expected function in the animal:

– if viral vectors or known zoonotic organisms have been used, information on their natural hosts, target organs, transmission mode, pathogenicity, and potential for recombination with endogenous or exogenous pathogens; and

C) intermediate host organisms including the organisms (e.g. bacteria) used to produce or process DNA for producing the initial recombinant DNA animal.

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

A) the primary DNA sequence if the recombinant-DNA was synthesized and it is not from a known natural source

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

C) the size and identity;

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

E) the function.

DESCRIPTION OF THE METHODS USED TO PRODUCE INITIAL RECOMBINANT-DNA ANIMAL AND THE PROCESSES TO PRODUCE THE RECOMBINANT DNA ANIMAL ULTIMATELY USED AS FOOD OR FOR FOOD PRODUCTION

31. Information should be provided on the various techniques and processes that are used to introduce the recombinant-DNA to obtain the initial recombinant-DNA animal. Examples of possible techniques may include transformation of gametes, microinjection of early embryos, nuclear transfer of transgenic cells.

32. A description of the methods used to demonstrate heritability should be provided, including descriptions of how heritability is attained (e.g. breeding mosaic animals to obtain true germ-cell transmissible insertions).

33. Although initial recombinant-DNA animals are generally not intended to be used as food or for food production, knowledge of the method to generate these animals may be useful in hazard identification.

34. Information should also be provided on how the initial recombinant-DNA animal leads to the production of the animal ultimately used as food or for food production. This information should, if applicable, include information on the breeding partners, or surrogate dams including genotype and phenotype, husbandry, and conditions under which they are raised or harvested.

35. The history of use of food products from the animals used to generate the animals ultimately used for food production from the initial recombinant-DNA animal (e.g. breeding partners, surrogate dams) may include information on how the animals breed and grow, its food products are obtained (e.g. harvest, slaughter, milking), and the conditions under which those food products are made available to consumers (e.g. storage, transport, processing).

CHARACTERIZATION OF THE GENETIC MODIFICATION(S) IN THE RECOMBINANT-DNA ANIMAL ULTIMATELY USED AS FOOD OR FOR FOOD PRODUCTION

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

37. Information should be provided on the DNA insertions into the animal genome; this should include:

A) the characterization and description of the inserted genetic materials. This should include an analysis of the potential for mobilization or recombination of any construct material used;

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 scientifically 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 insertion with contiguous animal genomic DNA, including those that could result in fusion proteins.

38. Information should be provided on any newly expressed substances in the recombinant-DNA animal; this should include:

A) the gene product(s) (e.g. a protein or an untranslated RNA) or other information such as analysis of transcripts or expression products to identify any new substances that may be present in the food;

B) the gene product(s)' function;

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

D) the level and site of expression in the animal of the expressed gene product(s), and the levels of its metabolites in the food; 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.

39. In addition, information should be provided to:

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

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

C) demonstrate whether the intended effect of the modification has been achieved and that all expressed traits are stable and are expressed as expected. 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) 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) indicate whether there is any evidence to suggest that one or several genes in the recombinant-DNA animal has been affected by the transformation process; and

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

SAFETY ASSESSMENT OF THE RECOMBINANT-DNA ANIMAL ULTIMATELY USED AS FOOD OR FOR FOOD PRODUCTION

Health Status of the Recombinant-DNA Animal

40. In contrast to the situation with plants, animals that have a history of safe use as sources of food generally do not contain genes encoding for toxic substances. Because of this, the health of a conventional animal has traditionally been used as a useful indicator of the safety of derived foods. The practice of only allowing animals with known and acceptable health status to enter the human food supply has been and continues to be an essential step to ensuring safe food.

41. An evaluation of the health of the animal is one of the essential steps in ensuring safety of food derived from recombinant-DNA animals. In undertaking this evaluation, it is important to compare the health status of the recombinant-DNA animal to the health status of the appropriate conventional counterpart, taking into account developmental stage.

42. The evaluation should include the following:

A) General health and performance indicators, including behaviour, growth and development, general anatomy, and reproductive function, if appropriate;

B) Physiological measures including clinical and analytical parameters;

C) Other species-specific considerations, where appropriate.

Expressed Substances (non-nucleic acid substances)

Assessment of possible toxicity or bioactivity

43. In vitro nucleic acid techniques enable the introduction of DNA that can result in the synthesis of new substances in recombinant-DNA animals. The new substances can be conventional components of animal derived foods, such as proteins, fats, carbohydrates, vitamins, which are novel in the context of that recombinant-DNA animal. New substances might also include new metabolites resulting from the activity of enzymes generated by the expression of introduced DNA.

44. It is recognized that the evaluation of the health status of the recombinant-DNA animals may give information about possible toxicity and bioactivity of the expressed substances. However, it is still generally expected that the safety assessment will include evaluation of these substances.

45. The safety assessment should take into account the chemical nature and function of the newly expressed substance and identify the concentration of the substance in the edible tissues and other derived food products of the recombinant-DNA animal, including variations and mean values. Current dietary exposure and possible effects on population sub-groups should also be considered.

46. Information should be provided to ensure that genes coding for known toxins or anti-nutrients present in donor organisms, if applicable, are not transferred to recombinant-DNA animals that do not normally express those toxic or anti-nutritious characteristics. This assurance is particularly important in cases where food derived from the recombinant-DNA animal is processed differently from the donor organism, since conventional food processing techniques associated with the donor organisms may deactivate, degrade or eliminate anti-nutrients or toxicants.

47. 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 substances may be necessary.

48. 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, taking into account its biological function in the animal where known.

49. 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 animal 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.

50. In the case of newly expressed bioactive substances, recombinant-DNA animals should be evaluated for potential effects of those substances as part of the overall animal health evaluation. It is possible that such substances may be active in humans. Consideration should therefore be given to potential dietary exposure to the substance, whether the substance is likely to be bioactive following consumption and, if so, its potential to exert effects in humans.

51. Assessment of potential toxicity may require the isolation of the new substance from the recombinant-DNA animal, 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 animal.

Assessment of possible allergenicity (proteins)

52. 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 21, the data should be obtained using sound scientific methods. A detailed presentation of issues to be considered can be found in the Annex to this document[10].

53. The transfer of genes from commonly allergenic foods should be avoided unless it is documented that the transferred gene does not code for an allergen.

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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 Annex to these guidelines.

Compositional Analysis of Key Components

54. Analyses of concentrations of key components[11] of the recombinant-DNA animal and, especially those typical of the food, should be compared with an equivalent analysis of a conventional counterpart grown and bred under the same husbandry conditions. Depending on the species (and the nature of the modification) it may be necessary to make comparisons between products from recombinant-DNA animals and appropriate conventional counterparts raised under more than one set of typical husbandry 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. However, it should be acknowledged that, particularly in the case of certain animal species, the available number of samples may be limited and there is likely to be large variation between animals, even those bred and raised under the same husbandry conditions. The comparator(s) used in this assessment should ideally be matched in housing and husbandry conditions, breed, age, sex, parity, lactation, or laying cycle (where appropriate). In practice, this may not be feasible at all times, in which case conventional counterparts as close as possible should be chosen. The purpose of this comparison, in conjunction with an exposure assessment as necessary, is to establish that substances that are nutritionally important or that can affect the safety of the food have not been altered in a manner that would have an adverse impact on human health.

Food Storage and Processing

55. The potential effects of food processing, including home preparation, on foods derived from recombinant-DNA animals should also be considered. For example, alterations could occur in the heat stability of a toxicant or the bioavailability of an important nutrient after processing. Information should therefore be provided describing the processing conditions used in the production of a food ingredient from the animal.

56. If the modification is intended to change storage or shelf-life, the impact of the modification on food safety and/or nutritional quality should be evaluated.

Intended Nutritional Modification

57**.** The assessment of possible compositional changes to key nutrients, which should be conducted for all recombinant-DNA animals, has already been addressed under 'Compositional analyses of key components'. However, foods derived from recombinant-DNA animals that have undergone modification to intentionally alter nutritional quality or functionality should be subjected to additional nutritional assessment to assess the consequences of the changes and whether the nutrient intakes are likely to be altered by the introduction of such foods into the food supply.

58. Information about the known patterns of use and consumption of a food, and its derivatives should be used to estimate the likely intake of the food derived from the recombinant-DNA animal. The expected intake of the food should be used to assess the nutritional implications of the altered nutrient profile both at customary and maximal levels of consumption. Basing the estimate on the highest likely consumption provides assurance that the potential for any undesirable nutritional effects will be detected. Attention should be paid to the particular physiological characteristics and metabolic requirements of specific population groups such as infants, children, pregnant and lactating women, the elderly and those with chronic diseases or compromised immune systems. Based on the analysis of nutritional impacts and the dietary needs of specific population subgroups, additional nutritional assessments may be necessary. It is also important to ascertain to what extent the modified nutrient is bioavailable and remains stable with time, processing and storage.

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[11] Key nutrients are those components in a particular food that may have a substantial impact in the overall diet. They may be major constituents (fats, proteins, carbohydrates as nutrients or enzyme inhibitors as anti-nutrients) or minor compounds (minerals, vitamins). Key toxicants are those toxicologically significant compounds known to be inherently present in the organism, such as those compounds whose toxic potency and level may be significant to health and allergens. In animals, the presence of toxicants would be rare, whereas the presence of allergens would be common in some species.

59. The use of animal breeding, including *in vitro* nucleic acid techniques, to change nutrient levels in animal derived foods can result in broad changes to the nutrient profile in two ways. The intended modification in animal constituents could change the overall nutrient profile of the animal product and this change could affect the nutritional status of individuals consuming the food. Unexpected alterations in nutrients could have the same effect. Although the recombinant-DNA animal components may be individually assessed as safe, the impact of the change on the overall nutrient profile should be determined.

60. When the modification results in a food product with a composition that is significantly different from its conventional counterpart, it may be appropriate to use additional conventional foods or food components (i.e. foods or food components whose nutritional composition is closer to that of the food derived from the recombinant-DNA animal) as appropriate comparators to assess the nutritional impact of the food.

61. Because of geographical and cultural variation in food consumption patterns, nutritional changes to a specific food may have a greater impact in some geographical areas or in some cultural population than in others. Some animal derived foods serve as the major source of a particular nutrient in some populations. The nutrient and the populations affected should be identified.

62. Some foods may require additional testing. For example, animal feeding studies may be warranted for foods derived from recombinant-DNA animals if changes in the bioavailability of nutrients are expected or if the composition is not comparable to conventional foods. Also, foods designed for health benefits may require specific nutritional, toxicological or other appropriate studies. If the characterization of the food indicates that the available data are insufficient for a thorough safety assessment, properly designed animal studies could be requested on the whole foods.

SECTION 5 — OTHER CONSIDERATIONS

POTENTIAL ALTERED ACCUMULATION OR DISTRIBUTION OF SUBSTANCES OR MICROORGANISMS SIGNIFICANT TO HUMAN HEALTH

63. Some recombinant-DNA animals may exhibit traits that may result in the potential for altered accumulation or distribution of xenobiotics (e.g. veterinary drug residues, metals), which may affect food safety. Similarly, the potential for altered colonization by and shedding of human pathogens or new symbiosis with toxin-producing organisms in the recombinant-DNA animal could have an effect on food safety. The safety assessment should take the potential for these alterations into account, and where such alterations are identified, consideration should be given to the potential impacts on human health using conventional procedures for establishing safety.

USE OF ANTIBIOTIC RESISTANCE MARKER GENES

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

65. Gene transfer from animals 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].

66. 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 animals.)

[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.

B) whether the presence in food of the enzyme or protein encoded by the antibiotic resistance marker gene would compromise the therapeutic efficacy of 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 enzyme 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.

67. 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 food. Antibiotic resistance genes used in food production that encode resistance to clinically used antibiotics should not be present in foods.

REVIEW OF SAFETY ASSESSMENTS

68. The goal of the safety assessment is a conclusion as to whether the new food is as safe as the conventional counterpart taking into account dietary impact of any changes in nutritional content or value. Nevertheless, the safety assessment should be reviewed in the light of new scientific information that calls into question the conclusions of the original safety assessment.

ANNEX: ASSESSMENT OF POSSIBLE ALLERGENICITY

SECTION 1 — INTRODUCTION

1. All newly expressed proteins[13] in recombinant-DNA animals that could be present in the final food should be assessed for their potential to cause allergic reactions. This should include consideration of whether a newly expressed protein is one to which certain individuals may already be sensitive as well as whether a protein new to the food supply is likely to induce allergic reactions in some individuals.

2. At present, there is no definitive test that can be relied upon to predict allergic response in humans to a newly expressed protein, therefore, it is recommended that an integrated, stepwise, case by case approach, as described below, be used in the assessment of possible allergenicity of newly expressed proteins. This approach takes into account the evidence derived from several types of information and data since no single criterion is sufficiently predictive.

3. The endpoint of the assessment is a conclusion as to the likelihood of the protein being a food allergen.

SECTION 2 — ASSESSMENT STRATEGY

4. The initial steps in assessing possible allergenicity of any newly expressed proteins are the determination of: the source of the introduced protein; any significant similarity between the amino acid sequence of the protein and that of known allergens; and its structural properties, including but not limited to, its susceptibility to enzymatic degradation, heat stability and/or, acid and enzymatic treatment.

5. As there is no single test that can predict the likely human IgE response to oral exposure, the first step to characterize newly expressed proteins should be the comparison of the amino acid sequence and certain physicochemical characteristics of the newly expressed protein with those of established allergens in a weight of evidence approach. This will require the isolation of any newly expressed proteins from the recombinant-DNA animal, or the synthesis or production of the substance from an alternative source, in which case the material should be shown to be structurally, functionally and biochemically equivalent to that produced in the recombinant-DNA animal. Particular attention should be given to the choice of the expression host, since post-translational modifications allowed by different hosts (i.e. eukaryotic vs. prokaryotic systems) may have an impact on the allergenic potential of the protein.

6. It is important to establish whether the source is known to cause allergic reactions. Genes derived from known allergenic sources should be assumed to encode an allergen unless scientific evidence demonstrates otherwise.

SECTION 3 — INITIAL ASSESSMENT

SECTION 3.1 – SOURCE OF THE PROTEIN

7. As part of the data supporting the safety of foods derived from recombinant-DNA animals, information should describe any reports of allergenicity associated with the donor organism. Allergenic sources of genes would be defined as those organisms for which reasonable evidence of IgE mediated oral, respiratory or contact allergy is available. Knowledge of the source of the introduced protein allows the identification of tools and relevant data to be considered in the allergenicity assessment. These include: the availability of sera for screening purposes; documented type, severity and frequency of allergic reactions; structural characteristics and amino acid sequence; physicochemical and immunological properties (when available) of known allergenic proteins from that source.

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[13] This assessment strategy is not applicable to the evaluation of foods where gene products are down regulated for hypoallergenic purposes.

SECTION 3.2 – AMINO ACID SEQUENCE HOMOLOGY

8. The purpose of a sequence homology comparison is to assess the extent to which a newly expressed protein is similar in structure to a known allergen. This information may suggest whether that protein has an allergenic potential. Sequence homology searches comparing the structure of all newly expressed proteins with all known allergens should be done. Searches should be conducted using various algorithms such as FASTA or BLASTP to predict overall structural similarities. Strategies such as stepwise contiguous identical amino acid segment searches may also be performed for identifying sequences that may represent linear epitopes. The size of the contiguous amino acid search should be based on a scientifically justified rationale in order to minimize the potential for false negative or false positive results.[14] Validated search and evaluation procedures should be used in order to produce biologically meaningful results.

9. IgE cross-reactivity between the newly expressed protein and a known allergen should be considered a possibility when there is more than 35% identity in a segment of 80 or more amino acids (FAO/WHO 2001) or other scientifically justified criteria. All the information resulting from the sequence homology comparison between the newly expressed protein and known allergens should be reported to allow a case-by-case scientifically based evaluation.

10. Sequence homology searches have certain limitations. In particular, comparisons are limited to the sequences of known allergens in publicly available databases and the scientific literature. There are also limitations in the ability of such comparisons to detect non-contiguous epitopes capable of binding themselves specifically with IgE antibodies.

11. A negative sequence homology result indicates that a newly expressed protein is not a known allergen and is unlikely to be cross-reactive to known allergens. A result indicating absence of significant sequence homology should be considered along with the other data outlined under this strategy in assessing the allergenic potential of newly expressed proteins. Further studies should be conducted as appropriate (see also sections 4 and 5). A positive sequence homology result indicates that the newly expressed protein is likely to be allergenic. If the product is to be considered further, it should be assessed using serum from individuals sensitised to the identified allergenic source.

SECTION 3.3 – PEPSIN RESISTANCE

12. Resistance to pepsin digestion has been observed in several food allergens; thus a correlation exists between resistance to digestion by pepsin and allergenic potential.[15] Therefore, the resistance of protein to degradation in the presence of pepsin under appropriate conditions indicates that further analysis should be conducted to determine the likelihood of the newly expressed protein being allergenic. The establishment of a consistent and well-validated pepsin degradation protocol may enhance utility of this method. However, it should be taken into account that a lack of resistance to pepsin does not exclude that the newly expressed protein can be a relevant allergen.

13. Although the pepsin resistance protocol is strongly recommended, it is recognized that other enzyme susceptibility protocols exist. Alternative protocols may be used where adequate justification is provided[16].

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[14] It is recognized that the 2001 FAO/WHO consultation suggested moving from 8 to 6 identical amino acid segments in searches. The smaller the peptide sequence used in the stepwise comparison, the greater the likelihood of identifying false positives, inversely, the larger the peptide sequence used, the greater the likelihood of false negatives, thereby reducing the utility of the comparison.

[15] The method outlined in the U.S. Pharmacopoeia (1995) was used in the establishment of the correlation (Astwood *et al*. 1996).

[16] Report of the Joint FAO/WHO Expert Consultation on Allergenicity of Foods Derived from Biotechnology (2001): Section "6.4 Pepsin Resistance".

SECTION 4 — SPECIFIC SERUM SCREENING

14. For those proteins that originate from a source known to be allergenic, or have sequence homology with a known allergen, testing in immunological assays should be performed where sera are available. Sera from individuals with a clinically validated allergy to the source of the protein can be used to test the specific binding to IgE class antibodies of the protein in *in vitro* assays. A critical issue for testing will be the availability of human sera from sufficient number of individuals.[17] In addition, the quality of the sera and the assay procedure need to be standardized to produce a valid test result. For proteins from sources not known to be allergenic, and which do not exhibit sequence homology to a known allergen, targeted serum screening may be considered where such tests are available as described in paragraph 17.

15. In the case of a newly expressed protein derived from a known allergenic source, a negative result in *in vitro* immunoassays may not be considered sufficient but should prompt additional testing, such as the possible use of skin test and *ex vivo* protocols.[18] A positive result in such tests would indicate a potential allergen.

SECTION 5 — OTHER CONSIDERATIONS

16. The absolute exposure to the newly expressed protein and the effects of relevant food processing will contribute toward an overall conclusion about the potential for human health risk. In this regard, the nature of the food product intended for consumption should be taken into consideration in determining the types of processing which would be applied and its effects on the presence of the protein in the final food product.

17. As scientific knowledge and technology evolves, other methods and tools may be considered in assessing the allergenicity potential of newly expressed proteins as part of the assessment strategy. These methods should be scientifically sound and may include targeted serum screening (i.e. the assessment of binding to IgE in sera of individuals with clinically validated allergic responses to broadly-related categories of foods); the development of international serum banks; use of animal models; and examination of newly expressed proteins for T-cell epitopes and structural motifs associated with allergens.

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[17] According to the Report of the Joint FAO/WHO Expert Consultation on Allergenicity of Foods Derived from Biotechnology (22-25 January 2001, Rome, Italy) a minimum of 8 relevant sera is required to achieve a 99% certainty that the new protein is not an allergen in the case of a major allergen. Similarly, a minimum of 24 relevant sera is required to achieve the same level of certainty in the case of a minor allergen. It is recognized that these quantities of sera may not be available for testing purposes.

[18] *Ex vivo* procedure is described as the testing for allergenicity using cells or tissue culture from allergic human subjects (Report of the Joint FAO/WHO Expert Consultation on Allergenicity of Foods derived from Biotechnology).

Appendix III

PROPOSED DRAFT ANNEX: FOOD SAFETY ASSESSMENT OF FOODS DERIVED FROM RECOMBINANT-DNA PLANTS MODIFIED FOR NUTRITIONAL OR HEALTH BENEFITS

(At Step 5/8 of the Procedure)

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[1].
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 i) introduction of a new nutrient(s) or related substance(s), or ii) alteration of either the quantity or bioavailability of a nutrient(s) or related substance(s), iii) removal or reduction of undesirable substance(s) (e.g. allergens or toxicants), or iv) alteration of the interaction(s) of nutritional or health relevance of these substances.

SECTION 2 - DEFINITION

3. The definition below applies to this Annex:

   Nutrient[2] - 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.
4. This Annex draws, where appropriate, on the definitions of key nutritional concepts to be found or to be developed in relevant Codex texts, especially those elaborated by the Codex Committee on Nutrition and Foods for Special Dietary Uses.

SECTION 3 – FOOD SAFETY ASSESSMENT

5. The Codex General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 09-1987) 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[3] 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.
6. 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[4].

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[1] Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003, paragraph 19)

[2] General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 09-1987)

[3] Paragraphs 18-21 (Safety Framework) and 48-53 (Nutrition Modification)

[4] Further guidance for susceptible and high-risk population groups is provided in paragraph 49 of the Codex Plant Guideline.

7. 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[5]. 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[6] is of great importance for the safety assessment addressed in this Annex. Those alterations identified in a plant modified to obtain nutritional or health benefits are the subject of this safety assessment.

8. Upper levels of intake for many nutrients that have been set out by some national, regional and international bodies[7] may be considered, as appropriate. The basis for their derivation should also be considered in order to assess the public health implications of exceeding these levels.

9. The safety assessment of related substances should follow a case-by-case approach taking into account upper levels as well as other values, where appropriate.

10. 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 expected or foreseeable exposure would be consistent with those historical safe levels.

11. With conventional fortification of food, typically a nutrient or a related substance is added at controlled concentrations and its chemical form is characterized. Levels of plant nutrients or related substances may vary in both conventionally bred and recombinant-DNA plants due to growing conditions. In addition, more than one chemical form of the nutrient might be expressed in the food as a result of the modification and these may not be characterized from a nutrition perspective. Where appropriate, information may be needed on the different chemical forms of the nutrient(s) or related substance(s) expressed in the portion of the plant intended for food use and their respective levels .

12. 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. If more than one chemical form of the nutrient(s) or related substance(s) is present, their combined bioavailability should be established, where appropriate.

13. Bioavailability will vary for different nutrients, and methods of testing for bioavailability 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* methods to determine bioavailability 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 animals are of limited value in assessing nutritional value or nutrient bioavailability for humans and would require careful design in order to be relevant. *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.

[5] Codex Plant Guideline, paragraph 4

[6] Codex Plant Guideline, paragraph 51

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

14. 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 expected or foreseeable consumption of that food, and any known factors that influence 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. When evaluating the exposure, it is appropriate to consider information on whether the consumption of the modified food could lead to adverse nutritional effects as compared to consumption of the food that it is intended to replace. Most, if not all, aspects of exposure assessment are not unique to recombinant-DNA plants modified for nutritional or health benefits[8].

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 Codex Plant Guideline.[9]

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 on estimation of exposure in a given population(s) [10]. When national or regional food consumption data is unavailable, food availability data may provide a useful resource[11].

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).

[8] Additional applicable guidance on dietary exposure assessment of nutrients and related substances is provided in the Report of a Joint FAO/WHO Technical Workshop on Nutrient Risk Management, 2-6 May 2005.

[9] 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

[11] Data on staple food products may also be supplemented by information from FAO Food Balance Sheets.

Appendix IV

PROPOSED DRAFT ANNEX: FOOD SAFETY ASSESSMENT IN SITUATIONS OF LOW-LEVEL PRESENCE OF RECOMBINANT-DNA PLANT MATERIAL IN FOOD

(At Step 5/8 of the Procedure)

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 the food safety assessment in such situations of low-level presence of recombinant-DNA plant material or in advance preparation for such potential circumstances[1].
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 Guideline14; countries can decide when and how to use the Annex within the context of their regulatory systems; or
   - 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.

[1] 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.

SECTION 2 – GENERAL AND OTHER CONSIDERATIONS

7. For the food safety assessment in situations of low-level presence of recombinant DNA plant materials in food, sections 4 and 5 of the Codex Plant Guideline apply as amended as follows. The applicable paragraphs are specifically indicated. Those paragraphs of the Codex Plant Guidelines that are not listed can be omitted from consideration.

DESCRIPTION OF THE RECOMBINANT-DNA PLANT

8. Paragraph 22 of the Codex Plant Guideline applies.

DESCRIPTION OF THE HOST PLANT AND ITS USE AS A FOOD

9. Paragraphs 23, 24 and 25 of the Codex Plant Guideline apply.

DESCRIPTION OF THE DONOR ORGANISM(S) DESCRIPTION

10. 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)[2].

DESCRIPTION OF THE GENETIC MODIFICATION(S)

11. Paragraphs 27, 28 and 29 of the Codex Plant Guideline apply.

CHARACTERIZATION OF THE GENETIC MODIFICATION(S)

12. Paragraphs 30 and 31 of the Codex Plant Guideline apply.

13. 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.[3]

14. Paragraph 33 of the Codex Plant Guideline applies.

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[2] The text of this paragraph was adapted from paragraph 26 of the Codex Plant Guideline.

[3] The text of this paragraph was adapted from paragraph 32 of the Codex Plant Guideline.

SAFETY ASSESSMENT

Expressed Substances (non-nucleic acid substances)

Assessment of possible toxicity

15. The safety assessment 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.[4]

16. 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.[5]

17. Paragraph 37 of the Codex Plant Guideline applies.

18. 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[6] 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.[7]

19. Paragraphs 39 and 40 of the Codex Plant Guideline apply.

Assessment of possible allergenicity (proteins)

20. Paragraphs 41, 42 and 43 of the Codex Plant Guideline apply.

Analyses of Key Toxicants and Allergens

21. Analyses of key toxicants[8] 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.[9]

[4] The text of this paragraph was adapted from paragraph 35 of the Codex Plant Guideline.

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

[6] The text of this paragraph was adapted from paragraph 36 of the Codex Plant Guideline.

[7] The text of this paragraph was adapted from paragraph 38 of the Codex Plant Guideline.

[8] 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).

[9] The text of this paragraph was adapted from paragraph 44 of the Codex Plant Guideline.

22. 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.[10]

Evaluation of Metabolites

23. 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. Food safety assessment in situations of 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).[11]

Food Processing

24. 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.[12]

POTENTIAL ACCUMULATION OF SUBSTANCES SIGNIFICANT TO HUMAN HEALTH

25. 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.[13]

USE OF ANTIBIOTIC RESISTANCE MARKER GENES

26. Paragraphs 55, 56, 57 and 58 of the Codex Plant Guideline apply.

SECTION 3 – GUIDANCE ON DATA AND INFORMATION SHARING

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

28. Codex Members should make available to a publicly accessible central database to be maintained by FAO information on recombinant-DNA plants authorized in accordance with the Codex Plant Guideline. This information should be presented in accordance with the following format:

    a. name of product applicant;

    b. summary of application;

[10] The text of this paragraph was adapted from paragraph 45 of the Codex Plant Guideline.

[11] The text of this paragraph was adapted from paragraph 46 of the Codex Plant Guideline.

[12] The text of this paragraph was adapted from paragraph 47 of the Codex Plant Guideline.

[13] The text of this paragraph was adapted from paragraph 54 of the Codex Plant Guideline.

c. country of authorization;

d. date of authorization;

e. scope of authorization;

f. unique identifier;

g. links to the information on the same product in other databases maintained by relevant international organizations, as appropriate;

h. summary of the safety assessment, which should be consistent with the framework of food safety assessment of the Codex Plant Guideline;

i. where detection method protocols and appropriate reference material (non-viable, or in certain circumstances, viable) suitable for low-level situation may be obtained[14]; and

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

29. This process should facilitate rapid access by importing Codex Members to additional information relevant to the assessment of food safety assessment in situations of low-level presence of recombinant-DNA plant material in foods in accordance with this Annex.

30. The authorizing Codex Members should make available complementary information to other Codex Members on its safety assessment in accordance with the Codex Plant Guideline, in conformity with its regulatory/legal framework.

31. The product applicant should 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 suitable for low level situations and appropriate reference materials (non-viable, or in certain circumstances, viable). This is without prejudice to legitimate concerns to safeguard the confidentiality of commercial and industrial information.

32. 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 Codex member should be made available.

[14] This information may be provided by the product applicant or in some cases by Codex members.