codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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ALINORM 07/30/34

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Thirtieth Session
Rome, Italy, 2 - 7 July 2007

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

Chiba, Japan, 27 November – 1 December 2006

Note: This document incorporates Circular Letter CL 2006/54-FBT

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CX 4/80.2 **CL 2006/54-FBT**
December 2006

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 Sixth Session of the Codex *ad hoc* Intergovernmental Task Force on Foods Derived from Biotechnology (ALINORM 07/30/34) and Request for Comments on the Proposed Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals**

The Report of the Sixth Session of the Codex *ad hoc* Intergovernmental Task Force on Foods derived from Biotechnology is attached. It will be considered by the Thirtieth Session of the Codex Alimentarius Commission (Rome, Italy, 2-7 July 2007).

REQUESTS FOR COMMENTS

The Task Force agreed to return the section on "Use of Antibiotic Resistance Marker Genes" (paragraphs 64-67) of the Proposed Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals to Step 3 for comments (see ALINORM 07/30/34 para. 50 and Appendix III).

Governments and interested international organizations wishing to submit their comments should do so, preferably by E-mail, to Dr Nakabayashi Keiichi, Counselor, Minister's Secretariat, Ministry of Health, Labour and Welfare. 1-2-2 Kasumigaseki, Chiyoda-ku 100-8916 Tokyo, Japan (Fax: +81 3 3503 7965; Email: codexj@mhlw.go.jp), with a copy to the Secretary of the Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Viale delle Terme di Caracalla, 00153 Rome, Italy (Fax No.: +39-06-570-54593; Email: codex@fao.org; Fax +39 06 570 54593) **no later than 30 June 2007**.

SUMMARY AND CONCLUSIONS

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

Matters for Consideration by the Commission

The Task Force agreed to forward the project document contained in Appendix IV, through the Executive Committee for critical review, to the 30th Session of the Commission for approval of new work to develop 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 (para. 77 and Appendix IV).

Matters of Interest to the Commission

The Task Force:

- agreed to return the section on "Use of Antibiotic Resistance Marker Genes" (paragraphs 64-67) to Step 3 for comments and hold the remaining sections of the Proposed Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals at Step 4 (paras 50-51 and Appendix III);

- agreed to return the proposed draft Annex to the Guideline for the Conduct of Foods Safety Assessment of Foods Derived from Recombinant-DNA Plants: Food Safety Assessment of Foods Derived from Recombinant-DNA Plants Modified for Nutritional or Health Benefits to Step 2 for further drafting by a physical working group. The proposed draft Annex, prepared by the working group, would be circulated for comments at Step 3 and be considered by the next session of the Task Force at Step 4 (para. 59).

Matters of Interest to Other Codex Committees and Task Forces

The Task Force agreed that the matter on safety assessment of foods derived from animals exposed to protection against diseases through gene therapy or recombinant-DNA vaccines be referred to the Committee on Residues of Veterinary Drugs in Foods for information and advice as appropriate (para. 71).

Other Matters

The Task Force:

- agreed to monitor the progress of the ongoing work by OIE with respect to food safety relating to foods derived from animals exposed to protection against diseases through gene therapy or recombinant-DNA vaccines. In this regard, the Task Force decided to request the Codex Secretariat to liaise with OIE so that a report of OIE's activities in this area would be submitted to the next session of the Task Force, while informing OIE of the expectation of the Task Force on the ongoing work of the *ad hoc* Group (para. 71);

- agreed to forward those questions regarding marker and reporter gene and non-heritable applications to FAO and WHO for scientific advice (para. 45 and Appendix II).

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INTRODUCTION

1. The Codex *ad hoc* Intergovernmental Task Force on Foods Derived from Biotechnology held its Sixth Session in Chiba, Japan, from 27 November to 1 December 2006, 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 182 delegates representing 40 members of the Commission and 5 international intergovernmental and 12 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. Naohito Takahashi, Director-General, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare, who welcomed the participants to Chiba and wished a successful meeting. The Representatives of FAO and WHO also welcomed the participants.

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

3. The Task Force agreed to amend the Provisional Agenda and include, as a new Item 9, the proposal of the United States to discuss the issue on food safety assessment of the low level presence of recombinant-DNA plant material in food resulting from asynchronous authorizations.

4. The Task Force adopted the amended Agenda as the Agenda of the Session with the addition of the item as mentioned above and renumbering the Provisional Agenda Items 9 through 11 as new Items 10 through 12.

5. The Task Force noted that the declaration of the division of competence between the European Community and its Member States, as presented in CRD 1.[2]

MATTERS REFERRED TO THE TASK FORCE BY THE COMMISSION AND THE OTHER CODEX COMMITTEES (Agenda Item 2)[3]

6. The Task Force noted the information presented in document CX/FBT 06/6/2 concerning the matters of interest to the Codex *ad hoc* Intergovernmental Task Force on Foods Derived from Biotechnology arising from the 29th Session of the Codex Alimentarius Commission and the recent sessions of other Codex Committees.

7. The Delegation of European Community recalled the work underway in CCMAS on the detection and identification of foods derived from biotechnology and encouraged this committee to intensify its work on this agenda item.

REVIEW OF THE WORK BY INTERNATIONAL INTERGOVERNMENTAL ORGANIZATIONS RELATED TO FOODS DERIVED FROM BIOTECHNOLOGY (Agenda Item 3)[4]

8. The Task Force noted the information presented in document CX/FBT 06/6/3 and CRD 16 submitted by several international intergovernmental organizations concerning their work related to foods derived from biotechnology.

9. The Codex Secretariat drew the attention of the Task Force to the written contribution from the Secretariat for the Convention on Biological Diversity (CBD). The Task Force noted that the Third meeting of the Conference of the Parties serving as the meeting of the Parties to the Biosafety Protocol (COP-MOP 3) had agreed on the detailed requirements for documentation accompanying shipments of living modified organisms intended for direct use as food or feed, or for further processing. The Task Force also noted that

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1 CX/FBT 06/6/1; CX/FBT 06/6/1-Add.1

2 The Task Force was informed that the division of competence for Agenda Item 9 of the adopted agenda should read: European Community competence – European Community vote.

3 CX/FBT 06/6/2

4 CX/FBT 06/6/3; CRD 16 (Information from OIE)

COP-MOP3 requested the Executive Secretary of CBD to continue pursuing, reinforcing, and intensifying cooperative arrangements with several international organizations including Codex.

10. The Representative of FAO highlighted a number of activities carried out by FAO or jointly with WHO, which included the development of several tools, such as an FAO/WHO guidance document aimed at assisting countries to implement Codex food safety assessment guidelines, technical assistances to countries, as well as the development of networks for information exchange among public and private entities in charge of biosafety at the regional level. The Representative also informed that the Organization was, in cooperation with WHO, prepared to hold an expert consultation in order to provide scientific advice on specific issues which would be identified by the Task Force at the present session.

11. The Representative of WHO stated that it had been carrying out a number of activities in the field of biotechnology and human health, among which only those related with biotechnology in food production were explained in its written contribution contained in CX/FBT 05/5/3. The Representative further mentioned that all detailed information on the activities of the Organization in this field at the national and regional levels was available at the WHO website.

12. The Representative of the Organisation of the Economic Cooperation and Development (OECD), referring to the written submission, highlighted some of the activities undertaken by the OECD Task Force for the Safety of Novel Foods and Feeds. Recently, non-OECD member countries were actively participating in the work of the Task Force, including development of consensus documents of particular importance to developing countries, such as on papaya and cassava. Furthermore, work was started on the updating of consensus documents which had already been published, in the light of new scientific information; the Working Group on Harmonization of Regulatory Oversight in Biotechnology revised the OECD Guidance for the Designation of a Unique Identifier for Transgenic Plants; and a new version of OECD's database of products of modern biotechnology approved for commercial application was launched.

13. The Representative of the World Organization for Animal Health (OIE) informed the Task Force that the OIE *ad hoc* Group on Biotechnology had started to work on reproductive animal biotechnologies, on vaccines and on nanotechnology. The *ad hoc* Group also revised the draft chapter on principles of veterinary vaccine production in the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals. Recently, the terms of reference of the Group had been revised to include development of guidelines on the animal health risks arising from somatic cell nuclear transfer (SCNT) cloning of production animals and guidelines for new vaccine technologies, monitoring of developments on nanotechnology and advising the OIE on suitable procedures for the identification and tracing of animals and animal products resulting from biotechnology interventions. While current emphasis of work was placed on the development of guidelines on SCNT cloning in livestock, the Group was addressing vaccine-related issues as well.

14. The Delegation of European Community thanked the international organizations for their activities complementing the work of the Codex Task Force, and encouraged these organizations, especially OECD, to strengthen programmes related to information gathering and sharing.

PROPOSED DRAFT GUIDELINE FOR THE CONDUCT OF FOOD SAFETY ASSESSMENT OF FOODS DERIVED FROM RECOMBINANT-DNA ANIMALS (Agenda Item 4)[5]

15. The Task Force recalled that at its Fifth Session it had agreed to establish a physical working group, co-chaired by Australia and Japan, to elaborate a proposed draft guideline for the conduct of food safety assessment of foods derived from recombinant-DNA animals (hereinafter referred to as "the proposed draft guideline") and that the proposed draft guideline contained in CL 2006/27-FBT was circulated for comments at Step 3, prior to consideration at Step 4 at its current session.

16. The Delegation of Australia, speaking on behalf of the co-chairs of the working group and referring to the report of the working group, highlighted some major points as follows: i) it was agreed to use the existing plant guideline as a template in elaborating the proposed draft guideline; ii) it was also agreed to follow an approach whereby deviations from the language in the plant guideline be made only when scientifically justified on the basis of biological differences between plants and animals; and iii) the working group

[5] CL2006/27-FBT; CX/FBT06/6/4; CRD 7 (Comments from CI); CRD 9 (Comments of Thailand); CRD 10 (Comments of Philippines); CRD 11 (Comments of South Africa); CRD 12 (Comments of Iran); CRD 14 (Comments of Republic of Korea)

recognized that the Fifth Session of the Task Force had agreed that the initial work would focus on developing a guideline for recombinant-DNA animals in general.

17. The Task Force congratulated the working group for its achievement and agreed to consider the proposed draft guideline contained in Annex 1 to the report of the working group, paragraph by paragraph. In doing so, the Task Force paid particular attention to those parts kept in square brackets for which the working group could not reach conclusion or consensus.

18. The Task Force agreed to ensure terminological consistency throughout the proposed draft guideline; a phrase "used as food" was replaced with "used as food or for food production" in several paragraphs, in addition to other editorial changes. Other discussion held and amendments agreed upon on specific paragraphs are as follows.

Paragraph 2

19. The Task Force had intensive discussion on this paragraph of the proposed draft guideline, which contained five different options in square brackets. There were diverse views among members on which option would be the most appropriate and on the reasoning behind.

20. Several delegations and observers supported Option 2 as, in their view, it clearly articulated the legitimate factors to be taken into account by Codex members in the decision making process. These delegations and observers also proposed to maintain the third bullet under the paragraph and to delete the word "exclusively", in order to stress that the proposed draft guideline should not address the animals developed for pharmaceutical or other non-food uses and that these animals should not enter the food chain. The Representative of European Community highlighted that there was no intension in the EU to develop guidelines for the assessment of recombinant-DNA animals for pharmaceutical uses in relation to foods.

21. Some other delegations were of the opinion that there was no rationale to discriminate between plant and animals in this paragraph, therefore proposed to adopt Option 3 to ensure consistency with the plant guideline.

22. Several other delegations supported Options 4 because its chapeau part did not contain statements on the importance, legitimacy or need for other bodies or instruments to address non food safety-related factors associated, or potentially associated, with recombinant-DNA animals. Some of these delegations proposed to maintain all the bullet points. The other delegations proposed deletion of the third bullet point because there might be legitimate circumstances in which a country might wish to apply a food safety assessment to recombinant-DNA animals intended for non-food purposes. There was a divergence of views as to whether to maintain the term "exclusively" if the third bullet was retained.

23. After a lengthy discussion, the Task Force agreed, as a compromise, to the text in Option 5 by deleting the word "additional" from the chapeau part and deleting the third bullet point.

24. The Task Force noted that, with the solution reached, the document would remain silent as to whether the guideline could be applied to the safety assessment of food derived from recombinant-DNA animals intended to non-food use and that it was entirely up to member countries to decide on the most appropriate approach.

Paragraph 16

25. The Task Force considered whether the two sentences in square brackets should be retained as proposed by several delegations, while noting that the working group was of the view that consideration of secondary metabolites was not always required in the context of recombinant-DNA animals.

26. After some discussion, the Task Force agreed to retain the first sentence, and delete the second sentence, which was felt as overly descriptive, as proposed by the Representative of OIE.

Paragraph 27

27. The Task Force agreed to change the word "if" to "whether" under sub paragraph A) for clarity in English version.

Title over paragraphs 31-35

28. The Task Force agreed to amend the title over paragraphs 31-35 to bring it in line with the provisions of these paragraphs.

Paragraph 37 C)

29. Several delegations and one observer were of the view that full molecular characterization of inserted materials and other relevant information at each insertion site including surrounding regions should be provided, and, if applicable, other information such as analysis of transcripts with a view to appropriately conducting safety assessment of recombinant-DNA animals in accordance with paragraph 36 of the proposed draft guideline. These delegations were in favour of retaining the text added in square brackets.

30. Several other delegations proposed the deletion of the texts in square brackets on the ground that the provisions should remain as the same as in the plant guideline except where scientifically justified on the basis of biological differences between plants and animals.

31. After some discussion, the Task Force agreed to delete all the text in square brackets and amend the phrase, in conjunction with the second set of square brackets, to read "or where scientifically more appropriate".

Paragraph 38

32. The Task Force agreed to insert a word "newly" in the chapeau sentence for clarity and delete the reference to milk and eggs as examples in point D of this paragraph and in paragraph 45, as such explanation was unnecessary in the guideline applied to animals in general.

Paragraph 39

33. The Task Force noted that the working Group did not have time to discuss the square-bracketed text. Several delegations suggested to retain the square bracketed sentence, however, the Task Force agreed to the deletion of the text, in view of the scope of the guideline applicable to all animals. The Task Force however noted the view of the delegations supporting the retention of the text that the examining of new traits under more than one typical husbandry condition might be relevant to recombinant-DNA fish in particular.

Paragraph 42

34. In reply to a proposal to insert a reference to susceptibility to disease, the Task Force agreed that the concept was already covered by Bullets A and B and therefore there was no need to amend the text.

Paragraph 63

35. For clarity, the Task Force agreed to modify the final sentence of this paragraph to state that the safety assessment should take the potential for these alterations into account. Insertion of a reference to shedding of pathogens was made to the second sentence.

Paragraphs 64 - 67

36. The Delegation of the European Community expressed the view that the use of antibiotic-resistance marker genes should be excluded in the recombinant-DNA animals with a view to addressing safety concerns in relation to the integration of transgenes derived from inserted antibiotic-resistance marker genes into the animal genome and proposed to revisit these paragraphs for further discussion after the outcome of an expert consultation to be convened in early 2007 become available.

37. The Delegation of Canada expressed the view that, at the working group discussions, agreement to the two sets of questions being proposed for the expert consultation was based on the understanding that due to the nature of these questions, the outcome of the consultation should not affect the content of the proposed draft guideline. Other delegations were of the view that the current text did not require revision at this moment because no scientific justification existed to apply criteria different from those in the plant guideline.

38. The Task Force agreed that it would consider the need to further work on these paragraphs at its next session, prior to which the report of the expert consultation should be circulated.

Annex: Assessment of possible allergenicity

39. The Task Force agreed to the annex attached to the proposed draft guideline "Assessment of Possible Allergenicity", noting that the text in the annex was identical to that attached to the plant guideline, with the exception of the deletion of references to gluten sensitivity, which was considered as not relevant to the safety assessment of recombinant-DNA animals.

QUESTIONS TO BE ADDRESSED TO AN FAO/WHO EXPERT CONSULTATION[6]

40. The Delegation of Australia, on behalf of the co-chairs of the working group, referring to the report of the working group, noted that the three questions[7] raised at the Fifth Session of the Task Force had adequately been addressed during the course of elaboration of the proposed draft guideline and did not require further consideration by an expert consultation. This view was confirmed by the Task Force.

41. The Task Force was invited to consider two sets of questions listed in Annex 2 of the report of the working group on: i) marker and reporter genes; and ii) non-heritable applications, with a view to forwarding them to FAO and WHO for scientific advice.

42. Some delegations and one observer, referring to CRD 2 prepared by Argentina, in collaboration with Brazil and Norway, expressed the view that some new scientific information had become available since the Codex guidance on the assessment of allergenicity was adopted and that it was necessary to review the relevant information and to assess the need for revision of the annex on allergenicity attached to the proposed draft guideline as well as the two adopted guidelines on recombinant-DNA plants and on recombinant-DNA microorganisms. These delegations requested that scientific advice be sought on the advances made in the assessment of allergenicity in terms of bioinformatics methods, *in vivo* and *ex vivo* methods and on how to take into account the effect of food processing. They also requested expert advice as to whether consideration should be given to expressed substances which might act as adjuvants.

43. Some other delegations, noting the importance of allergenicity assessment for assuring the safety of foods derived from recombinant-DNA organisms, were of the view that it was not clear whether the evidence and information that became available since the last FAO/WHO expert consultation in 2001 was such that the recommendations of the previous expert consultations should be revisited right now. Several delegations pointed out that it might be difficult for FAO and WHO to address at once a large number of questions covering distinct areas and requiring different expertise.

44. The Representative of FAO, speaking on behalf of FAO and WHO, recognized practical difficulties in addressing those diverse and complex questions together at a single expert consultation and requested the Task Force to prioritize the questions so that an expert consultation to be convened in early 2007 could address the most urgent ones and provide scientific advice required for further development of the proposed draft animal guideline within the agreed timeframe of the Task Force. The Representative also indicated that it might be possible to convene another expert consultation at an appropriate time during the next biennium (2008-2009) to address other questions including issues related to allergenicity.

45. After some discussion, the Task Force agreed to forward only those questions regarding marker and reporter gene and non-heritable applications to FAO and WHO for scientific advice. The list of questions is attached to the present report as Appendix II.

46. The Task Force noted that the background information on non-heritable applications as contained in CRD 2 would be provided as a working document to the forthcoming expert consultation.

47. The Task Force agreed that all the questions on the list should be addressed by the expert consultation in the context of the food safety assessment of recombinant-DNA animals used as food or for food production, while some delegation noted that there would be no impediment for the expert consultation to consider, where appropriate, horizontal aspects of the questions related to non-heritable construct as the technology could also be potentially applied to plants.

48. The Task Force noted, with satisfaction, that all square brackets had been removed from the proposed draft guideline and all the sections were finalized from a technical point of view and were ready, in principle, for adoption by the Commission, with the exception of paragraphs 64-67. The Task Force expressed their appreciation of the excellent work of the working group co-chaired by Australia and Japan in developing this document.

49. There was extensive discussion about the advancing of the document to reflect the achievement of the Task Force. Several delegations supported advancing the document to Step 5/8 with recommendation of omitting Steps 6 and 7, while other delegations were in favour of taking a more cautious approach.

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6 CRD 2 (Comments of Argentina)

7 ALINORM 06/29/34, para. 27

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

50. The Task Force agreed to return the section on "Use of Antibiotic Resistance Marker Genes" (paragraphs 64-67) to Step 3 for comments and hold the remaining sections of the proposed draft guideline at Step 4. The Proposed Draft Guideline, as amended by the current session, is attached to the present report as Appendix III.

51. The Task Force noted that at its next Session, discussion should focus on: i) the section of the Use of Antibiotic Resistance Marker Genes (paragraphs 64-67); and ii) any other amendments necessary to accommodate non heritable applications, if possible and appropriate, fully taking into account the outcome of the forthcoming expert consultation.

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 OR HEALTH BENEFITS (Agenda Item 5)[8]

52. The Task Force recalled that the Fifth Session of the Task Force had decided to initiate new work on the development of an annex to the Plant Guideline, which would provide further guidance on the food safety assessment of foods derived from recombinant-DNA plants modified for nutritional or health benefits, and to establish an electronic working group led by Canada to formulate a scoping document to be presented at the present session. The Task Force further recalled that the new work was subsequently approved by the Commission.

53. The Delegation of Canada introduced the report of the electronic working group contained in CX/FBT 06/6/5 and briefly explained the process by which the scoping document contained in the Appendices to the document was prepared. Many delegations expressed their appreciation to the work by the electronic working group and to Canada's contribution to this process, recognized the prospective value of the proposed draft Annex and agreed to further proceed with the work, preferably through the establishment of a physical working group. The Task Force noted that there was general agreement on pursuing the work on the basis of the proposed structure for the Annex and invited delegations to provide further comments on the scoping document.

54. Several delegations stated that the special reference to developing countries in the context of stability of the level of expression of a particular trait was inappropriate, as the most important factor was the agro-ecological conditions of the place in question and not the development status of the country concerned.

55. The Delegation of Argentina, supported by other delegations of the countries in Latin America and the Caribbean Region, proposed that the Annex should address not only staple crops but all crops and should not introduce differences in food safety assessment guidance for developing versus developed countries.

56. The Delegation of the European Community, referring to its written comments contained in CX/FBT 06/6/5-Add.1, highlighted the importance of (1) comparative animal feeding study and (2) selection of the most appropriate comparator. In this regard, the ongoing work by the European Food Safety Authority would be of interest to the Task Force. The Delegation of Germany suggested that in certain cases post-market monitoring may also be useful.

57. The Delegation of Mexico, referring to the provisions of paragraph 20 of the Principles for the Risk Analysis of the Foods Derived from Modern Biotechnology (CAC/GL 44-2003), pointed out that any risk assessment might leave scientifically-founded doubts as to nutrient intake estimate and identification of health risks and benefits, which could not necessarily be verified prior to the entry into market of the products, and that further study, including post-market monitoring, might be required where such approach was scientifically justified.

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[8] CX/FBT 06/6/5; CX/FBT 06/6/5-Add. 1 (Comments of Argentina, Australia, Costa Rica, European Community, Japan, Kenya, Mexico, New Zealand and the United States of America); CRD 9 (Comments of Thailand); CRD 10 (Comments of Philippines); CRD 11 (Comments of South Africa); CRD 12 (Comments of Iran); CRD 15 (Comments of Indonesia)

58. The Delegation of New Zealand pointed out that the Annex was being developed as part of the safety assessment guideline and that the outcome of this new work should support the existing guideline.

Status of the 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 or Health Benefits

59. The Committee agreed to return the proposed draft Annex to Step 2 for further drafting by a physical working group led by Canada, co-chaired by Argentina and New Zealand, and open to all the members and observers[9]. The working group would prepare the proposed draft Annex to the Plant Guideline on the basis of the report of the previous electronic working group and the comments at Step 3 contained in documents CX/FBT 06/6/5 and CX/FBT 06/6/5-Add.1, as well as comments provided during the present Session. The working group, which would probably meet in Ottawa in early April 2007, would work primarily in English, however, subject to the availability of resources, translation of the working documents into French and Spanish would be considered. The proposed draft Annex, prepared by the working group, would be circulated for comments at Step 3, well in advance of the next Session of the Task Force, and be considered by the next session of the Task Force at Step 4.

DISCUSSION PAPER ON COMPARATIVE FOOD COMPOSITION ANALYSIS OF STAPLE FOODS (Agenda Item 6)[10]

60. The Delegation of India, referring to working document CX/FBT 06/6/6, explained the background, objectives and expected benefits of the proposal. The Delegation observed that there were the limitations in existing knowledge on compositional analysis of genetically engineered staple crops, namely macro- and micro-nutrients, inherent plant toxins, anti-nutrients, plant metabolites and allergens. The Delegation was of the view that the absence of globally acceptable analytical methods for food consumption analysis constituted an obstacle to conducting these analyses.

61. The Representative of OECD informed the Task Force that the OECD had already produced a number of consensus documents containing compositional and other relevant information for the staple crops listed in the annex of document CX/FBT 06/6/3, including wheat, maize and rice, and that the OECD Task Force had started discussion on how to update these documents to make them more complete. The Representative welcomed increasing participation of non OECD members in the work of the OECD Task Force on consensus documents.

62. The Representative of FAO stated that under the coordination of the International Network of Food Data Systems (INFOODS), FAO had produced a number of food composition tables using data from different parts of the world and that these were available to all members of FAO. The Representative suggested that Codex should not duplicate the existing or ongoing work of other international organizations. The Task Force also noted that a number of methods of analysis for nutrients were already included in the Codex Alimentarius and other international publications.

63. After some discussion, the Task Force decided not to initiate new work in this area.

DISCUSSION PAPER ON SANITARY SURVEILLANCE AFTER PLACING ON THE MARKET OF FOODS DERIVED FROM BIOTECHNOLOGY (Agenda Item 7)[11]

64. The Delegation of Mexico, referring to working document CX/FBT 06/6/7, explained that the objective of the proposed new work project was to collect scientific information which could support and complement risk assessment of food derived from biotechnology when there was a scientifically founded doubt. However, recognizing that the work on the "proposed draft Annex to the Guideline for the Conduct of

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9 The following members and observers expressed their interest in taking part in the working group: Argentina, Australia, Belgium, Brazil, Canada, China, European Community, France, Germany, India, Italy, Japan, Mexico, New Zealand, Norway, Paraguay, Philippines, Republic of Korea, South Africa, Sweden, Thailand, United States of America, 49P, BIO, CI, CropLife International, ETA, EUROPABIO and IICA

10 CX/FBT 06/6/6; CRD 3 (comments of Mexico); CRD 11 (comments of South Africa); CRD 12 (comments of Iran); CRD 15 (comments of Indonesia)

11 CX/FBT 06/6/7; CRD 4 (Comments of Kenya and Peru); CRD 11 (Comments of Mexico); CRD12 (Comments of Iran); CRD 15 (Comments of Indonesia)

Food Safety Assessment of Foods Derived from Recombinant-DNA Plants: Food Safety Assessment of Foods Derived from Recombinant-DNA Plants Modified for Nutritional or Health Benefits" had already started, the Delegation considered that it was not appropriate to start new work until being able to analyse the result of the already initiated work.

65. The Task Force, noting that the matter could be covered, at least partly, by another ongoing work of the Task Force (see Agenda Item 5 of the present report), decided not to initiate new work.

DISCUSSION PAPER ON SAFETY ASSESSMENT OF FOODS DERIVED FROM ANIMALS EXPOSED TO PROTECTION AGAINST DISEASES THROUGH GENE THERAPY OR RECOMBINANT-DNA VACCINES (Agenda Item 8)[12]

66. The Task Force recalled that the Fifth Session of the Task Force had considered the proposal by Kenya on future work for the safety assessment of foods derived from animals exposed to protection against diseases through gene therapy or recombinant-DNA vaccines and had decided to invite Kenya to submit a discussion paper to the present session in order to further consider the matter, noting that OIE had ongoing work on the application of these techniques[13].

67. The Delegation of Kenya introduced document CX/FBT 06/6/8 to the Task Force and stressed that possible risks to human health by the application of these techniques should be carefully examined although the possibility of such occurrences might be very low. The Delegation further pointed out that the activities of OIE were centred on animal health and may not address the food safety aspects and that this should therefore be addressed by Codex.

68. The Task Force expressed its appreciation to the contribution of Kenya in developing the discussion paper.

69. The Task Force noted that the subgroup of vaccine established under the OIE *ad hoc* Group on Biotechnology was working in this area and that the mandate of OIE included food safety aspects as they relate to animal health. The Task Force further recalled its earlier decision to include the "non-heritable applications" in the questions addressed to the FAO/WHO expert consultation to be held in early 2007, which could partly cover the issues in question.

70. While some delegations recognized that there was certain information gap to be filled in this area, several delegations believed that the proposed work would be more appropriately done by OIE and did not support the work by the Task Force. Some delegations believed that there was no clear justification for dealing with recombinant-DNA vaccines differently from the conventional ones and that the approval system for pharmaceuticals usually had regard to the food safety dimension.

71. After some discussion, the Task Force decided not to initiate the new work for the present and agreed to monitor the progress of the ongoing work by OIE with respect to food safety aspects. In this regard, the Task Force decided to request the Codex Secretariat to liaise with OIE so that a report of OIE's activities in this area would be submitted to the next session of the Task Force, while informing OIE of the expectation of the Task Force on the ongoing work of the *ad hoc* Group. The Task Force further agreed that this matter also be referred to the Committee on Residues of Veterinary Drugs in Foods for information and advice as appropriate.

DISCUSSION PAPER ON FOOD SAFETY ASSESSMENT OF THE LOW-LEVEL PRESENCE OF RECOMBINANT-DNA PLANT MATERIAL IN FOOD RESULTING FROM ASYNCHRONOUS AUTHORIZATIONS (Agenda Item 9)[14]

72. The Delegation of the United States, referring to document CX/FBT 06/6/1 Add.1, provided a brief account of the proposal, whose objective would be to provide guidance on the food safety assessment of

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12 CX/FBT 06/6/8; CRD 5 (Comments of Argentina, Kenya, Mexico, and the United States of America); CRD 11 (Comments of South Africa); CRD 12 (Comments of Iran); CRD 15 (Comments of Indonesia)

13 ALINORM 06/29/34, paras 63-66

14 CX/FBT 06/6/1-Add.1; CRD 6 (Comments of Mexico); CRD 8 (Comments from CI); CRD 10 (Comments of Philippines); CRD 11 (Comments of South Africa); CRD 13 (Comments of EC); CRD 17 (Proposed project document prepared by the in-session physical working group); CRD 18 (Draft terms of reference prepared by the in-session physical working group)

foods derived from recombinant-DNA plants in which those plants have already been authorized in one or more countries for commercialization for food use based on an assessment according to the Codex Guideline for the Conduct of Food Safety Assessment of Food Derived from Recombinant-DNA Plants (CAC/GL 45-2003), but are unintentionally present in low levels in food in countries in which the recombinant-DNA plants are not authorized.

73. Many delegations strongly recommended that new work be started by the Task Force in this area. The Delegation of the European Community explained that it already had a comprehensive legal framework governing the assessment of recombinant-DNA material in plants, whereby the presence of unauthorized adventitious material at whatever level is illegal. It could only agree to work commencing subject to the condition outlined in CRD 13. Moreover it considered that the focus of any such work should be on strengthening data and information sharing mechanisms. The Delegation of Mexico did not support the content of the proposal from the United States because importing countries' concerns with regard to the contamination with recombinant-DNA plants that were unauthorized by any regulatory authority were not adequately addressed. However recognizing the importance of the subject, the delegation supported the beginning of work provided that the countries' concerns from regulatory point of view would be reflected and these national concerns were shared by other delegation. Some delegations and observers objected to the use of the term "asynchronous" since the term implied that the recombinant-DNA plant in question would later be authorized by both exporting and importing countries. Instead, it was proposed to refer to "asymmetric authorizations". Some observers stated that there was no need for new work by Codex since the framework of the Convention on Biological Diversity and its Biosafety Clearing-House already provided useful instruments for information sharing on modified food plants, and the occurrence of adventitious presence of unauthorized recombinant-DNA plant material in food was primarily a legal and not a scientific issue.

74. Several delegations were of the opinion that the establishment of mechanisms for data sharing and information exchange would be a key to ensuring the food safety in situations of the low-level presence of unauthorized recombinant-DNA plants. The Delegation of New Zealand expressed the view that the Biosafety Clearing-House did not serve this purpose as it had been designed to deal exclusively with living modified organisms. The Delegation of the European Community pointed out that there was less than satisfactory progress in constructing databases and relevant mechanisms to make information available for this purpose and there was the need to share, among regulatory authorities, relevant information including detection methods, molecular characterizations and testing protocols. Other delegations also pointed out that the need for information on detection methods and reference materials.

75. The Representative of FAO indicated that FAO was prepared to consult with other international bodies such as CBD and OECD, as well as industry consortiums with a view to designing and establishing a data-sharing mechanism while giving due considerations to the protection of confidential information. Several observers representing developers of recombinant-DNA plants expressed their willingness and commitment to contributing to information sharing mechanisms by providing relevant food safety data and information that has been previously reviewed by the country or countries that have satisfactorily completed their food safety assessment. In this context, reference was also made to the ILSI database.

76. To reach consensus on the scope and other content of the project document for new work, the Task Force agreed to establish an in-session physical working group[15]. The working group submitted a revised project document contained in CRD 17, on the basis of which the Task Force pursued its deliberation.

77. After some discussion, during which some editorial and other amendments were made, the Task Force agreed on a project document for future work: 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 and agreed to forward the project document (attached to this report as Appendix IV) to the Executive Committee for critical review and for approval by the next Session of the Commission in July 2007.

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[15] Chaired by the United States of America. The following members and observers participated in the in-session physical working group: Argentina, Australia, Austria, Belgium, Canada, Brazil, Chile, China, Costa Rica, Denmark, European Community, Finland, France, Germany, Iran, Japan, Kenya, Thailand, Mexico, New Zealand, Nigeria, Norway, Paraguay, Philippines, Republic of Korea, South Africa, Sweden, Switzerland, the United States of America, 49P, BIO, CI, CropLife International, ETA, EUROPABIO, ICA and IICA.

78. In order to proceed with the elaboration of the proposed draft Annex without delay and to complete the work within the timeframe of the Task Force, the Task Force agreed to establish a physical working group on low-level presence of recombinant-DNA plant material, chaired by the United States and co-chaired by Germany and Thailand[16]. Its terms of reference were agreed as follows:

- To develop recommendations to the Task Force on performing a safety assessment in situations of low-level presence in which the recombinant-DNA plant has already been found to be safe and authorized for commercialization for food by one or more countries through an assessment performed according to the Codex Plant Guideline, but the importing country has not determined its food safety, and on the requisite data and information sharing systems to facilitate this process[17].
- The working group will:
  - Identify and incorporate into a draft annex the relevant sections of the Plant Guideline essential to the safety assessment in situations of low-level presence; and
  - Identify information-sharing mechanisms to facilitate utilization of the Annex and to determine whether it should apply, and the data necessary to conduct an assessment of food safety in the importing country.
- The draft annex would not:
  - Address risk management measures; national authorities will determine when a recombinant-DNA plant material is present at a level low enough for this Annex to be appropriate.
  - Preclude national authorities from conducting a full risk assessment; countries can decide when and how to use the Annex within the context of their regulatory systems.
  - Eliminate the responsibility of industries, exporters, and when applicable, national competent authorities to continue to meet countries' relevant import requirements, including in relation to unapproved recombinant- DNA material.

79. The Task Force agreed that the physical working group would first meet either in the end of February or March 2007 in the United States, using English, French and Spanish as working languages. Germany expressed its willingness to host a second meeting of the working group, if required.

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

OTHER BUSINESS AND FUTURE WORK (Agenda Item 10)

81. The Task Force noted that there was no request to discuss additional matters under this Agenda Item.

DATE AND PLACE OF THE NEXT SESSION (Agenda Item 11)

82. The Seventh Session of the Task Force was tentatively scheduled to take place from 24 - 28 September 2007 in Chiba, Japan, subject to further confirmation by the host government in consultation with the Codex Secretariat.

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

[17] The guidance would not be intended for a recombinant-DNA plant that was not authorized in an importing country as a result of that country's food safety assessment.

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	3/4	Members/Observers Seventh Session of the Task Force	Paras 50-51 Appendix III
Proposed Draft Annex to the Guideline for the Conduct of Foods Safety Assessment of Foods Derived from Recombinant-DNA Plants: Food Safety Assessment of Foods Derived from Recombinant-DNA Plants Modified for Nutritional or Health Benefits	2/3	Working Group Members/Observers Seventh Session of the Task Force	Para. 59
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	1/2/3	30th CAC Working Group Members/Observers Seventh Session of the Task Force	Paras 77-80 Appendix IV

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Appendix II

QUESTIONS FOR AN EXPERT CONSULTATION

Marker and Reporter Genes

- What developments have occurred in the development and use of reporter and selectable marker genes?

- Are there non-antibiotic resistance marker or reporter genes that have been demonstrated to be safe to humans in food products, and if so, what are they?

- When removal of specific DNA sequences is desired, are reliable and safe techniques available to do this on a routine basis?

Non-heritable Applications

The term 'non-heritable applications' covers the direct introduction of nucleic acids into non-germline tissue of animals that will enter the food supply.

- Are there relevant differences from a food safety perspective between animals with heritable and non-heritable traits, and if so, what are they?

- Are there specific food safety questions (e.g. with regard to types of vectors) that should be considered relative to the assessment of safety of food from animals containing heritable versus non-heritable traits?

Appendix III

PROPOSED DRAFT GUIDELINE FOR THE CONDUCT OF FOOD SAFETY ASSESSMENT OF FOODS DERIVED FROM RECOMBINANT-DNA ANIMALS
(At Step 3/4 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.

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.

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.[1] In assessing the safety of food from recombinant-DNA animals, the approach should take into account all of the following:

[1] 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

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.

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[2].

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.

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.

FAO/WHO Expert Consultation on the Safety Assessment of Foods Derived from Genetically Modified Animals, Including Fish.

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

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 relative to its conventional counterpart[3,4]. 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.

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

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[3] The concept of substantial equivalence as described in the report of the 2000 joint FAO/WHO expert consultations (Document WHO/SDE/PHE/FOS/00.6, WHO, Geneva, 2000).

[4] The concept of substantial equivalence was further considered in the context of comparative safety assessment at the FAO/WHO expert consultation on the Safety Assessment of Foods Derived from Genetically Modified Animals, Including Fish, 2003.

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[5] 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[6,7] 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.

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.

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5 Not to be confused with a surrogate dam.

6 First animal produced as a result of introducing the recombinant-DNA construct.

7 Sometimes referred to as the founder animal.

8 Reference is made to General Criteria for the Selection of Methods of Analysis in the Codex Alimentarius Procedural Manual (Appendix).

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.

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;

1. 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.

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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.

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.

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.

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

[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.

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.

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.)

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.

[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.

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.

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

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

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].

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.

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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 Joint FAO/WHO Expert Consultation on Allergenicity of Foods Derived from Biotechnology (2001): Section “6.4 Pepsin Resistance”.

[17] According to the Joint Report of the 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.

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.

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

Appendix IV

PROJECT DOCUMENT

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

1. Purpose and scope of the proposed work

The goal of the project will be to develop recommendations to the Task Force on performing a safety assessment in situations of low-level presence in which the recombinant-DNA plant has already been found to be safe and authorized for commercialization for food by one or more countries through an assessment performed according to the Codex Plant Guideline, but the importing country has not determined its food safety, and on the requisite data and information sharing systems to facilitate this process.[1]

With this in mind, the objectives of the project will be to:

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

The project would not:

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

2. Relevance and timeliness

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 in one or more countries may on occasion be present in food in countries in which the food safety of the relevant recombinant-DNA plants has not been determined. This Annex is intended to aid countries that want to determine the food safety of a recombinant-DNA plant under such circumstances or in advance preparation for such potential circumstances.

3. The main aspects to be covered

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

[1] The guidance would not be intended for a recombinant-DNA plant that was not authorized in an importing country as a result of that country's food safety assessment.

4. Assessment against the *Criteria for the establishment of work priorities*

Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries:

The project would provide additional guidance for countries to use in assessing the food safety of the low-level presence of unauthorized recombinant-DNA foods, thus evaluating the underlying safety of the food and appropriate protection of consumers. The project could particularly assist countries that have limited experience with food safety risk assessments.

Diversification of national legislations and apparent resultant or potential impediments to international trade:

The project would provide internationally recognized scientific guidance and information and data exchange mechanisms that countries may use to establish individual standards or guidance. Such internationally agreed guidance can help ensure consistent approaches for the food safety assessment for such foods.

Scope of work and establishment of priorities between the various sections of the work:

The scope of the work relates to work previously undertaken by the Task Force on a high priority basis.

Work already undertaken by other organizations in this field:

The project does not duplicate work undertaken by other international organizations, and is an extension of work developed in the first Codex *Ad Hoc* Intergovernmental Task Force on Foods Derived from Biotechnology.

5. Relevance to Codex Strategic Objectives

This proposal is consistent with the following strategic goals presented in the Codex Draft Strategic Plan 2008-2013:

- Promoting Sound Regulatory Frameworks; and
- Promoting Widest and Consistent Application of Scientific Principles and Risk Analysis;

6. Information on the relation between the proposal and other existing Codex documents

The work product would be an Annex that complements and extends the Codex *Guideline for the Conduct of Food Safety Assessment of Food Derived from Recombinant-DNA Plants* (CAC/GL 45-2003).

7. Identification of any requirement for and availability of expert scientific advice

None identified.

8. Identification of any need for technical input to the standard from external bodies that this can be planned for

None identified.

9. The proposed timeline for completion of the new work, including start date, the proposed date for adoption at Step 5 and the proposed date for adoption by the Commission; the timeframe for developing a standard should not normally exceed 5 years

It is expected that the work can and should be completed within the remaining timeframe for the Task Force.

If the proposal is approved as new work by the 30th Session of the Codex Alimentarius Commission (July 2007) a proposed draft Annex would be circulated for comments at Step 3 and be considered by the Task Force at its next Session (2007) at Step 4.