

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
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ORGANIZATION



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ALINORM 01/34A

JOINT FAO/WHO FOOD STANDARD PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Twenty-fourth Session

Geneva, 2-7 July 2001

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

Chiba, 25-29 March 2001

Note: This document incorporates Codex Circular Letter 2001/11-FBT

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April 2001

To: Codex Contact Points
Interested International Organizations

From: Secretary, Codex Alimentarius Commission, FAO Viale delle Terme di Caracalla, 00100 Rome, Italy

Subject: Distribution of the Report of the Second Session of the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology (ALINORM 01/34A)

A. MATTERS FOR ADOPTION BY THE 24TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION

Proposed Draft Principles and Guideline at Step 5 of the Procedure

1. Proposed Draft Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (para. 49, Appendix II)
2. Proposed Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (para 77, Appendix III)

Governments wishing to submit comments on the implications which the Proposed Draft Principles and Guideline may have for their economic interests should do so in writing in conformity with the Procedure for the Elaboration of World-wide standards at Step 5 to the Secretary, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy **before 15 May 2001.**

SUMMARY AND CONCLUSIONS

The Second Session of the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology reached the following conclusions:

MATTERS FOR CONSIDERATION BY THE CODEX ALIMENTARIUS COMMISSION

The Task Force:

- (a) Agreed to advance the Proposed Draft Principles for the Risk Analysis of Foods Derived from Modern Biotechnology to Step 5 of the procedure for the consideration of the 24th Session of the Codex Alimentarius Commission (para. 49, Appendix II);
- (b) Agreed to advance the Proposed Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants to Step 5 of the procedure for the consideration of the 24th Session of the Codex Alimentarius Commission (para. 77, Appendix III);
- (c) Adopted a preliminary report for submission to the 24th Session of the Codex Alimentarius Commission (para. 90, Appendix V).
- (d) Agreed, subject to the approval by the 24th Session of the Codex Alimentarius Commission, to initiate a new work at Step 1 on the elaboration of a guideline for conduct of food safety assessment of modified microorganisms in food (para. 91);

OTHER MATTERS OF INTEREST TO THE COMMISSION

The Task Force:

- (a) Agreed to develop, for the Guideline document, a separate annex containing detailed procedures for the allergenicity assessment and also agreed to establish an open-ended Working Group to be chaired by the Government of Canada to this end (para.70);
- (b) Agreed to request comments on the papers on traceability provided by the Delegations of France and the United States by means of a circular letter for further discussion at its next session (para. 83)
- (c) Agreed to document the present status of validation of the methods that had been reported by the member countries and recommended that a register or depository containing relevant information on methods for the detection or identification of foods or food ingredients derived from biotechnology (as well as the availability of reference materials) be established (para. 86);
- (d) Recommended that a future joint FAO/WHO Expert Consultation should consider safety assessment where an appropriate conventional counterpart was absent for example in the case of modified microorganisms used in food production and processing (para. 28)
- (e) Welcomed the initiative of FAO and WHO to convene expert consultations to support the scientific aspects of its work in the area of foods derived from genetically modified microorganisms and fish (para. 92)

TABLE OF CONTENTS

| | <u>Paragraphs</u> |
|---|-------------------|
| INTRODUCTION | 1 |
| OPENING OF THE SESSION | 2 |
| ADOPTION OF THE AGENDA | 3 |
| MATTERS REFERRED TO THE TASK FORCE BY OTHER CODEX COMMITTEES | 4-8 |
| REVIEW OF THE WORK BY INTERNATIONAL ORGANIZATIONS ON THE EVALUATION OF THE SAFETY AND NUTRITIONAL ASPECTS OF FOODS DERIVED FROM BIOTECHNO | 9-14 |
| PROPOSED DRAFT GENERAL PRINCIPLES FOR THE RISK ANALYSIS OF FOODS DERIVED FROM MODERN BIOTECHNOLOGY | 15-49 |
| PROPOSED DRAFT GUIDELINE FOR THE CONDUCT OF SAFETY ASSESSMENT OF FOODS DERIVED FROM RECOMBINANT-DNA PLANTS | 50-78 |
| DISCUSSION PAPER ON TRACEABILITY | 79-83 |
| INFORMATION PAPER ON FAMILIARITY | 84 |
| CONSIDERATION OF ANALYTICAL METHODS | 85-89 |
| OTHER BUSINESS, FUTURE WORK AND DATE AND PLACE OF NEXT SESSION | 90-95 |

LIST OF APPENDICES

| | <u>Pages</u> |
|---|--------------|
| Appendix I List of Participants | 17 |
| Appendix II Proposed Draft Principles for the Risk Analysis of Foods Derived from Modern Biotechnology | 38 |
| Appendix III Proposed Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants | 42 |
| Appendix IV Answers by the 2000 FAO/WHO Expert Consultation on Foods Derived from Biotechnology to the Questions from the Codex <i>ad hoc</i> Intergovernmental Task Force | 53 |
| Appendix V Preliminary Report of the <i>Ad Hoc</i> Intergovernmental Task Force on Foods Derived from Biotechnology | 57 |

ALINORM 01/34A

**DRAFT REPORT OF THE SECOND SESSION OF THE CODEX AD HOC
INTERGOVERNMENTAL TASK FORCE ON FOODS DERIVED FROM BIOTECHNOLOGY
*Chiba, Japan 25-29 March 2001***

INTRODUCTION

1. The Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology (CX/FTB) held its Second Session in Chiba, Japan from 25 to 29 March 2001, by courtesy of the Government of Japan. The Session was presided over by Professor Hiroshi Yoshikura, Inspection and Safety Division, Department of Food Sanitation, Pharmaceutical and Medical Service Bureau, Ministry of Health, Labour and Welfare. A complete list of participants is included as Appendix I to this report.

OPENING OF THE SESSION

2. The Session was opened by Mr Jungoro Kondo, Vice-Minister for Health, Labour and Welfare, who welcomed the participants to Makuhari, Chiba, Japan. Mr Kondo mentioned that the food safety and consumer health were a most serious interest in recent years and the safety of foods derived from modern biotechnology attracted most serious public concerns both in importing and exporting countries and thus it was strongly expected that a worldwide consensus in this area be reached as quickly as possible. Mr Ezzeddine Boutrif, Officer-in-Charge, Food Quality and Standards Service, FAO and Dr Jørgen Schlundt, Cordinator, Programme of Food Safety, WHO, gave welcome addresses on behalf of FAO and WHO, respectively. Both representatives expressed their sincere gratitude toward the Government of Japan for its hospitality and wished a successful meeting. It was stressed that FAO and WHO would provide continuous support to the work of the Task Force particularly by providing scientific advice on pertinent issues. In this regard it was mentioned that two Joint FAO/WHO Expert Consultations had been organized in 2000 and 2001 and their outcome would be expected to be incorporated in the work of the Task Force. Both speakers urged the Task Force to make efforts to advance the finalization of the texts on its Agenda to respond to the pressing demand for these texts.

ADOPTION OF THE AGENDA (AGENDA ITEM 1)¹

3. The Task Force adopted the Provisional Agenda as the Agenda of the Session, under the understanding that the issue of traceability (Agenda Item 6) would be discussed prior to the discussion on paragraph 19 of the draft General Principles under Agenda Item 4. The Task Force agreed that the drafting of an interim report for submission to the 24th Session of the Codex Alimentarius Commission should be included as a subject matter for discussion under Agenda Item 9 (Other Business, Future Work and Date and Place of Next Session).

**MATTERS REFERRED TO THE TASK FORCE BY OTHER CODEX COMMITTEES
(AGENDA ITEM 2)²**

4. The Task Force noted the information presented in document CX/FBT 01/2. It noted in particular that the 47th session of the Executive Committee had approved as new work the Proposed Draft General Principles for Risk Analysis of Foods Derived from Biotechnology, the Proposed Draft Guideline on the Risk Assessment of Foods Derived from Biotechnology, and a List of Available Analytical Methods for

¹ CX/FBT 01/1

² CX/FBT 01/2

the Detection and Identification of Foods Derived from Biotechnology. It noted that the exact titles of the first two documents had yet to be confirmed.

5. The Task Force noted the progress of the work undertaken by the Executive Committee on the Medium Term Plan 2003-2007 in which work was foreseen on the development of standards or guidelines for the production, processing, labelling and marketing of foods derived from biotechnology
6. The Task Force was further informed of the decision by the 47th Session of the Executive Committee that responsibility of the consideration of “other legitimate factors” should rest with the Committee on General Principles (CCGP).
7. Among the matters arising from other Codex Committees relevant to its work, the Task Force noted in particular the work undertaken by the Codex Committee on Food Labelling (CCFL) concerning the elaboration of Recommendation for the Labelling of Foods Obtained through Biotechnology. The Task Force was further informed by the Secretariat that the 23rd Session of the Codex Committee on Methods of Analysis and Sampling (CCMAS) had agreed that the CCMAS should have a general coordination role as regards the development of methods of analysis for foods derived from biotechnology.
8. The Task Force noted that the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS), in view of the system-wide interest and involvement in traceability, had recommended that a short paper be prepared by the Secretariat for consideration by the Codex Alimentarius Commission at its next Session in order to obtain the Commission’s guidance in this matter. The CCFICS had noted that certain aspects of traceability fell within its Terms of Reference. The Task Force noted that concept of “traceability” was being dealt with by the *Ad Hoc* Intergovernmental Task Force on Animal Feeding as well. The Delegation of Sweden, speaking on behalf of the Member States of the European Union present at the session, expressed its preference for traceability to be considered by the CCGP rather than the CCFICS.

REVIEW OF THE WORK BY INTERNATIONAL ORGANIZATIONS ON THE EVALUATION OF THE SAFETY AND NUTRITION ASPECTS OF FOODS DERIVED FROM BIOTECHNOLOGY (AGENDA ITEM 3)³

9. The Task Force noted that in line with its terms of reference, that when elaborating standards, guidelines, or other principles, as appropriate, for foods derived from biotechnology it should take full account of existing work carried out by national authorities, FAO, WHO, other international organizations and other relevant international fora. The document before the Task Force provided information on the following:
 - FAO/WHO Joint activities;
 - The Convention on Biological Diversity – Cartagena Protocol on Biosafety;
 - International Centre for Genetic Engineering and Biotechnology;
 - United Nations Environment Programme;
 - United Nations Industrial Development Organization;
 - Organization for Economic Cooperation and Development; and
 - G-8 Head of State and Government Meetings.
10. The Representative of the World Trade Organization (WTO) reported that there had been over 40 notifications relating to biotechnology under the Transparency provisions of the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and over 30 notifications under the same provisions of the Agreement on Technical Barriers to Trade (TBT Agreement). The Representative noted that this information and other unrestricted documents of the WTO were available from the WTO website, and unrestricted SPS documents also through a public email subscription list.

³ CX/FBT 01/3

11. The Representative of FAO informed the Task Force that FAO and WHO had convened a preliminary meeting in Rome on 27 February 2001 to discuss ways and means of responding to the request of the G-8 to organize regular meetings of food safety regulators to advance the process of science-based public consultations on food safety issues. At the present time it was envisaged that such a meeting would be held in October 2001 and that preparations, in consultation with Member governments of FAO and WHO, would be developed during May 2001.
12. The Representative of the WHO highlighted the procedures used for the identification and selection of experts for the FAO/WHO Expert Consultations on Foods derived from Biotechnology and for Microbiological Risk Assessment. In response to a question from Thailand, it was noted that Codex Contact Points were invited to submit names and curricula vitae of potential experts for these Consultations. However, since the appointment of experts to expert panels was made on the basis of the experts' personal capacities and not as a representative of her or his Member government, Codex Contact Points were not consulted on this aspect.

REPLY BY THE 2000 FAO/WHO EXPERT CONSULTATION ON FOODS DERIVED FROM BIOTECHNOLOGY TO THE QUESTIONS FROM THE FIRST SESSION OF THE TASK FORCE

13. The Task Force recalled that at its First Session⁴ it had requested the scientific advice of the FAO/WHO Expert Consultation to five specific questions, namely
 - What overarching scientific principles should be applied to the safety and nutritional assessment?
 - What is the role, and what are the limitations, of substantial equivalence in the safety and nutritional assessment? Are there alternative strategies to substantial equivalence that should be used for the safety and nutritional assessment?
 - What scientific approach can be used to monitor and assess possible long-term health effects or unintended/unexpected adverse effects?
 - What scientific approach can be used to assess the potential allergenicity?
 - What scientific approach can be used to assess the possible risks arising from the use of antibiotic resistance marker genes in plants and microorganisms?
14. The Task Force noted that the responses of the 2000 Joint FAO/WHO Expert Consultation as contained in Annex 1 to document CX/FBT 01/3 represented the current state of scientific opinion and were subject to further development as more scientific information came to hand. However, on this basis it expressed its satisfaction with the responses received. It agreed that these responses should form part of the interim report to the Commission. The responses are presented in Appendix IV of the present report.

CONSIDERATION OF PROPOSED DRAFT GENERAL PRINCIPLES FOR THE RISK ANALYSIS OF FOODS DERIVED FROM MODERN BIOTECHNOLOGY AT STEP 4 (AGENDA ITEM 4)⁵

BACKGROUND

15. The Task Force recalled that at its First Session, a consensus had emerged that general principles for the risk analysis of foods derived from biotechnology should be developed, and established a Working Group under the chairmanship of Japan to prepare an initial draft for consideration by the Task Force. Following the approval of this work by the Executive Committee, the Working Group met in Japan in July and

⁴ ALINORM 01/34, paras. 37, 38; Appendix III

⁵ CX/FBT 1/4; CX/FBT 1/4-Add.1 (Comments of Brazil; Canada; Japan; Norway; United States of America; European Community; Consumers International; International Association of Consumer Food Organizations); CRD 1 (Comments of Mexico); CDR 2 (Comments of Malaysia, New Zealand, Thailand); CRD 4 (Comments of The Philippines); CRD 6 (Comments of Cuba); CRD 7 (Comments of Argentina).

October 2000 for this purpose. The draft text was subsequently sent to Member governments and interested international organizations for comment at Step 3.

16. The Chairperson of the Working Group, Dr Kazuaki Miyagishima (Japan) noted that the draft text contained elements drawn from several existing Codex documents and some documents in the course of elaboration, for example the work of CCFICS on the Principles of Import and Export Certification and that of CCGP on the Proposed Draft Working Principles of Risk Analysis. The Cartagena Protocol on Biosafety had also been used as a basis for some elements, in particular the proposed definition for “modern biotechnology”.
17. Several delegations expressed their appreciation at the progress made by the Working Group and their general satisfaction with the document.
18. The Task Force agreed to consider the draft paragraph-by-paragraph, except that prior to discussing Paragraph 19 (later renumbered as Paragraph 21)⁶, it would first consider paper CX/FBT 01/6 on “Traceability”.

TITLE

19. The Task Force agreed to maintain the Title of the document as “Proposed Draft Principles for the Risk Analysis of Foods Derived from Modern Biotechnology.”

SECTION I – INTRODUCTION

20. The Task Force amended Paragraphs 1 and 3 to improve their clarity. In particular, it noted that existing principles for the food safety risk analysis of specific hazards had not been elaborated to take into account the risk analysis of whole foods (Paragraph 3).
21. The Task Force agreed to specify that the Principles should be read in conjunction with the Working Principles for Risk Analysis, currently under development by the Codex Committee on General Principles (Paragraph 5).

SECTION II - SCOPE AND DEFINITIONS

22. In Paragraph 6, the Task Force accepted a proposal to indicate that the purpose of the Principles was to provide a framework for risk analysis, rather than to provide advice. It decided not to make a reference to intended or unintended effects other than safety and nutritional aspects in this statement of scope as these were dealt with at appropriate points in the subsequent text. On the other hand, it agreed to extend the list of factors not covered by the Principles, to cover in particular ethical factors other than safety, and the moral and socio-economic aspects of research, development, production and marketing of these foods. Although the Codex definition of *food* related exclusively to products for human consumption, the Task Force agreed to include a footnote to indicate that animal feed and animals fed such feed were excluded from the Scope of the Principles, except insofar that these animals had been genetically modified (i.e. all genetically modified animals would be covered).
23. The Task Force noted that the Definition of *Modern Biotechnology* had been taken from the Cartagena Protocol on Biosafety. Although it noted that the Codex Committee on Food Labelling had developed a separate definition for labeling purposes and that in general consistency between Codex texts was desirable, the Task Force was strongly of the opinion that consistency with other internationally agreed instruments was critically important in this case. It recommended that the Codex Committee on Food Labelling give consideration to using the same definition in its work. However, some Delegations and observers were of the opinion that for labeling purposes, it may be appropriate to use terms and definitions that were easier for consumers to understand. No change was made to the definition.

⁶ In the subsequent discussions, paragraph numbers refer to the numbers that appear in Appendix II to this report.

24. The Task Force had an extended discussion on the definition of *Conventional Counterpart*, in particular on whether or not a genetically modified food could serve as a “conventional counterpart” for comparison purposes. Several Delegations stated that once a food derived from biotechnology had been approved and in common use for an extended period, there was no scientific reason for not using such a food as the basis for comparison. It was pointed out that the FAO/WHO Expert Consultation had stated in its reply to the Task Force on the question concerning the evaluation of unintended effects, that the comparator used to detect unintended effects should ideally be the “near isogenic parental line grown under identical conditions” which could indicate a food derived from biotechnology. Other Delegations pointed out that the confidence of consumers in foods derived from biotechnology depended on their being able to relate the safety of such foods to un-modified foods that had a well-established history of safe use and that the traditional unmodified food supply provided a sound baseline for this purpose. In their opinion, at the present time and for the foreseeable future, foods derived from biotechnology could not be considered as meeting this criterion.
25. The Task Force agreed to modify the definition by the inclusion of a footnote to the effect that for the foreseeable future, foods derived from modern biotechnology will not be used as conventional counterparts. It also modified the definition to indicate that components or products of foods could serve as a “conventional counterpart” to components or products of foods derived from biotechnology.

Risk Assessment

26. The Task Force agreed that the Principles should be “consistent” with the proposed draft Working Principles under development by the CCGP, rather than “in compliance” with them (Paragraph 9). The Task Force generally agreed that the notion of “safety assessment” was characterized by an assessment of a whole food or component thereof relative to an appropriate conventional counterpart for the purpose of the identification of new or altered hazards taking into account both intended and unintended effects. In this regard, the Delegation of the United States noted that in the current draft there was no indication of how to proceed if a new or altered hazard was identified by the safety assessment. The Task Force agreed to amend Paragraph 10 to deal with this situation.
27. The Task Force agreed to adopt a rewording of Paragraph 11 for clarity, using a proposal of the European Commission.
28. The Representative of WHO noted that within the present concept, safety assessment could only be conducted when an appropriate conventional counterpart existed and recommended that consideration should be given to situations where a conventional counterpart was absent, for example in the case of modified micro-organisms used in food production and processing. The Task Force recommended that this matter be considered by a future joint FAO/WHO Expert Consultation.
29. The Task Force made several minor changes to Paragraphs 12 to 15 to improve their clarity. In particular, it noted that risk assessment should be based on scientific data and information (Paragraph 13); that methods used for risk assessment should be scientifically sound (Paragraphs 12 and 15); and that assessment methods need not be limited to internationally agreed methods although they should be scientifically sound and use parameters that allow comparison (Paragraph 15).

Risk Management

30. The Task Force agreed that both the outcome of the risk assessment and other legitimate factors would be the basis for risk management. A proposal was made to include examples of other legitimate factors such as the protection of the environment, consumer choice, ethics, fair trade practices and sustainable developments. Different views were exchanged on whether other legitimate factors should be considered by the Task Force, whether or not they should be enumerated or they should be left to the discretion of the CCGP. The Task Force recalled that its terms of reference limited its consideration to “other legitimate factors relevant to the health of consumers and the promotion of fair trade practices”. It agreed that the wording used in paragraph 2 of the Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which Other Factors are taken into Account should

be used to describe the nature of other legitimate factors and that reference would also be made to the Working Principles on Risk Analysis under development by the CCGP which would provide more detail on the application of these Statements of Principle (Paragraph 16).

31. For the purpose of conformity of terminology the Task Force agreed to replace the words “risk management decisions” with “risk management measures” (Paragraph 16). It also agreed that risk management measures may include conditions for marketing approvals (Paragraph 19).
32. The Task Force had an extended discussion concerning the need for the development of analytical methods for detection or identification of foods derived from modern biotechnology, including the possibility of requiring that such methods be available as a condition for pre-market approval. It agreed that the wording of Paragraph 19 provided sufficient guidance in this matter by generally allowing conditions for pre-market approval and removed the square brackets surrounding this text.
33. The Task Force agreed that post-market monitoring (Paragraph 20) may be an appropriate risk management measure. Some Delegations expressed their concern about the practicability and financial implications in relation to the use of post-market monitoring. The Task Force agreed that the need and utility of post-market monitoring should be considered during risk assessment and practicably in addition during risk management. The Delegation of Thailand expressed its concern about the possibility that relying on post-market monitoring might lead to the reduction of efforts to perform efficient risk assessment for the pre-market approval of foods derived from modern biotechnology, with the subsequent release into the market of foods that were not properly tested and approved. This concern was supported by all Delegations that spoke and the Task Force agreed that the purpose of post-market monitoring should be to verify the conclusion about the absence or the possible occurrence, impact and significance of potential consumer health effects.

TRACEABILITY (PARAGRAPH 21)

34. As agreed during the Adoption of the Agenda, the Delegation of France introduced its discussion paper⁷ on the issue of traceability prior to consideration of this paragraph. The Delegation stated that the issue was linked to risk management, especially in regard to product recall, post market monitoring, the right of consumers to choose the foods that they wish to eat and also on the obligation of vendors to meet the labelling requirements applied in many countries. The Delegation noted that Traceability was defined in standard ISO 8402 in general terms as being “the ability for the retrieval of the history and use or location of an article or an activity through a registered identification”.
35. The Delegation of France stated that within this context traceability in the food system provided mechanisms of continuous flow of relevant information that allowed the retrieval of the history and of the origin of a product at any point in the food chain, based on record keeping and documentation. The Delegation stated that traceability was less costly and more reliable than using systematic analysis of product throughout the food chain. The Delegation further noted that many aspects of traceability were common to all foods, but that because of consumer interest in foods derived from biotechnology, special consideration for the application of traceability to these foods was needed.
36. Many Delegations and Observer Organizations supported the conclusions of the discussion paper and recommended that reference be made to traceability in the context of Risk Management in the present document. Several of these Delegations also pointed out that traceability should be considered in the general context of risk management for all foods as it was pointed out that traceability had a role to play in post-market monitoring. Reference was made to the future identification requirements under the Cartagena Protocol for living modified organisms intended for direct use for food or feed or for processing⁸

⁷ CX/FBT 01/6.

⁸ Cartagena Protocol, Article 18.2.(a): “Each Party shall take measures to require that documentation accompanying living modified organisms that are intended for direct use as food or feed, or for processing, clearly

37. Other Delegations were of the opinion that reference to traceability was not appropriate for inclusion in the current Principles since the issue at stake was not one of food safety risk analysis, but rather a matter of consumer choice or labelling. Although they agreed that the ability to trace defective products that had entered the food chain was an integral part of food control and risk management, it was not appropriate to require traceability for products that had received pre-market approval. Moreover, these Delegations pointed out that the cost of traceability was significant and that the economic impact of such a requirement could fall heavily on developing countries wishing to export food products. They agreed that traceability should be considered as a general issue within Codex and looked forward to the guidance of the Commission on this matter.
38. The Task Force noted that aspects of traceability were being treated in several other Codex Committees, notably the Codex Task Force on Animal Feeding, the Codex Committee on Fish and Fishery Products, the CCFICS, the CCFL and the Codex Committee on Food Hygiene (CCFH). It also noted that the traceability was different from the concept of "Identity Preservation (IP)". Referring to the work of ISO, the Task Force noted that in addition to the definition in ISO 8402, the Draft ISO Standard ISO/DIS 17161.2 "Guidelines on the application of ISO 9001:2000 for the food and drink industry" contained reference to traceability.
39. In view of the divergence of opinion surrounding the issues of traceability, an open-ended *Ad Hoc* Working Group, chaired by Japan, was convened to provide a further text for the consideration of the Task Force.
40. The *Ad Hoc* Working Group tabled a report indicating that the concept of traceability, a system which guarantees a continuous flow of appropriate information at all stages of placing on the market of foods, was a broad, horizontal issue and should be discussed on a Codex-wide basis. The report contained the following proposals:
- deleting paragraph 21⁹; and
 - adding the following text as a footnote to the heading of Risk Management section.

It was recognized that discussion on the applicability of traceability or other equivalent approaches as a tool in support of risk management measures is under consideration by the Codex Alimentarius Commission and its subsidiary bodies. The Task Force encouraged an early completion of this discussion.

41. The Task Force agreed that the traceability was a broad, horizontal issue and should be discussed on a Codex-wide basis. While several Delegations supported the proposal submitted by the *Ad Hoc* Working Group, a large number of Delegations asked that Paragraph 21 be retained in the Proposed Draft Principles, albeit in brackets. The Task Force agreed to retain Paragraph 21 in brackets and to attach to it the footnote. The Task Force did not address further the report of *Ad Hoc* Working Group with respect to traceability or its meaning.
42. The Task Force expressed its appreciation to the *Ad Hoc* Working Group for its efforts in resolving this and other issues referred to it.

Risk Communication

43. The Task Force agreed that risk communication was essential at all phase of risk assessment and risk management and that academia should be also involved in risk communication.

identifies that they "may contain" living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall take a decision on the detailed requirements for this purpose, including specification of their identity and any unique identification, no later than two years after the date of entry into force of this Protocol."

⁹ The Delegation of France expressed its reservation during the meeting of the Working Group to this proposal.

Harmonization

44. The representative of WTO observed that, in the context of the SPS Agreement, Codex guidelines were to be used as the basis for national sanitary measures, presumably including risk analysis systems for foods derived from biotechnology rather than as an element of these measures, in the context of the SPS and TBT Agreements. Others preferred that these guidelines be considered only as an element of national systems. The Task Force noted that the question of the status of Codex guidelines was not specific to work of the Task Force and that deletion of the paragraph would be without consequence.
45. The Task Force agreed that remaining provision should be placed better under the introduction part of the Principles (where it appears as Paragraph 5) and accordingly this section was deleted.

Consistency

46. The Task Force agreed to the current wording included under this section.

Capacity Building and Information Exchange

47. The Task Force had requested the *Ad Hoc* Working Group to discuss the relationship between this Section and Paragraph 19 concerning the development and application of methods of detection and identification. It agreed to separate the two issues into separate paragraphs (Paragraphs 27 and 28) and agreed to strengthen the paragraph dealing with the exchange of information on analytical methods by making a special reference to Codex Contact Points. It also agreed that capacity building for enforcement should be referred to.

Review Process

48. The Delegation of the United State, while recognizing the importance of taking into account the newest scientific information for safety assessment, expressed its concern about the practicability should a routine review be required. This view was generally supported and the Task Force agreed to solve this problem by modifying Paragraph 30. An additional sentence was introduced to ensure that the assessment be reviewed to incorporate new relevant information and, if necessary, risk management measures be adapted when such information became available.

STATUS OF THE PROPOSED DRAFT GENERAL PRINCIPLES FOR THE RISK ANALYSIS OF FOODS DERIVED FROM MODERN BIOTECHNOLOGY

49. The Task Force advanced the Proposed Draft Principles, as presented in Appendix II of this report, to Step 5 of the Procedure for the consideration of the 24th Session of the Codex Alimentarius Commission.

CONSIDERATION OF PROPOSED DRAFT GUIDELINE FOR THE CONDUCT OF SAFETY ASSESSMENT OF FOODS DERIVED FROM RECOMBINANT-DNA PLANTS AT STEP 4 (AGENDA ITEM 5)¹⁰

50. The Delegation of Japan introduced document CX/FBT 01/5 which had been developed by the Working Group established by the Task Force at its First Session. The Delegation reported that work had begun on the development of the text following the approval of the work by the Executive Committee in June 2000. The Working Group had met in July and October 2000. The working group had given consideration to the preparation of general guidance for all foods derived from biotechnology, but given the experience acquired in Member countries, decided to concentrate on developing guidance for foods derived from genetically modified plants as there seemed to be better prospects for harmonization, at least in the short term. Within this group, it decided to concentrate on recombinant-DNA plants and to exclude

¹⁰ CX/FBT 01/5; CX/FBT 01/5-Add.1 (Comments of Brazil, Japan, Norway, United States of America, European Community, Consumers International, International Association of Consumer Food Organizations); CX/FBT 01/5 – Add.2 (Canada); CRD 1 (Mexico); CRD 2 (Malaysia, New Zealand, Thailand); CRD 4 (Philippines); CRD 6 (Cuba); CRD 7 (Argentina); CRD 8 (South Africa); CRD 9 (FAO/WHO); CRD 10 (Canada, Japan, United Kingdom and United States – Joint comment).

plants derived from cell fusion. It noted however, that the guidelines would need to be completed in the future to take into account experience gained in the safety assessment and regulatory approval of the latter.

51. The Delegation noted that the Working Group had introduced a new term, “safety assessment” so as to differentiate the process of evaluation from the risk assessment process used for the evaluation of chemicals or microbiological contaminants. The Proposed Draft Guideline was organized around the concept of *substantial equivalence*, but in the sense that this concept was a starting point for the safety assessment and not an end-point of the assessment. Section 4 of the Guidelines described the step-by-step evaluation process including the consideration of potential toxicity, allergenicity and nutritional consideration. Section 5 took into account several practical considerations.
52. The proposed draft Guidelines had been circulated for comment at Step 3 and the comments received were available to the Task Force.
53. The Task Force proceeded to examine the draft paragraph by paragraph. The main changes made are described below. Editorial and minor changes made for the purpose of clarity are not reported unless they are of significance in understanding the document.

TITLE

54. In view of the restricted scope of the document, the Task Force agreed to amend to Title so as to refer only to recombinant-DNA plants.

SECTION 1 – SCOPE

55. Consistent with its earlier decision, the Task Force agreed that the Guidelines did not apply to animal feeds or to animals fed these feeds nor did they address environmental risks (Paragraph 2).
56. The Task Force agreed to use the previously defined term “conventional counterpart” when referring to the product against which a recombinant-DNA plant would be assessed. (see paras. 24 and 25 above) It also agreed that the comparative assessment was not, in itself, a safety assessment and therefore deleted a statement that could have been interpreted to this effect (Paragraph 4).
57. The Delegation of China proposed to delete the second sentence of Paragraph 6 to maintain the conformity with the amended title of the Guideline. The Task Force decided to maintain the sentence for future consideration.

SECTION 2 – DEFINITIONS

58. The Task Force decided to retain the same definition of *Conventional Counterpart* as agreed to in the context of Agenda Item 4. The Task Force did not include a definition of “substantial equivalence” as suggested by Mexico in its written comments.

SECTION 3 – INTRODUCTION TO FOOD SAFETY ASSESSMENT

59. The Task Force agreed to modify the Title of the Section to indicate that the assessment referred to **food safety** and not to assessment for other purposes. Similar changes were made throughout the document.
60. In the description of the concept of **substantial equivalence**, the Task Force agreed that reference, in the footnote, should only be made to the most recent statement of the concept, as contained in the 2000 Joint FAO/WHO Expert Consultation (Paragraph 11).

Unintended Effects

61. Some Delegations expressed concern at the reference to unintended effects that arose during the course of conventional plant breeding, and stated that the Guidelines should deal exclusively with recombinant-DNA plants. The Task Force however, was of the opinion that the reference to conventional breeding was appropriate, as it provided additional perspective and insight into the safety assessment process (Paragraph 13).

62. It was pointed out that the treatment of “predictable” and “unexpected” unintentional effects in Paragraph 15 was unbalanced. The Task Force noted however that the safety assessment framework described in the document was intended to detect both types of unintended effects, even though more information would normally be available for predictable effects. The Task Force also agreed to simplify this paragraph by deleting specific reference to a few selected factors that needed to be taken into consideration, in favour of a more general statement and complete description in the following Section.

Framework of Food Safety Assessment

63. It was noted that Good Laboratory Practices were not applicable to all scientific experiments used for the safety assessment of plants, and modified Paragraph 19 accordingly. Consistent with its previous decision, it also deleted reference to the use of validated methods of assessment, but recognised that such methods should be sufficiently sound to withstand scientific peer review.

64. The Task Force agreed that safety assessments needed to take into account the best available scientific knowledge (Paragraph 20).

SECTION 4 – GENERAL CONSIDERATION

Description of the Host Plant and its use as Food/Description of the Donor Organism(s)

65. The Task force agreed that information to be provided should be on traits that might affect human health and that the Points B and C of Paragraph 22 as well as Point D of Paragraph 25 should be modified accordingly.

Characterization of the Genetic Modification(s)

66. The Delegation of Belgium, supported by many Delegations, stated that the sequence data of the inserted material and also of surrounding regions should be always provided as they were considered essential for safety assessment. The Delegation of the United States was of the opinion that only those sequence data related to possible impact on human health should be required. This view was supported by many Delegations, and the Task Force noted that other techniques were available to determine whether insertion sequences had been preserved or rearranged. The Task Force agreed to modify Point D to read “identification of any open reading frames within the inserted DNA or created by the insertions with contiguous plant genomic DNA including those that could result in fusion protein.” The Task Force agreed that the number of copies of the inserted gene should be also provided (Paragraph 30).

Safety Assessment of Expressed Substances (Non-Nucleic Acid Substances)

67. The Task Force agreed that safety assessment should be conducted on expressed substances rather than introduced substances and changed the wording accordingly throughout the text.

Assessment of possible toxicity

68. The Task Force noted the proposal of the Delegation of Canada for reorganization of this Section; it decided, however, that this should be considered at a later stage. The Task Force agreed that the words “conventional processing techniques” would describe the nature of the techniques that may deactivate anti-nutrients or toxicants found in the donor organisms (Paragraph 36).

Assessment of possible allergenicity (proteins)

69. The Task Force observed that the section on allergenicity was an important part of the Guideline document and that the report of the Joint FAO/WHO Expert Consultation on the Evaluation of Allergenicity of Genetically Modified Foods¹¹ offered considerably useful information. It observed further that the report introduced a new approach for the assessment of allergenicity of genetically modified

¹¹ *Evaluation of Allergenicity of Genetically Modified Foods: Report of a FAO/WHO Expert Consultation on Allergenicity of Foods Derived from Biotechnology 22-25 January 2001*: FAO Food and Nutrition Paper (in press), FAO, Rome 2001. Also available from the websites of FAO and WHO.

foods, different significantly from that used as the basis for the drafting of the current wording. The Task Force agreed therefore that the section on allergenicity needed to receive a considerable amount of changes. Some Delegations regretted that there had not been sufficient time to consider the contents of the report in detail.

70. In order to proceed, the Task Force agreed to develop a separate annex containing detailed procedures for the allergenicity assessment. It also agreed to establish an open-ended Working Group on Allergenicity to develop such an annex and accepted the offer of the Government of Canada to host the Working Group. The Working Group was also invited to prepare a reorganization of the section on toxicology (see para. 68 above) and to ensure the scientific accuracy.
71. Under the understanding that detailed procedures for the allergenicity assessment should be removed from the body of the Guideline, the Task Force agreed to replace the whole section on allergenicity (Paragraphs 38 to 42). The paragraphs dealing with gluten-sensitive enteropathy were retained without change. The Task Force agreed further that the transfer of genes from commonly allergenic foods should be “avoided” rather than “discouraged”, but retained the restriction that such genes should not code for an allergen or a protein involved in gluten-sensitive enteropathy.

Evaluation of metabolites

72. The Task Force agreed that the title should read “Evaluation of metabolites” rather than Metabolic evaluation.

Nutritional modification

73. The Task Force agreed that attention should be paid also to the particular physiological characteristics and metabolic requirements of population groups with compromised immune systems.

SECTION 5 - OTHER CONSIDERATIONS

USE OF ANTIBIOTIC RESISTANCE MARKER GENES

74. The Task Force agreed that use of alternative transformation technologies not resulting in antibiotic resistance marker genes in foods should be more strongly promoted in the text (Paragraph 53).
75. The Delegation of Sweden on behalf of the Member States of the European Union present at the session welcomed the inclusion in the Guideline of the restriction of the presence of antibiotic resistant marker genes in foods. It proposed that the restriction should be applied not only to clinically important antibiotics but to all kinds of antibiotics in use in medical and veterinary treatments. This view was supported by many Delegations (Paragraph 56). The Delegation of the United States, supported by other Delegations, stated that the restriction should be limited to clinically important antibiotics. The Delegation of Australia noted that the language used in Paragraph 56 was in conformity with the relevant section of the report of the 2000 FAO/WHO Expert Consultation.
76. The Task Force agreed that antibiotic resistance genes used in food production that encode resistance to clinically used antibiotics should not be present in widely disseminated foods.

STATUS OF THE PROPOSED DRAFT GUIDELINE FOR THE CONDUCT OF FOOD SAFETY ASSESSMENT OF FOODS DERIVED FROM RECOMBINANT-DNA PLANTS

77. The Task Force advanced the Proposed Draft Guideline, as presented in Appendix III of this report, to Step 5 of the Procedure for the consideration of the 24th Session of the Codex Alimentarius Commission. It was noted that the Proposed Draft Guideline required rearrangement in the Section dealing with *Toxicity*, and several editorial amendments to improve the scientific accuracy.
78. The Annex (Allergenicity Assessment) would be circulated for comments at Step 3.

DISCUSSION PAPER ON TRACEABILITY (AGENDA ITEM 6)¹²

79. The Task Force recalled that at its 1st Session, the issue of traceability was raised by several delegations. It noted that a better understanding of this concept and its implications was required before it could be included definitively in the text on General Principles for Risk Analysis to be developed and agreed that a discussion paper should be prepared by the Delegation of France on this issue. It also agreed that, if time allowed, the paper might be considered by the ad hoc Working Group responsible for developing the first draft of the General Principles and the Guidelines on Safety Assessment.¹³ A draft paper was prepared and subsequently revised following the input of several Delegations at the meetings of the Working Group. The Task Force noted that the general orientation and conclusions of the paper has been discussed in the context of the Task Force's discussion of Paragraph 21 of the proposed draft General Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (see paras. 34 to 42 above).
80. The Delegation of France noted that in addition to the continuing debate in the Task Force, the matter of traceability needed to be discussed at a general level within Codex since the issue was one of a horizontal nature. It stated that the most appropriate forum for such general discussions would be the CCGP, while the specific issues relating to foods derived from biotechnology should continue to be examined by the Task Force. This view was shared by many other Delegations and Observer Organizations.
81. The Delegation of the United States, supported by some other Delegations, stated that traceability was an important issue in the broader context, and also in many other areas, including in particular, public health. The Delegation suggested that CCFICS should be the most appropriate Codex Committee to consider this issue. It agreed that consensus was needed about the application of traceability in Codex work and noted the proposal of the CCFICS to request the advice of the Commission on how to proceed in this matter.
82. The Delegation of India, supported by Indonesia, stated that the concept was new to developing countries and that while the need for documentation was recognized, in view of the likely cost implications of relying solely on analytical detection of products, the implications of introducing the concept of traceability into the food system needed to be explained and carefully considered. These Delegations noted that production and marketing systems in developing countries were not the same as those of the developed countries, even though the same consumer concerns had to be met. These Delegations expressed interest in the development of equivalent systems that would meet the same objectives.
83. The Task Force agreed to request comments on the papers provided by the Delegations of France and the United States by means of a circular letter (see Footnote 12 above). It further agreed that these papers and the comments received would be discussed at its next session, taking into account the guidance provided by the Commission in this matter. In the meantime it agreed to inform other Codex subsidiary bodies and the Commission of the present discussion.

INFORMATION PAPER ON FAMILIARITY (AGENDA ITEM 7)¹⁴

84. The Task Force noted with interest the papers provided by the Organization for Economic Cooperation and Development (OECD) and the International Association of Plant Breeders for the Protection of Plant Varieties (ASSINSEL). The Representative of the OECD noted that the concept of familiarity was used primarily in environmental risk assessments and that there was no intention to expand the concept beyond this field.

¹² CX/FBT 01/6; CRD 3 (Comments of the United States of America).

¹³ ALINORM 01/34, paras. 27, 31, 35).

¹⁴ CX/FBT 01/7.

CONSIDERATION OF ANALYTICAL METHODS (AGENDA ITEM 8)¹⁵

85. The Task Force recalled that at its 1st Session it had agreed to establish a list of available analytical methods, including those for the detection or identification of foods or food ingredients derived from biotechnology and had established a Working Group on Analytical Methods under the Chairmanship of Germany to undertake this work.¹⁶ The Working Group on Analytical Methods met on Friday, 23 March 2001. The Working Group found that different countries use different methods and that there were no internationally validated methods available at present.
86. On the basis of the recommendations of the Working Group on Analytical Methods, the Task Force agreed to document the present status of validation of the methods that had been reported by the member countries. It recommended that a register or depository containing relevant information on methods for the detection or identification of foods or food ingredients derived from biotechnology (as well as the availability of reference materials) be established. The Task Force agreed to prepare a Circular Letter requesting Member countries and interested international organizations:
- to complement the existing list with documented information on further validated detection methods as well as extraction methods;
 - to provide information on the criteria of validation as well as performance criteria and specificity of methods;
 - to comment on the status of publication of validated methods;
 - to provide opinions on the purpose of a register containing relevant information on methods suitable for the detection of modifications in foods or food ingredients derived from biotechnology and on criteria for their inclusion into a register;
 - to comment on the appropriate place(s) of a register;
 - to provide opinions on how the access to reference materials could be guaranteed.
87. The Task Force agreed that there be a collaborative exchange between it and the CCMAS with a view to CCMAS considering appropriate means to validate methods of analysis with respect to biotechnology and ultimately to their endorsement. The Task Force also agreed to inform the CCFL of the progress made in this area.
88. In relation to the proposal to establish a register of validated methods, the Secretariat and the Representative of FAO noted that an international information exchange mechanism for food safety and agricultural health was being considered by FAO together with WHO and other partners. This internet-based system was intended to provide official information on national and international food regulations and related measures to all interested parties. Where appropriate, the information could be part of other nationally or internationally maintained data systems.
89. The Delegation of France drew attention to the Biosafety Clearinghouse mechanism established under the Cartagena Protocol and expressed the view that care should be taken not to duplicate the work of other UN bodies in this area. The Delegation of Italy drew attention to a register of methods being established by the Joint Research Centre of the European Commission.

¹⁵ CX/FBT 01/8; Circular Letter CL 2000/29 – FBT/MAS; CRD 5 (Report of the first meeting of the Working Group Analytical Methods on 23 March 2001 to the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology).

¹⁶ ALINORM 01/34, paras 32 and 36.

**OTHER BUISINESS, FUTURE WORK AND DATE AND PLACE OF NEXT SESSION
(AGENDA ITEM 9)*****Preliminary report of the Task Force***

90. Following its terms of reference the Task Force considered its preliminary report for submission to the 24th Session of the Codex Alimentarius Commission. The report as adopted by the Task Force is attached as Appendix V to this report.

Future Work

91. Referring to the priorities identified at its 1st Session¹⁷, the Task Force agreed, subject to the approval by the 24th Session of the Codex Alimentarius Commission, to initiate a new work on the elaboration of a guideline for conduct of food safety assessment of modified microorganisms in food. It further agreed to establish an open-ended Working Group to advance the preparation of the draft proposed guideline, being aware of the fact that the new work should be proceeded in an expeditious manner in order to be completed before the 25th Session of the Codex Alimentarius Commission in 2003 when the Task Force would cease to exist. The Government of the United States offered to host the Working Group, which was accepted by the Task Force with appreciation.
92. The Representatives of FAO and WHO offered to convene a joint FAO/WHO expert consultation to address the safety assessment of genetically modified microorganisms in food to facilitate the work of the Task Force by providing scientific back grounds in this area. Both representatives stressed that the organization, in particular the selection of experts participating in the consultation would be conducted in a transparent manner. The Representatives of FAO and WHO also offered to consider the convening of a Joint Expert Consultation on the food safety evaluation of genetically modified fish to provide the scientific framework for any future work in this area. The Task Force expressed its appreciation for these initiatives.

Agenda of the Third Session

93. The Task Force noted that the following matters would be included on the provisional agenda for its next session:
- Matters referred or raising from the Codex Alimentarius Commission and other Codex Committees;
 - Matters of interest from other international organizations;
 - Consideration of draft principles for the risk analysis of foods derived from modern biotechnology
 - Consideration of draft guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants and the proposed draft annex on allergenicity assessment;
 - Consideration of proposed draft guideline for the conduct of food safety assessment of recombinant-DNA microorganisms in food (subject to approval by the Commission);
 - Discussion paper on traceability
 - Consideration of analytical methods
94. The Task Force noted the views of some Delegations that the issue of traceability should be discussed early in the session.

Date and Place of Next Session

95. The Consultation noted that the Third Session of the Task Force was tentatively scheduled to be held in Japan from 4 to 8 March 2002.

¹⁷ ALINORM 01/34, para. 28).

SUMMARY STATUS OF WORK

| Subject Matter | Step | Action by | Document Reference in ALINORM 01/34A |
|---|-------|--|--------------------------------------|
| Proposed Draft Principles for the Risk Analysis of Foods Derived from Modern Biotechnology | 5 | Governments, 24 th CAC | para. 49 Appendix II |
| Proposed Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants | 5 | Governments, 24 th CAC | para. 77 Appendix III |
| Proposed Draft Annex on allergenicity assessment | 1/2/3 | Working Group on Allergenicity chaired by Canada | paras. 70 and 78 |
| Proposed Draft Guideline for the Conduct of Food Safety Assessment of Modified Microorganisms in Food | 1/2/3 | Government, 24 th CAC, Working Group on Microorganisms Chaired by the United States | para. 91 |
| List of Analytical Methods | 3 | Governments, Working Group on Methods chaired by Germany | para. 86 |
| Discussion Paper on Traceability | - | Governments | para. 83 |
| Scientific backgrounds for food safety assessment for recombinant-DNA microorganisms and fish | - | FAO/WHO | para. 95 |

Appendix I

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LISTE DES PARTICIPANTS
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Figuran en primer lugar los Jefes de las delegaciones, los Suplentes y Asesores aparecen
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Appendix II

**PROPOSED DRAFT PRINCIPLES FOR THE RISK ANALYSIS OF
FOODS DERIVED FROM MODERN BIOTECHNOLOGY**

(At Step 5 of the Elaboration Procedure)**SECTION 1 - INTRODUCTION**

1. For many foods, the level of food safety generally accepted by the society reflects the history of their safe consumption by humans. It is recognised that in many cases the knowledge required to manage the risks associated with foods has been acquired in the course of their long history of use. Foods are generally considered safe, provided that care is taken during development, primary production, processing, storage, handling and preparation.
2. The hazards associated with foods are subjected to the risk analysis process of the Codex Alimentarius Commission to assess potential risks and, if necessary, to develop approaches to manage these risks. The conduct of risk analysis is guided by general decisions¹ of the Codex Alimentarius Commission (CAC) as well as the Codex Working Principles for Risk Analysis².
3. While risk analysis has been used over a long period of time to address chemical hazards (*e.g.* residues of pesticides, contaminants, food additives and processing aids), and it is being increasingly used to address microbiological hazards and nutritional factors, the principles were not elaborated specifically for whole foods.
4. The risk analysis approach can, in general terms, be applied to foods including foods derived from modern biotechnology. However, it is recognised that this approach must be modified when applied to a whole food rather than to a discrete hazard that may be present in food.
5. The principles presented in this document should be read in conjunction with the Codex Working Principles for Risk Analysis to which these principles are supplemental.
6. Where appropriate, the results of a risk assessment undertaken by other regulatory authorities may be used to assist in the risk analysis and avoid duplication of work.

SECTION 2 – SCOPE AND DEFINITIONS

7. The purpose of these Principles is to provide a framework for undertaking risk analysis on the safety and nutritional aspects of foods derived from modern biotechnology. This document does not address environmental, other ethical, moral and socio-economic aspects of the research, development, production and marketing of these foods³.
8. The definitions below apply to these Principles:
 - “**Modern Biotechnology**” means the application of:

¹ These decisions include the *Statements of principle concerning the role of science in the Codex decision-making process and the extent to which other factors are taken into account* and the *Statements of principle relating to the role of food safety risk assessment* (Codex Alimentarius Commission Procedural Manual; Eleventh edition).

² Currently under consideration at Step 3 in CCGP (ALINORM 01/33 APPENDIX III, Report of the Fifteenth Session of the Codex Committee on General Principles).

³ This document does not address animal feed and animals fed such feed insofar as these animals have been genetically modified (i.e. genetically modified animals are covered).

(i). *In vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

(ii). Fusion of cells beyond the taxonomic family,

that overcome natural physiological reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection⁴.

- “**Conventional Counterpart**” means a related organism/variety, its components and/or products for which there is experience of establishing safety based on common use as food⁵.

SECTION 3 – PRINCIPLES

9. The risk analysis process for foods derived from modern biotechnology should be consistent with the Codex Working Principles for Risk Analysis⁶.

RISK ASSESSMENT

10. Risk assessment includes a safety assessment, which is designed to identify whether a hazard, nutritional or other safety concern is present, and if present, to gather information on its nature and severity. The safety assessment should include a comparison between the food derived from modern biotechnology and its conventional counterpart focusing on determination of similarities and differences. If a new or altered hazard, nutritional or other safety concern is identified by the safety assessment, the risk associated with it should be characterized to determine its relevance to human health.
11. A safety assessment is characterized by an assessment of a whole food or a component thereof relative to the appropriate conventional counterpart:
- a) taking into account both intended and unintended effects;
 - b) identifying new or altered hazards;
 - c) identifying changes, relevant to human health, in key nutrients.
12. A pre-market safety assessment should be undertaken following a structured and integrated approach and be performed on a case-by-case basis. The data and information, based on sound science, obtained using appropriate methods and analysed using appropriate statistical techniques, should be of a quality and quantity that would withstand scientific peer review.
13. Risk assessment should apply to all relevant aspects of foods derived from modern biotechnology. The risk assessment approach for these foods is based on a consideration of science-based multidisciplinary data and information taking into account the factors mentioned in the accompanying Guidelines⁷.
14. Scientific data for risk assessment are generally obtained from a variety of sources, such as the developer of the product, scientific literature, general technical information, independent scientists, regulatory agencies, international bodies and other interested parties. Data should be assessed using appropriate science-based risk assessment methods.
15. Risk assessment may be based on the data and information derived from different testing procedures, provided that the procedures are scientifically sound and the parameters being measured are comparable.

⁴ This definition is taken from the Cartagena Biosafety Protocol under the Convention on Biological Diversity.

⁵ It is recognized that for the foreseeable future, foods derived from modern biotechnology will not be used as conventional counterparts.

⁶ At Step 3 in CCGP.

⁷ Reference is made to the Proposed Draft Guideline for the Conduct of Safety Assessment of Foods Derived from Recombinant-DNA Plants.

RISK MANAGEMENT

16. Risk management measures for foods derived from modern biotechnology should be proportional to the risk, based on the outcome of the risk assessment and, where relevant, taking into account other legitimate factors⁸ in accordance with the general decisions of the Codex Alimentarius Commission (CAC) as well as the Codex Working Principles for Risk Analysis⁹.
17. It should be recognised that different risk management measures may be capable of meeting the same objective with regard to the management of risks associated with safety and nutritional impacts on human health, and therefore would be equivalent.
18. Risk managers should take into account the uncertainties identified in the risk assessment and implement appropriate measures to manage these uncertainties.
19. Risk management measures may include, as appropriate, food labelling,¹⁰ conditions for marketing approvals, post-market monitoring and development of analytical methods for the detection or identification of foods derived from modern biotechnology.
20. Post-market monitoring may be an appropriate risk management measure in specific circumstances. Its need and utility should be considered, on a case-by-case basis, during risk assessment and practicability in addition during risk management. Post-market monitoring may be undertaken for the purpose of:
 - A) verifying conclusions about the absence or the possible occurrence, impact and significance of potential consumer health effects; and
 - B) monitoring changes in nutrient intake levels, associated with the introduction of foods likely to significantly alter nutritional status, to determine their human health impact.
21. [Risk management may include traceability.]¹¹

RISK COMMUNICATION

22. Effective risk communication is essential at all phases of risk assessment and risk management. It is an interactive process involving all interested parties, including government, industry, academia, media and consumers.
23. Risk communication should include transparent safety assessment and management decision-making processes. These processes should be fully documented at all stages and open to public scrutiny, whilst respecting legitimate concerns to safeguard the confidentiality of commercial and industrial information. In particular, reports prepared on the safety assessments and other aspects of the decision-making process should be made available to all interested parties.
24. Effective risk communication should include responsive consultation processes. Consultation processes should be interactive and may include consultation with existing bodies. The views of all interested parties should be sought and relevant food safety and nutritional issues that are raised during consultation should be addressed during the risk analysis process.

⁸ The Working Group recalled that work was in progress in CCGP on this matter.

⁹ See footnotes 1 and 2 above.

¹⁰ Reference is made to the CCFL in relation to the Proposed Draft Recommendations for the Labelling of Foods and Food Ingredients obtained through certain techniques of genetic modification/genetic engineering (proposed Draft Amendment to the General Standard for the Labelling of Prepacked Foods) at Step 3 of the procedures.

¹¹ It was recognized that discussion on the applicability of traceability or other equivalent approaches as a tool in support of risk management measures is under consideration by the Codex Alimentarius Commission and its subsidiary bodies. The Task Force encouraged an early completion of this discussion.

CONSISTENCY

25. A consistent approach should be adopted to characterise and manage safety and nutritional risks associated with foods derived from modern biotechnology. The acceptable level of risk for these foods should be consistent with that for similar foods already on the market.
26. A transparent and well-defined regulatory framework should be provided in characterising and managing the risks associated with foods derived from modern biotechnology. This should include consistency of data requirements, assessment frameworks, acceptable level of risk, communication and consultation mechanisms and timely decision processes.

CAPACITY BUILDING AND INFORMATION EXCHANGE

27. Efforts should be made to improve the capability of regulatory authorities, particularly those of developing countries, to assess and manage risks, including enforcement, associated with foods derived from modern biotechnology or to interpret assessments undertaken by other authorities or recognised expert bodies, including access to analytical technology.
28. Regulatory authorities, international organisations and expert bodies and industry should facilitate through appropriate contact points including but not limited to Codex Contact Points and other appropriate means, the exchange of information including the information on analytical methods.

REVIEW PROCESSES

29. Risk analysis methodology and its application should be consistent with new scientific knowledge and other information relevant to risk analysis.
30. Recognising the rapid pace of development in the field of biotechnology, the approach to safety assessments of foods derived from modern biotechnology should be reviewed as necessary to ensure that emerging scientific information is incorporated into the risk analysis. Where new scientific information relevant to a risk assessment becomes available the assessment should be reviewed to incorporate that information and, if necessary, risk management measures adapted accordingly.

Appendix III

**PROPOSED DRAFT GUIDELINE FOR THE CONDUCT OF
FOOD SAFETY ASSESSMENT OF FOODS DERIVED FROM
RECOMBINANT-DNA PLANTS**

(At Step 5 of the Elaboration Procedure)

SECTION 1 - SCOPE

1. This Guideline supports the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology and addresses safety and nutritional aspects of foods derived from plants that have a history of safe use as sources of food and that have been modified to exhibit new traits.
2. This document does not address animal feed or animals fed the feed. This document also does not address environmental risks.
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 have been assessed scientifically in a manner that would fully characterise all risks 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 plant varieties, including recombinant-DNA plants, 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. The Guideline describes the recommended approach to making safety assessments of foods derived from recombinant-DNA plants where a conventional counterpart exists, and identifies the data and information that are generally applicable to making such assessments. While this Guideline is designed for foods derived from recombinant-DNA plants, the approach described could, in general, be applied to foods derived from plants that have been altered by other techniques.

SECTION 2 - DEFINITIONS

7. The definitions below apply to this Guideline:
 - “Recombinant-DNA Plant” - means a plant 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” - means a related plant variety, its components and/or products for which there is experience of establishing safety based on common use as food¹.

SECTION 3 - INTRODUCTION TO FOOD SAFETY ASSESSMENT

8. Traditionally, new varieties of food plants have not been systematically subjected to extensive chemical, toxicological, or nutritional evaluation prior to marketing, with the exception of foods for specific groups, such as infants, where the food may constitute a substantial portion of the diet. Thus, new varieties of corn, soya, potatoes and other common food plants are evaluated by breeders for agronomic and phenotypic characteristics, but generally, foods derived from such new plant varieties are not subjected to the rigorous and extensive food safety testing procedures, including studies in animals, that are typical of chemicals such as food additives or pesticide residues that may be present in food.
9. 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 characterised, 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 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 upper limits by the application of appropriate safety factors.
10. Animal studies cannot readily be applied to testing the risks associated with whole foods, which are complex mixtures of compounds, often characterised by a wide variation in composition and nutritional value. Due to their bulk and effect on satiety, they can usually only be fed to 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 which 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. Another consideration in deciding the need for animal studies is whether it is appropriate to subject experimental animals to such a study if it is unlikely to give rise to meaningful information.
11. Due to the difficulties of applying traditional toxicological testing and risk assessment procedures to whole foods, a more focused approach is required for the safety assessment of foods derived from food plants, including recombinant-DNA plants. 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 plant or in the foods derived from it, using the concept of *substantial equivalence*.
12. The concept of substantial equivalence is a key step in the safety assessment process. However, it is not a safety assessment in itself; rather it represents the starting point which is used to structure the safety assessment of a new food relative to its conventional counterpart. This concept is used to identify similarities and differences between the new food and its conventional counterpart². It aids in the identification of potential safety and nutritional issues and is considered the most appropriate strategy to date for safety assessment of foods derived from recombinant-DNA plants. 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 comparator.

¹ It is recognized that for the foreseeable future, foods derived from modern biotechnology will not be used as conventional counterparts.

² 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).

UNINTENDED EFFECTS

13. In achieving the objective of conferring a specific target trait (intended effect) to a plant 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. Unintended effects may be deleterious, beneficial, or neutral with respect to the health of the plant or the safety of foods derived from the plant. Unintended effects in recombinant-DNA plants may also arise through the insertion of DNA sequences and/or they may arise through subsequent conventional breeding of the recombinant-DNA plant. Safety assessment should include data and information to reduce the possibility that a food derived from a recombinant-DNA plant would have an unexpected, adverse effect on human health.
14. Unintended effects can result from the random insertion of DNA sequences into the plant 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. For example, the expression of enzymes at high levels may give rise to secondary biochemical effects or changes in the regulation of metabolic pathways and/or altered levels of metabolites.
15. Unintended effects due to genetic modification 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. Due to the expanding information on plant genome and the increased specificity in terms of genetic materials introduced through recombinant-DNA techniques compared with other forms of plant breeding, it may become easier to predict unintended effects of a particular modification. Molecular biological and biochemical techniques can also be used to analyse potential changes at the level of gene transcription and message translation that could lead to unintended effects.
16. The safety assessment of foods derived from recombinant-DNA plants 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 health. These data and information, when considered in total, provide assurance that the food is unlikely to have an adverse effect on human health. The assessment for unintended effects takes into account the agronomic/phenotypic characteristics of the plant that are typically observed by breeders in selecting new varieties for commercialization. These observations by breeders provide a first screen for plants that exhibit unintended traits. New varieties that pass this screen are subjected to safety assessment as described in Sections 4 and 5.

FRAMEWORK OF FOOD SAFETY ASSESSMENT

17. The safety assessment of a food derived from a recombinant-DNA plant follows a stepwise process of addressing relevant factors that include:
 - A) Description of the new variety;
 - B) Description of the host plant and its use as food;
 - C) Description of the donor organism(s);
 - D) Description of the genetic modification(s);
 - E) Characterization of the genetic modification(s);
 - F) Safety assessment:
 - a) expressed substances (non-nucleic acid substances);
 - b) compositional analyses of key components;

- c) evaluation of metabolites ;
 - d) food processing;
 - e) nutritional modification; and
- G) Other considerations.
18. In certain cases, the characteristics of the product may necessitate development of additional data and information to address issues that are unique to the product under review.
19. Experiments intended to develop data for safety assessments 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. The sensitivity of all analytical methods should be documented.
20. 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. The expected endpoint of such an assessment will be a conclusion regarding whether or not the new food is as safe and nutritious as the conventional counterpart against which it has been compared and for which there exists a history of safe use. 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 and if so to make well-informed and appropriate decisions.

SECTION 4 - GENERAL CONSIDERATIONS

DESCRIPTION OF THE NEW VARIETY

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

DESCRIPTION OF THE HOST PLANT AND ITS USE AS FOOD

22. A comprehensive description of the host plant should be provided. The necessary data and information should include, but need not be restricted to:
- A) common or usual name; scientific name; and, taxonomic classification;
 - B) history of cultivation and development through breeding, in particular identifying traits that may adversely impact on human health ;
 - C) information on the host plant's genotype and phenotype relevant to its safety, including any known toxicity or allergenicity; and
 - D) history of safe use for consumption as food.
23. Relevant phenotypic information should be provided not only for the host plant, but also for related species and for plants that have made or may make a significant contribution to the genetic background of the host plant.
24. The history of use may include information on how the plant is typically cultivated, transported and stored, whether special processing is required to make the plant safe to eat, and the plant's normal role in the diet (e.g. which part of the plant is used as a food source, whether its consumption is important in particular subgroups of the population, what important macro- or micro-nutrients it contributes to the diet).

DESCRIPTION OF THE DONOR ORGANISM(S)

25. Information should be provided on the donor organism(s) and, when appropriate, on other members of the corresponding genus. It is particularly important to determine if the donor organism(s) or other closely

related members of the family naturally exhibit characteristics of pathogenicity or toxin production, or have other traits that affect human health (e.g. presence of antinutrients). The description of the donor organism(s) should include:

- A) its usual or common name;
- B) scientific name;
- C) taxonomic classification;
- D) information about the natural history as concerns food safety;
- E) information on naturally occurring toxins, anti-nutrients and allergens; for microorganisms, additional information on pathogenicity and the relationship to known pathogens; and
- F) information on the past and present use, if any, in the food supply and exposure route(s) other than intended food use (e.g. possible presence as contaminants).

DESCRIPTION OF THE GENETIC MODIFICATION(S)

- 26. Sufficient information should be provided on the genetic modification to allow for the identification of all genetic material potentially delivered to the host plant and to provide the necessary information for the analysis of the data supporting the characterization of the DNA inserted in the plant.
- 27. The description of the transformation process should include:
 - A) information on the specific method used for the transformation (e.g. *Agrobacterium*-mediated transformation);
 - B) information, if applicable, on the DNA used to modify the plant (e.g. helper plasmids), including the source (e.g. plant, microbial, viral, synthetic), identity and expected function in the plant; and
 - C) intermediate host organisms including the organisms (e.g. bacteria) used to produce or process DNA for transformation of the host organism;
- 28. Information should be provided on the DNA to be introduced, including:
 - A) the characterization of all the genetic components including marker genes, regulatory and other elements affecting the function of the DNA;
 - B) the size and identity;
 - C) the location and orientation of the sequence in the final vector/construct; and
 - D) the function.

CHARACTERIZATION OF THE GENETIC MODIFICATION(S)

- 29. In order to provide clear understanding of the impact on the composition and safety of foods derived from recombinant-DNA plants, a comprehensive molecular and biochemical characterization of the genetic modification should be carried out.
- 30. Information should be provided on the DNA insertions into the plant genome; this should include:
 - A) the characterization and description of the inserted genetic materials;
 - B) the number of insertion sites;
 - C) the organisation of the inserted genetic material at each insertion site including copy number and sequence data of the inserted material and, where appropriate, of surrounding region; and
 - D) identification of any open reading frames within the inserted DNA or created by the insertions with contiguous plant genomic DNA including those that could result in fusion proteins.
- 31. Information should be provided on any expressed substances in the recombinant-DNA plant; this should include:

- A) the gene product (e.g. a protein or an untranslated RNA);
- B) the gene product's function;
- C) the phenotypic description of the new trait(s);
- D) the level and site of expression in the plant of the expressed gene product(s), and the levels of its metabolites in the plant, particularly in the edible portions; and
- E) 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.

32. In addition, information should be provided:

- A) to demonstrate whether the arrangement of the genetic material used for insertion has been conserved or whether significant rearrangements have occurred upon integration;
- B) to demonstrate whether deliberate modifications made to the amino acid sequence of the expressed protein result in changes in its post-translational modification or affect sites critical for its structure or function;
- C) to demonstrate that the intended effect of the modification has been achieved and that all expressed traits are expressed and inherited in a manner that is stable through several generations consistent with laws of inheritance. It may be necessary to examine the inheritance of the DNA insert itself or the expression of the corresponding RNA if the phenotypic characteristics cannot be measured directly;
- D) to demonstrate that the newly expressed trait(s) are expressed as expected in the appropriate tissues in a manner and at levels that are consistent with the associated regulatory sequences driving the expression of the corresponding gene;
- E) to indicate whether there is any evidence to suggest that one or several genes in the host plant has been affected by the transformation process; and
- F) to confirm the identity and expression pattern of any new fusion proteins.

SAFETY ASSESSMENT OF EXPRESSED SUBSTANCES (NON-NUCLEIC ACID SUBSTANCES)

Assessment of possible toxicity

- 33. *In vitro* nucleic acid techniques enable the introduction of DNA which can result in the synthesis of new substances in plants. These can be conventional components of plant foods such as proteins, fats, carbohydrates, vitamins which are novel in context of that recombinant-DNA plant. Conventional toxicology studies are not considered necessary where the substance or a closely related substance has been consumed safely in food, taking into account its exposure, for the reasons described in Section 3.
- 34. In other cases, the use of conventional toxicology studies on the new substance will be necessary. This may require the isolation of the new substance from the recombinant-DNA plant, or the synthesis or production of the substance from an alternative source, in which case the material should be shown to be structurally, functionally and biochemically equivalent to that produced in the recombinant-DNA plant.
- 35. The safety assessment of the expressed substance should identify the concentration of the substance in the edible parts of the recombinant-DNA plant, including, as appropriate, variations and mean values. Current dietary exposure and possible effects on population sub-groups should also be considered. In the case of proteins, the assessment of potential toxicity should focus on amino acid sequence similarity between the protein and known protein toxins and anti-nutrients (e.g. protease inhibitors, lectins) as well as stability to heat or processing and to degradation in appropriate representative gastric and intestinal model systems. Appropriate oral toxicity studies³ may be carried out in cases where the protein is

³ Guidelines for oral toxicity studies have been developed in international fora, for example the OECD Guidelines for the Testing of Chemicals.

present in the food, is not similar to proteins that have been safely consumed in food, and has not previously been consumed safely in food.

36. The expressed trait should be shown to be unrelated to any characteristics of donor organisms that could be harmful to human health. Information should be provided to ensure that genes coding for known toxins or anti-nutrients present in the donor organisms are not transferred to recombinant-DNA plants that do not normally express those toxic or anti-nutritious characteristics. This assurance is particularly important in cases where a recombinant-DNA plant is processed differently from a donor plant, since conventional processing techniques associated with the donor organisms may deactivate anti-nutrients or toxicants.
37. Additional *in vivo* or *in vitro* studies may be needed on a case-by-case basis to assess the toxicity of expressed substances. The types of studies depend on the original source of the expressed substances and their function. Such studies may include assays of metabolism, toxicokinetics, chronic toxicity/carcinogenicity, impact on reproductive function, and teratogenicity.
38. The safety assessment should take into account the potential accumulation of any substances, toxic metabolites, contaminants, or pest control agents on plants that might result from genetic modification.

Assessment of possible allergenicity (proteins)

39. When the protein(s) resulting from the inserted gene is present in the food, it should be assessed for potential allergenicity in all cases. A detailed presentation of issues to be considered can be found in annex⁴.
40. A decision-tree strategy⁵ should be applied in the assessment of the potential allergenicity of the newly-expressed protein(s). The decision-tree approach should rely upon various criteria used in combination (since no single criterion is sufficiently predictive). As noted in Paragraph 19, the data should be obtained using sound scientific methods.
41. The newly expressed proteins in foods derived from recombinant-DNA plants should be evaluated for any possible role in the elicitation of gluten-sensitive enteropathy, if the introduced genetic material is obtained from wheat, rye, barley, oats, or related cereal grains.
42. The transfer of genes from commonly allergenic foods and from foods known to elicit gluten-sensitive enteropathy in sensitive individuals should be avoided unless it is documented that the transferred gene does not code for an allergen or for a protein involved in gluten-sensitive enteropathy.

COMPOSITIONAL ANALYSES OF KEY COMPONENTS⁶

43. Analyses of concentrations of key components⁷ of the recombinant-DNA plant and, especially those typical of the food, should be compared with an equivalent analysis of a conventional counterpart grown and harvested under the same conditions. In some cases, a further comparison with the recombinant-DNA plant grown under its expected agronomic conditions may need to be considered (e.g. application of an herbicide). The statistical significance of any observed differences should be assessed in the context of the range of natural variations for that parameter to determine its biological significance. The comparator(s) used in this assessment should ideally be the near isogenic parental line. In practice, this may not be feasible at all times, in which case a line as close as possible should be chosen. The purpose

⁴ To be developed, to reflect the two recent FAO/WHO expert consultation reports.

⁵ Decision tree strategies have been developed and modified on the basis of expert consultations in national and international fora, for example, the report of a Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology (WHO 2000) and the report of a Joint FAO/WHO Expert Consultation on Allergenicity of Foods Derived from Biotechnology (FAO 2001).

⁷ Key nutrients or key anti-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 plant, such as those compounds whose toxic potency and level may be significant to health (e.g. solanine in potatoes if the level is increased, selenium in wheat) and allergens.

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.

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

EVALUATION OF METABOLITES

45. Some recombinant-DNA plants may have been modified in a manner that could result in new or altered levels of various metabolites in the food. Consideration should be given to the potential for the accumulation of metabolites in the food that would adversely affect human health. Safety assessment of such plants requires investigation of residue and metabolite levels in the food and assessment of any alterations in nutrient profile. Where altered residue or metabolite levels are identified in foods, consideration should be given to the potential impacts on human health using conventional procedures for establishing the safety of such metabolites (e.g. procedures for assessing the human safety of chemicals in foods).

FOOD PROCESSING

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

NUTRITIONAL MODIFICATION

47. The assessment of possible compositional changes to key nutrients, which should be conducted for all recombinant-DNA plants, has already been addressed under 'Compositional analyses of key components'. However, foods derived from recombinant-DNA plants 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.
48. 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 plant. 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.
49. The use of plant breeding, including *in vitro* nucleic acid techniques, to change nutrient levels in crops can result in broad changes to the nutrient profile in two ways. The intended modification in plant constituents could change the overall nutrient profile of the plant 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 plant components may be individually assessed as safe, the impact of the change on the overall nutrient profile should be determined.

50. 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 alternative conventional foods (i.e. foods whose nutritional composition is closer to that of the food derived from recombinant-DNA plant) as appropriate comparators to assess the nutritional impact of the food.
51. 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 food plants serve as the major source of a particular nutrient in some populations. The nutrient and the populations affected should be identified.
52. Some foods may require additional testing. For example, animal feeding studies may be warranted for foods derived from recombinant-DNA plants 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

USE OF ANTIBIOTIC RESISTANCE MARKER GENES

53. Alternative transformation technologies that do not result in antibiotic resistance marker genes in foods should be used in the future development of recombinant-DNA plants, where such technologies are available and demonstrated to be safe.
54. Gene transfer from plants and their food products to gut microorganisms or human cells is considered a rare possibility because of the many complex and unlikely events that would need to occur consecutively. Nevertheless, the possibility of such events cannot be completely discounted⁸.
55. In assessing safety of foods containing antibiotic resistance marker genes, the following factors should be considered:
 - A) the clinical and veterinary use and importance of the antibiotic in question;
(Certain antibiotics are the only drug available to treat some clinical conditions (e.g. vancomycin for use in treating certain staphylococcal infections). Marker genes encoding resistance to such antibiotics should not be used in recombinant-DNA plants.)
 - B) whether the presence in food of the enzyme or protein encoded by the antibiotic resistance marker gene would compromise the therapeutic efficacy of the orally administered antibiotic; and
(This assessment should provide an estimate of the amount of orally ingested antibiotic that could be degraded by the presence of the enzyme in food, taking into account factors such as dosage of the antibiotic, amount of enzyme likely to remain in food following exposure to digestive conditions, including neutral or alkaline stomach conditions and the need for enzyme cofactors (e.g. ATP) for enzymatic activity and estimated concentration of such factors in food.)
 - C) safety of the gene product, as would be the case for any other expressed gene product.
56. 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

⁸In 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.

present in the food. In general, antibiotic resistance genes used in food production that encode resistance to clinically used antibiotics should not be present in widely disseminated foods.

REVIEW OF SAFETY ASSESSMENTS

57. The goal of the safety assessment is a conclusion as to whether the new food is as safe as and no less nutritious than the conventional counterpart against which it was compared. Nevertheless, the safety assessment should be reviewed in the light of new scientific information that calls into question the conclusions of the original safety assessment.

ANNEX

ASSESSMENT OF POSSIBLE ALLERGENICITY

[still to be developed by the Working Group on Allergenicity]

Appendix IV

*Answers by
the 2000 FAO/WHO Expert Consultation on Foods Derived from Biotechnology
to the Questions from the Codex ad hoc Intergovernmental Task Force¹*

1) WHAT OVERARCHING SCIENTIFIC PRINCIPLES SHOULD BE APPLIED TO THE SAFETY AND NUTRITIONAL ASSESSMENT?

Experience throughout the world has led to the identification of a number of common scientific principles currently used in safety and nutritional assessment.

The existing food supply has a long history of safe use, even though some foods are not safe for some individuals and many foods contain substances that would present health concerns if they were present above accepted levels. Most foods derived using recombinant-DNA techniques are obtained from traditional crops that have usually been modified to exhibit one or a few well-defined traits. The knowledge and experience gained in the use of traditional crops is an important component in the safety assessment of foods derived from such plants.

Safety assessment of whole foods and many complex food ingredients requires use of an approach that differs from the strategy used to assess safety of single, well-defined chemicals, such as food additives, pesticides and contaminants. The approach for whole foods is case-by-case, based on an evaluation of multi-disciplinary data and information, that is derived from, as appropriate, but is not limited to, agronomic, genetic, molecular biological, nutritional, toxicological and chemical properties. Toxicology testing in animals is not routinely employed, but when necessary based on an assessment of available data and information, tests should be designed to address specific issues.

The following issues are some of the main points considered in the evaluation: the new gene, the new protein and other food components, taking into account both intended and unintended changes in the food and steps to reduce the likelihood of adverse, unexpected effects. In specific cases, additional effects (such as antibiotic resistance) may be evaluated.

Genetically modified foods and conventional foods have many characteristics in common, and in many cases, the new food or food ingredient will be nutritionally equivalent to its conventional counterpart.

Analytical methods traditionally applied in the evaluation of food constituents such as total protein, fat, ash, fibre and micronutrients may need to be augmented with additional analyses using profiling methods to identify unexpected effects and modified nutrient profiles which may impact dietary intake and health.

Because of the potential for broad changes in nutrient levels and interactions with other nutrients as well as unexpected effects, it may be necessary in certain instances to undertake feeding tests in animals to determine outcomes that result from changes in nutrient profiles and nutrient bioavailability. Nutritional modifications which are within normal ranges of nutrient variation might require a less extensive evaluation than those outside normal ranges.

The data and information should be of a quality and quantity that would withstand scientific peer review. Safety assessment is designed to identify information on the nature and the severity of any hazards that may be present, allowing appropriate management methods to be defined.

In conclusion, safety assessment of food and food ingredients obtained using recombinant-DNA techniques does not require new scientific principles or methodology. Similar principles for the assessment of the safety and wholesomeness of genetically modified foods should be applied as practised for conventional

¹ extract from the Report of the Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology: "Safety Aspect of Genetically Modified Foods of Plant Origin," WHO, 2000

foods. Depending on the characteristics of the genetic modifications, specific safety and nutritional aspects are assessed.

2) WHAT IS THE ROLE, AND WHAT ARE THE LIMITATIONS, OF SUBSTANTIAL EQUIVALENCE IN THE SAFETY AND NUTRITIONAL ASSESSMENT? ARE THERE ALTERNATIVE STRATEGIES TO SUBSTANTIAL EQUIVALENCE THAT SHOULD BE USED FOR THE SAFETY AND NUTRITIONAL ASSESSMENT?

The concept of *substantial equivalence* is well established as an important component in safety assessment, and has been elaborated in several international reports. It is based on the idea that an existing organism (plant) used as food, or as a source of food, can serve as the basis for comparison when assessing the safety for human consumption of a food or a food component that has been modified or is new. There is a broad consensus that *substantial equivalence* is of value in safety assessment.

Application of the concept of substantial equivalence may lead to the identification of similarities and defined differences in the food and food ingredients. Further safety assessment will be focused on establishing the safety of the differences in the new product such that safety of the food or food ingredient can be established, relative to its comparator. The safety assessment carried out in this way does not provide an absolute safety warrant for the new product.

Another aspect of the concept of *substantial equivalence* is that it can only be applied where there is a suitable comparator. This requires that sufficient data is available or can be generated for the comparator. Where there is no comparator, *substantial equivalence* cannot be used to assess safety. In such cases, safety testing will be required based on the properties of the food concerned.

Current strategies for assessing the safety of foods derived from genetically modified plants are considered appropriate. There are presently no alternative strategies that would provide a better assurance of safety for genetically modified foods than the appropriate use of the concept of *substantial equivalence*. However, some aspects of the steps in safety assessment process could be refined to keep abreast of developments in genetic modification technology. Methodologies, such as profiling techniques, offer a means of providing a more detailed analytical comparison. However, much more developmental work would be necessary before such methods could be validated.

3) WHAT SCIENTIFIC APPROACH CAN BE USED TO MONITOR AND ASSESS POSSIBLE LONG-TERM HEALTH EFFECTS OR UNINTENDED/UNEXPECTED ADVERSE EFFECTS?

The Consultation considered that the methodologies for safety evaluation elaborated in the report are adequate to detect and evaluate any possible long-term effects of genetically modified foods.

The Consultation considered the issue of long-term effects from the consumption of genetically modified foods and noted that very little is known about the potential long-term effects of any foods. In many cases, this is further confounded by wide genetic variability in the population, such that some individuals may have a greater predisposition to food-related effects.

Against this background, the Consultation acknowledged that for genetically modified foods, the pre-marketing safety assessment already gives assurance that the food is as safe as its conventional counterpart. Accordingly it was considered that the possibility of long-term effects being specifically attributable to genetically modified foods would be highly unlikely.

An important aspect of the safety assessment is a consideration of the nature of the introduced gene product. Where there is no history of consumption of the introduced gene product or of the food, a 90-day study will probably be indicated. If such studies show evidence suggesting possible long-term effects, e.g. evidence of cell proliferation, further long-term studies would need to be considered if the development of the product was to continue.

The Consultation was of the view that monitoring to establish links between diet and disease is desirable. However, many chronic health effects are multifactorial and it was recognised that observational epidemiological studies would be unlikely to identify any such effects against a background of undesirable effects of conventional foods. Experimental studies, such as randomised controlled trials (RCTs), if properly

designed and conducted, could be used to investigate the medium/long term effects of any foods, including genetically modified foods. Such studies could provide additional evidence for human safety, but would be difficult to conduct. In this respect, it is also important to recognise the wide variation in diets from day to day and year to year.

The same problems apply to the detection of potential long-term beneficial health effects. Nevertheless, it was recognised that genetically modified foods intended to produce nutritional effects are under development for use in developed and developing countries. In such cases, a change in nutrient levels in a particular crop plant may impact overall dietary intake and it would be important to monitor changes in nutrient levels in such foods and evaluate their potential effect on nutritional and health status.

The potential occurrence of unintended effects is not specific for the application of recombinant-DNA techniques, rather it is an inherent and general phenomenon in conventional breeding. One of the approaches to cope with this problem is to select and discard plants with unusual and undesired phenotypic and agronomic parameters already at an early stage. The practice of consecutive back-crossing is also a major procedure used to eliminate unintended effects. Only in rare cases are these approaches accompanied by analytical screening of defined constituents.

Unintended effects due to genetic modification may be subdivided into two groups: those which are "predictable" based on metabolic connections to the intended effect or knowledge of the site of insertion and those which are "unexpected". Due to the increased precision of genetic modification compared to conventional breeding, it may become easier to predict pathways likely to be influenced by unintended effects.

The comparator used to detect unintended effects should ideally be the near isogenic parental line grown under identical conditions. In practice, this may not be feasible at all times, in which case a line as close as possible should be chosen. The resulting natural variation should be taken into account in assessing the statistical significance of the unintended effect.

Where statistically significant unintended differences are observed, their biological significance should be assessed. This may be assisted by knowledge of the mechanisms leading to the changes. In order to assess the biological and safety relevance of an unintended effect, data on the genetically modified plant should be compared to data on other conventional varieties and literature data. If the differences exceed natural variations in traditional food crops, further assessment is required.

Present approaches to assess possible unintended effects are based, in part, on the analysis of specific components (targeted approach). In order to increase the probability of detecting unintended effects, profiling techniques are considered as useful alternatives (non-targeted approach). Profiling techniques are used at different level e.g. genomics, proteomics and metabolomics.

In the future, genetic modifications of plants are likely to be more complex perhaps involving multiple between-species transfers and this may lead to an increased chance of unintended effects. In such cases, profiling techniques may contribute to the detection of differences in a more extensive way than targeted chemical analysis but they are not yet fully developed and have certain limitations. Having detected differences using profiling techniques, their safety implications of such difficulties will still need to be considered.

4) WHAT SCIENTIFIC APPROACH CAN BE USED TO ASSESS THE POTENTIAL ALLERGENICITY?

An assessment of the potential allergenicity should be made for all genetically modified foods. In the assessment, the novel proteins resulting from the inserted gene should be the focus of the investigation in most cases.

An assessment of the potential allergenicity of the genetically modified food should be conducted in all cases. Possible enhancement of the inherent allergenicity of the host plant food should also be included in the assessment only when the intended effect of the genetic modification involves a significant alteration of the protein content of the food product derived from the host plant.

A decision-tree strategy should be applied in the assessment of the potential allergenicity of the novel protein(s). When the transferred gene is obtained from a source with a known history of allergenicity, the assessment should focus initially upon the immunochemical reactivity of the newly introduced protein with IgE from the blood serum of individuals with known allergies to the source of the transferred genetic material. Where necessary (in cases where no evidence of immunochemical reactivity is obtained), skin tests with extracts of the novel protein and blinded oral food challenges with the genetically modified food should be conducted on individuals with known allergies to the source of the transferred genetic material to provide confirmation that the novel protein is not allergenic. This series of tests provides adequate evidence regarding the allergenicity (or lack thereof) of novel proteins expressed by genes obtained from known allergenic sources.

The decision-tree approach should rely upon various criteria used in combination (since no single criterion is sufficiently predictive). The current criteria include the sequence homology of the newly introduced protein to known allergens, the immunochemical reactivity of the newly introduced protein with IgE from blood serum of appropriate, allergic individuals when sequence homology is found, and the stability of the novel protein to digestion in gastric and intestinal model systems. This Consultation suggests that the incorporation of two additional criteria to the decision-tree approach when the genetic material is not known to be allergenic might be useful. The level and site of expression of the novel protein and the functional properties of the novel protein should be considered for addition to the list. These criteria taken together offer reasonable evidence that the novel protein is not allergenic, is not cross-reactive with known allergens, and has limited potential to become a food allergen. However, the development of additional criteria could offer additional confidence in the decision-tree approach. In particular, this Consultation advocated continued research on the development of a well-validated animal models for the assessment of the potential allergenicity of novel proteins from genetically modified foods. The Consultation also advocated additional research to identify allergenic proteins in food and to determine their protein sequences.

5) WHAT SCIENTIFIC APPROACH CAN BE USED TO ASSESS THE POSSIBLE RISKS ARISING FROM THE USE OF ANTIBIOTIC RESISTANCE MARKER GENES IN PLANTS AND MICROORGANISMS ?

In genetically modified plants, the product of an antibiotic resistance gene must be subjected to standard safety assessments as would be performed on any other introduced gene product. Thus the product of the antibiotic resistance gene must be assessed for toxicity and potential allergenicity.

Where antibiotic resistance marker genes are present in plants or microorganisms, the possibility of transfer of the genes to pathogenic microorganisms and possible clinical implications must be considered. Horizontal gene transfer from plants and plant products consumed as food to gut microorganisms or human cells is considered as a rare possibility, but cannot be completely discounted. The most important consideration with respect to horizontal gene transfer is the consequence of a gene being transferred and expressed in transformed cells. An important example is the transfer of antimicrobial resistance genes, if it were to occur, from genetically modified foods to gut microorganisms. Important considerations for the assessment of the consequences of the transfer and expression of this gene in transformed cells would be the clinical and veterinary importance of the antibiotic in question, the levels of natural resistance and the availability of effective alternative therapies. In general, antibiotic resistance genes used in food production that encode resistance to clinically important antibiotics should not be present in widely disseminated genetically modified organism or foods and food ingredients.

Appendix V

**PRELIMINARY REPORT OF
THE AD HOC INTERGOVERNMENTAL TASK FORCE ON FOODS DERIVED FROM
BIOTECHNOLOGY**

TO BE PRESENTED TO THE 24TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION

INTRODUCTION

1. The 23rd Session of the Codex Alimentarius Commission, held in June/July 1999 in Rome, decided to establish the *Ad Hoc* Intergovernmental Task Force on Foods Derived from Biotechnology (hereinafter referred to as the Task Force) to develop standards, guidelines or recommendations, as appropriate, for foods derived from biotechnology or traits introduced into foods by biotechnology. The Government of Japan was designated as host Government of the Task Force.

2. According to the time frame set out in its terms of reference, the Task Force shall complete its work within four years, and shall first submit a preliminary report to the Codex Alimentarius Commission in 2001, a mid-term report, where appropriate, to the Executive Committee in 2002, and a full report in 2003.

SESSIONS OF THE TASK FORCE

3. The Task Force held two Sessions in Chiba (Japan), the first being from 14-17 March 2000 and the second from 25 to 29 March 2001.

4. The First Session agreed to an overall work programme as follows¹:

- General principle for risk analysis of foods derived from biotechnology (precise title still to be determined);
- Specific guidance on the risk assessment of foods derived from biotechnology (precise title still to be determined);
- List of available analytical methods including those for the detection or identification of foods or food ingredients derived from biotechnology.

5. Two *ad hoc* open-ended Working Groups were established. A Working Group chaired by the Government of Japan was entrusted to elaborate draft texts of the General Principles and the Specific Guidance for Risk Assessment while a Working Group chaired by the Government of Germany prepared a list of available analytical methods.

6. The first of these Working Groups met twice in Tokyo, Japan, from 5-7 July and from 30 October to 1 November 2000 and the second Working Group held a half-day meeting on the afternoon of 23 March 2001 in Tokyo after working primarily by correspondence.

7. At its Second Session, the Task Force considered the Proposed Draft General Principles and the Proposed Draft Guideline, a report of the Working Group for Analytical Methods, and a discussion paper on the concept of traceability and an information paper on familiarity.

¹ All of the proposed work was approved by the 47th Session of the Executive Committee in June 2000.

PROGRESS OF THE WORK OF THE TASK FORCE

- **General principle for risk analysis of foods derived from biotechnology:** “Proposed Draft Principles for the Risk Analysis of Foods Derived from Modern Biotechnology” have been completed for submission to the 24th Session of the Codex Alimentarius Commission for consideration at Step 5;
- **Specific guidance on the risk assessment of foods derived from biotechnology:** “Proposed Draft Guideline for the Conduct of Safety Assessment of Foods Derived from Recombinant-DNA Plants” has been completed for submission to the 24th Session of the Codex Alimentarius Commission for consideration at Step 5. An annex on the assessment of allergenicity is under preparation;
- **List of available analytical methods including those for the detection or identification of foods or food ingredients derived from biotechnology:** A first “List of methods validated by inter-laboratory studies” was prepared and will be complemented by the Working Group for Analytical Methods.

JOINT FAO/WHO EXPERT CONSULTATIONS ON FOODS DERIVED FROM BIOTECHNOLOGY

8. Two Joint FAO/WHO Expert Consultations were convened in June/July 2000 (Geneva) and in January 2001 (Rome). The 2000 Consultation addressed overall aspects of safety assessment of genetically modified foods of plant origin and responded to five specific questions presented by the First Session of the Task Force. The answers, noted with satisfaction by the Second Session of the Task Force are attached to this report². The Task Force notes however that the responses represent the current state of scientific opinion and are subject to further development as more scientific information becomes available. The 2001 Consultation specifically addressed the allergenicity of foods derived from biotechnology.

9. The outcome of both Consultations was well taken into account during the drafting of the General Principles and the Guideline.

STATUS OF THE PRELIMINARY REPORT

10. This report was adopted by the Task Force in Chiba on 29 March 2001. The responses of the Expert Consultation to the five questions and the texts of the Proposed Draft Principles and Guidelines form an integral part of this preliminary report.

² see Appendix IV