codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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ALINORM 01/34

JOINT FAO/WHO FOOD STANDARD PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Twenty-fourth Session
Geneva, 2-7 July 2001

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

Chiba 14-17 March 2000

Note: This report incorporates Codex Circular Letter CL 2000/9-FBT

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CX 4/80.2

CL 2000/9-FBT
April 2000

To: Codex Contact Point
Interested International Organizations

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

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

The Report of the First Session of the Codex *Ad Hoc* Intergovernmental Task Force on Foods Derived from Biotechnology is attached. It will be considered by the Twenty-fourth Session of the Codex Alimentarius Commission (Geneva, Switzerland, 2 – 7 July 2001).

SUMMARY AND CONCLUSIONS

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

MATTERS FOR CONSIDERATION BY THE EXECUTIVE COMMITTEE AND/OR THE CODEX ALIMENTARIUS COMMISSION

The Task Force agreed to report to the Executive Committee for approval as new work at Step 1 the following work plan:

- elaboration of major texts, namely:
  - A set of broad 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) (para. 27).
- preparation of a list of available analytical methods including those for the detection or identification of foods or food ingredients derived from biotechnology (para. 32).

OTHER MATTERS OF INTEREST TO THE COMMISSION

The Task Force:

- decided to establish two open-ended *Ad Hoc* Working Groups, namely:
  - *Ad Hoc* Working Group, to be chaired by Japan, to develop texts mentioned in (a) above (The Woking Group is planned to meet twice before the Second Session of the Task Force)(para. 35);
  - *Ad Hoc* Working Group, to be chaired by Germany, to compile a list of analytical methods mentioned in (b) above (The Working Group will hold a half-day meeting immediately prior to the Second Session of the Task Force)(para.36).
- welcomed the initiative of FAO and WHO to convene an expert consultation to support the scientific aspects of its work and agreed upon five specific questions for which scientific advice of the expert consultation would be sought for. (paras. 37, 38; Appendix III)

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

Chiba, Japan 14-17 March 2000

INTRODUCTION

1. The Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology (CX/FTB) held its First Session in Chiba, Japan from 14 to 17 March 2000, by courtesy of the Government of Japan. The Session was presided over by Professor Hiroshi Yoshikura, Director General, Research Institute, International Medical Center of Japan. A complete list of participants is included as Appendix I to this report.

OPENING OF THE SESSION

2. The Session was opened by Mr Shingo Haketa, Vice-Minister for Health and Welfare, who welcomed the participants to Makuhari, Chiba, Japan. Mr Haketa stressed the expectation of the global community that this Task Force would reach an agreement toward the modality of safety assessment of food derived from biotechnology within its prescribed period of 4 years. Dr Hartwig de Haen, Assistant Director-General, Economic and Social Department of 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. They stressed the potential benefit of biotechnology if utilised in an appropriate manner and at the same time the concern of consumers about the safety of foods derived from biotechnology. It was also stressed that FAO and WHO, as parent organizations of the Codex Alimentarius Commission, would provide continuous support to the work of the Task Force.

3. Mr Thomas Billy, Chairman of the Codex Alimentarius Commission recalled that the Codex Alimentarius Commission had first raised the issue of safety evaluation of foods derived from biotechnology over decade ago and stressed the importance of a progressive and science-based exchange of views to reach a consensus in this controversial problem area.

ADOPTION OF THE AGENDA (AGENDA ITEM 1)[1]

4. The Task Force adopted the Provisional Agenda as the Agenda of the Session.

MATTERS REFERRED TO THE TASK FORCE BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES (AGENDA ITEM 2)[2]

5. The Task Force noted the information presented in document CX/FBT 00/2 concerning the matters referred to the Codex *Ad Hoc* Intergovernmental Task Force on Foods Derived from Biotechnology by the Codex Alimentarius Commission and other Codex Committees. The Task Force noted in particular the decision of the Commission amending the Rules of Procedures of the Codex Alimentarius Commission that every effort should be made to adopt Codex Standards by consensus (New Rule X.2).

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1 CX/FBT 00/1

2 CX/FBT 00/2

6. The Task Force noted the Terms of reference established by the Codex Alimentarius Commission for its work (Annex 2 to document CX/FBT 00/2).

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]

7. The Committee noted the information presented in documents CX/FBT 00/3 and CX/FBT 00/3 Add. concerning the work by international organizations on the evaluation of the safety and nutrition aspects of foods derived from biotechnology.

8. Regarding the Expert Consultation on biotechnology to be held in June 2000, delegations stressed the importance of transparency and asked further clarification on the scope of the Consultation. Representatives of FAO and WHO informed the Task Force of current discussions on further improvements in transparency of the identification and selection procedures for the expert body and that experts would be selected on the basis of their personal capacity, that the selection process would be transparent and that member Governments would be involved in the process of identification and endorsement of experts. International NGOs would also be invited to nominate potential experts. It was announced that the scope of the Consultation would be to review the current methodology on safety assessment, including the concept of substantial equivalence, and also to study the nutritional aspects of foods derived from biotechnology. It was noted that the scope would be modified in the light of discussions at the present session of the Task Force.

9. Attention was drawn to the recommendation of the 1996 FAO/WHO Expert Consultation that developing countries should be provided with assistance and education regarding approaches to the safety assessment of foods and food components produced by genetic modification. The Representatives of FAO and WHO reaffirmed the support of these Organizations for technical assistance to developing countries and the Task Force so noted.

CONVENTION ON BIOLOGICAL DIVERSITY: CARTAGENA PROTOCOL ON BIOSAFETY

10. The Task Force was informed that the Protocol was adopted at the extended extraordinary session of the Conference of the Parties to the Convention in January 2000 in Montreal, Canada and would enter into force ninety days following the deposit of the fiftieth instrument of ratification. The text of the Protocol, which had not been available at the time of the preparation of the Secretariat's paper, was made available to delegations.[4]

11. It was noted that the objective of the Protocol was "in accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements."

12. Noting that interpretation of the provisions of the Protocol was beyond the mandate of the Commission, the Task Force noted that the Protocol formed part of the international regulatory framework within which the development, adoption, acceptance and use of Codex standards had to be undertaken. The objective and provisions of the Protocol would therefore need to be taken into account during the development of appropriate Codex texts by the Task Force.

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3 CX/FBT 00/3, CX/FBT 00/3 Add..

4 The text provided was that obtained from the website of the Secretariat of the CBD: http://www.biodiv.org

CONSIDERATION OF THE ELABORATION OF STANDARDS, GUIDELINES OR OTHER PRINCIPLES FOR FOODS DERIVED FROM BIOTECHNOLOGY (AGENDA ITEM 4)[5]

13. Member countries and observer organizations were invited to express their views on identification of area of the work of the Task Force, work priorities, and key concepts and definitions to be developed by the Task Force. Member countries and observer organizations had been invited by means of CL 1999/27-FBT to submit their comments on these matters, and responses had been compiled in the working documents referenced for this agenda item.

14. Many delegations and observer organizations identified safety and nutrition assessment of foods derived from biotechnology as the main priority area of the work. While recognizing that the concept of the substantial equivalence was being used in safety assessment, several delegations and observer organizations stressed the need for further review of the concept and its applicability to safety assessment. Several delegations stated that risk management and especially pre-market approval were fundamental aspects of risk analysis in relation to foods derived from biotechnology. The Task Force noted the necessity to study marker genes and the potential for non-intentional and long-term health effects. Some delegations expressed the view that it would be useful to establish an international expert body that would be responsible for risk assessment.

15. Concerning legitimate factors other than science that were relevant to the health of consumers and the promotion of fair trade practice, several delegations and the observer from the European Commission proposed to develop a specific guideline to take into account those factors. Several other delegations were of the opinion that since the Codex Committee on General Principles (CCGP) was currently working on this issue, and that therefore the development of a guideline specific to the Task Force was not an immediate priority. The following factors were mentioned by some delegations as potential other legitimate factors: ethical/religious/cultural considerations, consumer concerns/interests, food security, enforcement capacity and environmental risk.

16. Many delegations and observers also pointed out the need for addressing precautionary principles/approaches to be recommended by the Task Force. Several other delegations stressed that the issue of precaution should first be discussed at the Codex Committee on General Principles (CCGP).

17. It was also proposed that the concept of "familiarity" used in environmental risk assessment should be considered. It was noted that this concept had not previously been used by Codex and that further clarification would be needed.

18. Many delegations and observers identified the development of a guideline for the monitoring and traceability of the foods derived from biotechnology as a priority, indicating that these issues were not related only to consumer information but to consumer health protection. Other delegations and observers stated that the concept of "traceability" was new to Codex and required further clarification and explanation including the implications for developing countries. It was also noted that the concept may not be exclusive to foods derived from biotechnology and may need to be considered at a more general level.

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[5] CX/FBT 00/4 Part I (Brazil, Canada, Denmark, Hungary, Mexico, New Zealand, Singapore, South Africa, Switzerland, United States, ASSINSEL, Consumers International, CRN, IACFO), Part I- Add.1 (Norway, The European Community), Part I- Add.2 (Japan, Thailand, United Kingdom, United States, CIAA), Part I- Add.3 (Argentina) CX/FBT 00/4 Part II (Argentina, Brazil, Canada, Denmark, Hungary, Singapore, South Africa, United States), Part II-Add.1(Norway, The European Community), Part II-Add.2 (Japan, Thailand, United Kingdom, United States), Part II-Add.3 (Argentina), Part II- Add.4 (Australia, Japan, Switzerland, United Kingdom), Part II- Add.5 (Switzerland), CRD6 (United States), CRD 7 and 9 (Nigeria), CRD 8 (IACFO). CX/FBT 00/4 reproduces comments and/or information submitted by Governments and international organizations in response to CL 1999/27 FBT. Part I contains comments on identification of areas of work of the Task Force, work priorities, key concepts and definitions, core principles for risk assessment, risk management and risk communication, and collection, dissemination and exchange of information. Part II contains information relating to national and regional experiences with foods derived from biotechnology. The full text of these documents, including Conference Room Documents (CRDs), may be consulted on the Codex web site at http://www.codexalimentarius.net.

19. The need to consider the methods of analysis, including the detection methods of genetically modified foods was also pointed out by some delegations. Several delegations were of the view that these issues also required the involvement of the Codex Committee on Food Labelling (CCFL) or the Codex Committee on Method of Analysis and Sampling (CCMAS).

20. The need to develop a specific guideline on transparency and involvement of all stakeholders particularly consumers in the decision making process was emphasised by many of the delegations and observer organizations.

21. Regarding key concepts and definitions, many delegations emphasised the need to establish clear definitions on several key words. The definitions of "modern biotechnology" and "substantial equivalence" were identified by many delegations and it was suggested that the Task Force refer to definitions established or to be established by other fora, e.g. the definition on modern biotechnology to be developed by the Codex Committee on Food Labelling. The words "Recombinant DNA technique" and "Genetically Modified Organism (GMO)" were also identified by several delegations and observers as possibly requiring definitions.

22. Among various food categories that may fall under the scope of the Task Force, many delegations and observer organizations identified genetically modified foods derived from plants, microorganism and animals in order of the priority, while others were of the opinion that these three categories should all be addressed. Animal feed and food additives were also identified. It was noted by some delegations that animal feeding would be covered by the Codex *Ad Hoc* Intergovernmental Task Force on Animal Feeding to be held in Denmark in June 2000.

23. The Task Force finally elaborated, on the basis of an *aide-mémoire* prepared by the Chairman, a list of subjects potentially to be dealt with in its work by summarizing the proposals made by delegations. The list is reproduced as Appendix II to this report and is considered to cover the maximum range of proposals made during discussions.

24. The Task Force recognized that the time frame prescribed in its terms of reference necessitated the prioritization of its work subjects and that a considerable part of the proposed subjects were duly or partly covered by other Codex Committees or other international organizations. The Task Force recalled also that, according to its terms of reference, the Task Force should coordinate and closely collaborate with appropriate Codex Committees and take full account of existing work carried out by other international organizations. It agreed to identify those subjects that were already under discussion by other Codex subsidiary bodies or other international organizations and which therefore would not need to be considered in detail in the priority areas of the work of the Task Force. It noted that the issue of labelling was covered by the Codex Committee on Food Labelling (CCFL) and agreed that the precautionary approach/ principle should be dealt with as a matter of priority by the Codex Committee on General Principles (CCGP). The Task Force further agreed that the environmental risk was addressed by other instruments or bodies such as the Cartagena Biosafety Protocol under the Convention on Biological Diversity, the International Plant Protection Convention (IPPC) and the Commission on Genetic Resources for Food and Agriculture (CGRFA).

25. For Methods (Analysis/Sampling) some delegations observed that this was primarily within the terms of reference of the Codex Committee on Methods of Analysis and Sampling (CCMAS) while others were of the opinion that the identification of methods appropriate for the detection of genetic modification should be done primarily by the Task Force. The Task Force agreed finally to include analytical methods within its work area, recognizing the use of such methods for control, monitoring and labelling purposes.

26. For other legitimate factors the Task Force recalled that this issue was dealt with by the Codex Committee on General Principles (CCGP) but other relevant Committees were also asked to identify legitimate factors other than science which were considered relevant for risk analysis. The Task Force noted that several factors had been proposed by delegations as such other legitimate factors but decided not to take a decision thereon at this stage, recognizing that the Task Force had not accumulated sufficient experiences on this subject.

PROGRAMME OF WORK

27. Taking into account the priorities discussed above, the Task Force decided that it would proceed with the elaboration of two major texts, namely:

- A set of broad general principles for risk analysis of foods derived from biotechnology including matters such as:
    - Science-based decision-making;
    - Pre-market assessment;
    - Transparency;
    - Post-market monitoring [including traceability]; and
    - Other legitimate factors as appropriate.
- Specific guidance on the risk assessment of foods derived from biotechnology including such matters as:
    - Food safety and nutrition;
    - "Substantial equivalence";
    - Potential long-term health effects; and
    - Non-intentional effects.

28. The Task Force agreed that in the preparation of these texts preference should be given to guidance that was applicable to all foods derived from biotechnology, however should it be necessary to prioritise the work, first priority should be given to foods of plant origin, followed by micro-organisms used directly in foods and then foods of animal origin. It was noted however, that early attention may have to be given to fish.

29. The Task Force also agreed that consideration should be given to the development of guidelines for transparency in decision-making and the participation of all stake-holders in the decision-making process. It was noted that the approach of establishing over-arching general principles would allow the development of further, detailed explanatory guidelines on specific issues if these were required and if time allowed.

30. It was agreed that careful attention should be paid to the development of adequate and appropriate definitions, drawing on definitions already developed and agreed to in other texts (such as the Cartagena Protocol) or by other bodies (such as the Codex Committee on Food Labelling).

31. Concerning the issues of *Traceability* and *Familiarity* raised by several delegations, the Task Force noted that a better understanding of these concepts and their implications was required before they could be included definitively in either of the main texts to be developed. It therefore agreed that discussion papers should be prepared on these issues as soon as possible. In the meantime, any reference to these issues in the main texts under development would remain in square brackets.

32. The Task Force agreed that a list of available **analytical methods** including those for the detection or identification of foods or food ingredients derived from biotechnology should be prepared, and that this list should indicate the performance criteria and status of the validation of each method. It was further agreed that the list of methods, once finalized, should be transmitted to the Codex Committee on Methods of Analysis and Sampling for endorsement.

33. The Task Force recognized that the work programme outlined above was very substantial taking into account the time-limited mandate assigned by the Codex Alimentarius Commission, and that it did not cover all of the items proposed for consideration. Nevertheless, there was a general consensus that the above issues had the highest priority and should be achievable within the time-frame allowed. It agreed that this programme of work should be reported to the Executive Committee for approval as new work at Step 1 of the Uniform Codex Procedure for the Elaboration of Standards and Related Texts.

34. Noting that finalization of its work programme would require the resolution of questions regarding labelling, the application and use of precautionary approaches, and consideration of legitimate factors other than science in decision-making, the Task Force called upon the Codex Committees on Food Labelling and on General Principles for an early resolution of these matters.

ESTABLISHMENT OF *AD HOC* WORKING GROUPS

35. In order to develop the programme of work as quickly as possible, the Task Force decided to establish two ad hoc Working Groups open to the participation of all Members and Observers participating in the present session and other Members and international organizations that might later indicate their interest. The first of these Working Groups, to be chaired by the Delegation of Japan, was charged with the development of the proposed draft general principles and guidelines indicated in paras. 27 and 28 above. This Working Group would also develop draft definitions. It would also review the discussion papers on traceability and familiarity if they became available in time. The Delegation of Japan indicated that it was its intention for the Working Group to meet twice before the Second Session of the Task Force, probably in July and November 2000, after which proposed draft texts would be sent to Member governments and interested international organizations for comment at Step 3.

36. The second *ad hoc* Working Group, to be chaired by the Delegation of Germany, would compile a list of appropriate analytical methods for consideration by the Task Force, together with their performance characteristics and the status of their validation. To facilitate this work it was agreed that a Circular Letter would be sent to Members and interested international organizations requesting information and that the information received would be compiled by the Delegation of Germany for review by the Working Group at a one-half day meeting to be held immediately prior to the next Session of the Task Force.

MATTERS REQUIRING EXPERT ADVICE

37. The Task Force welcomed the initiative of FAO and WHO to convene an Expert Consultation to support the scientific aspects of its work. In support of the programme of work outlined above, it requested advice on the five specific questions as contained in Appendix III to this report.

38. It requested FAO and WHO to make the results of the Consultation available as soon as possible to all interested parties and that responses to the questions contained in Appendix III be made available to the *ad hoc* Working Group chaired by Japan.

OTHER BUSINESS, FUTURE WORK AND DATE AND PLACE OF NEXT SESSION (AGENDA ITEM 5)

39. There was no other business.

40. The Task Force noted that the following matters would be included on the provisional agenda for its next Session:

- Matters referred or arising from other Codex Committees including the Executive Committee;
- Matters of interest from other international organizations;
- Discussion paper on *traceability*;
- Consideration of proposed draft general principles of a broad nature for the application of risk analysis to foods derived from biotechnology, guidelines (the precise title to be recommended by the *ad hoc* Working Group); including consideration of transparency and involvement of stakeholders in proposed draft general principles;
- Consideration of proposed draft guidelines for risk assessment with reference to food safety and nutrition for foods derived from biotechnology (the precise title to be recommended by the *ad hoc* Working Group);
- Information paper on *familiarity;* and

- Consideration of analytical methods.

41. It was noted that the Second Session of the Task Force would be held in Japan in March 2001, the precise dates and location to be identified by the Japanese and Codex Secretariats.

ANNEX

SUMMARY STATUS OF WORK

Subject	Step	Action by	Document Reference (ALINORM 01/34)
General principle for risk analysis of foods derived from biotechnology (precise title still to be determined)	1	47th CCEXEC *Ad Hoc* Working Group chaired by Japan	para. 27
Specific guidance on the risk assessment of foods derived from biotechnology (precise title still to be determined)	1	47th CCEXEC *Ad Hoc* Working Group chaired by Japan	para. 27
List of available analytical methods including those for the detection or identification of foods or food ingredients derived from biotechnology	1	47th CCEXEC Ad Hoc Working Group chaired by Germany	para. 32
Working Paper on traceability	-	France	para. 31
Information Paper on familiarity	-	OECD, ASSINSEL	para.31
reply to questions for which scientific advice of the expert consultation would be sought for.	-	FAO/WHO Joint Consultation	paras. 37, 38 Appendix III

APPENDIX I

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APPENDIX II

LISTS OF SUBJECTS DISCUSSED UNDER AGENDA ITEM 4

1. Area of the work of the Task Force (Focused on Risk Analysis)

- Science based decision making
- Pre-market approval

Risk Assessment

- Safety and nutrition assessment
- Marker genes
- Long-term health effects
- Non-intentional effects
- Substantial equivalence
- International Expert Body

Risk Management

- Elements for decision making
    - Precautionary approach/principle
    - Familiarity
    - Other legitimate factors
        - Ethical consideration
        - Religious consideration
        - Cultural consideration
        - Consumer concerns/interest
        - Food security
        - Enforcement capacity
        - Environmental risk
        - Facilitating international trade
        - Food diversity
- Monitoring
    - Traceability
    - Methods (Analysis/Sampling)
- Labelling
    - Consumer choice

Risk Communication

- Transparency at all stages
- Interactivity at all stages
- Consumer participation

2. Key principles, concepts and definitions

- Substantial Equivalence
- Modern Biotechnology
- Recombinant DNA Technique
- Genetically Modified Organisms (GMO)

3. Food categories

- Food
    - Plant origin
    - Microorganisms
    - Animal origin (including fish)
- Food additives
- Feed

APPENDIX III

QUESTIONS FOR A JOINT FAO/WHO EXPERT CONSULTATION

1. What over-arching scientific principles should be applied to safety and nutritional assessment?

2. What is the role and limitation of substantial equivalence in safety and nutrition assessment?

   Are there alternative strategies that should be used for safety and nutrition assessment?

3. What scientific approach can be used to monitor and assess possible long term health effects or unintended/unexpected adverse effects?

4. What scientific approach can be used to assess potential allergenicity?

5. What scientific approach can be used to assess the possible risks arising from the use of antibiotic resistance marker genes in plants and micro-organisms?