

codex alimentarius commission

FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD HEALTH
ORGANIZATION

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

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**REPORT OF THE THIRD SESSION OF THE
CODEX COORDINATING COMMITTEE FOR NORTH AMERICA
AND THE SOUTH-WEST PACIFIC**

Vancouver, Canada, 31 May - 3 June 1994

SUMMARY AND CONCLUSIONS

The Third Session of the Codex Coordinating Committee for North America and the South-West Pacific reached the following conclusions during its deliberations:

MATTERS FOR CONSIDERATION BY THE COMMISSION:

- Recommended that the Executive Committee consider proposals concerning the **broader application of the HACCP system** (para. 53);
- Requested that a comprehensive plan for **risk assessment methodology and decision making criteria** be developed by Codex, and that **risk analysis** be considered as part of the strategic planning exercise being undertaken by the Executive Committee (paras. 58-59);
- Agreed that the Executive Committee should pursue a means to achieve early consensus and international harmonization in the area of **genetically engineered foods** (para. 62);
- Agreed to recommend that the Executive Committee undertake further work on the sale of **potentially harmful herbs and botanical preparations as foods** (para. 68);
- Requested that its views on **expediting the work of Codex**, including the possible **establishment of a new Committee**, be brought to the attention of the Executive Committee (para. 73), and;
- Nominated Dr. P.J. O'Hara (New Zealand) for appointment as **Regional Coordinator** (para. 70).

MATTERS OF INTEREST TO THE COMMISSION:

- Agreed that the Executive Committee should be informed of concerns expressed as to whether the Committee was meeting the needs of **developing countries** within the Regions and whether a **realignment of membership of Codex Regional Committees** should be undertaken (para. 43);
- Encouraged member countries to consider suggestions regarding the strengthening of **consumer involvement in Codex** (para. 48); and
- Agreed that its **priority objectives for the medium term** would be information exchange and coordination of work within the countries of the Region (para. 75).

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**REPORT OF THE THIRD SESSION OF THE
CODEX COORDINATING COMMITTEE FOR NORTH AMERICA
AND THE SOUTH-WEST PACIFIC**

Vancouver, 31 May - 3 June 1994

INTRODUCTION

1. The Third Session of the Codex Coordinating Committee for North America and the South-West Pacific (CCNASWP) was held from 31 May to 3 June 1994 in Vancouver, British Columbia, Canada by courtesy of the Government of Canada. The Session was chaired by Mrs. Katharine E. Gourlie, Director General, Consumer Products Branch, Bureau of Consumer Affairs, Industry Canada.

2. The Session was attended by representatives of Australia, Canada, New Zealand and the United States of America as member countries of the North American and South-West Pacific Regions. An Observer from the International Organization of Consumers' Union (IOCU) also attended the meeting. A List of Participants, including members of the Secretariat, is attached as Appendix I to this report.

OPENING OF THE SESSION (Agenda Item 1)

3. The Session was opened by the Chair, Mrs. Katharine Gourlie (Canada), who welcomed participants on behalf of the Government of Canada. Mrs. Gourlie also expressed the thanks and appreciation of the Committee to the Department of Fisheries and Oceans for convening a workshop the preceding day on its Quality Management Program. This workshop had been attended by approximately 20 delegates from the participating countries and provided a practical overview of the application of HACCP to the Canadian fish industry, based on regulatory compliance.

4. The Chair called upon Mr. James Drum, representing the Grocery Products Manufacturers of Canada and a participant at Codex Sessions for more than 25 years, to give his views on issues of significance to industry at this point in the history of Codex. Mr. Drum commented initially that the world was very different now than when Codex had been formed more than 30 years earlier. In this regard, Mr. Drum noted that Canadian industry had not been a participant in the early days of Codex but was now actively involved with government in the development of Codex standards and that this was to their mutual benefit.

5. The importance of Codex as a science-based organization was also stressed. Mr. Drum expressed concern at the possible acceptance of non-scientific factors and criteria into Codex decision-making as evidenced by the decision at the 19th Session of the Commission not to adopt maximum residue limits for certain growth promotant hormones. Along with its science orientation, Mr. Drum remarked on the importance of initiatives to streamline Codex activities, particularly as a consequence of the recognition of Codex Standards, guidelines and recommendations in the GATT Agreement on the Application of Sanitary and Phytosanitary Measures.

6. The Chair then introduced Dr. David Cohen, President of the Consumers Association of Canada, who provided a consumer perspective of Codex activity. Dr. Cohen opened his remarks by noting that consumer groups now shared the recognition of industry as to the importance of participation in the development of Codex international food standards. In view of the difficulties associated with efforts by organizations such as IOCU to represent the varied interests of consumers in as many as 60-70 countries, Dr. Cohen stated that the focus of consumer involvement should be at the national level. Mechanisms had to be identified, however, to provide consumer groups with both the resources and opportunity to be full partners with government and industry.

7. Acceptance of international standards by governments would be difficult, according to Dr. Cohen, if there was a conflict with the "precautionary principle" which was increasingly the underlying philosophy which consumer groups bring to bear on consumer policy issues. This approach advocates that prudence and caution be exercised in situations of scientific uncertainty which may affect public health. Dr. Cohen also stated that public support for governmental adoption of Codex standards was contingent on the degree of their involvement in the elaboration process.

8. Mr. R. J. Dawson, Chief, Joint FAO/WHO Food Standards Programme, on behalf of the Directors-General of FAO and WHO, expressed appreciation to the Canadian government for hosting the third session of the Committee and to member countries for work that they had undertaken to strengthen Codex.

9. Referring to the 9th Session of the Regional Coordinating Committee for Asia held just one week earlier, Mr. Dawson reported that the involvement of consumers in the work of Codex had been an important subject of discussion and he looked forward to the deliberations of the Committee on this matter as well. There had also been considerable interest at CCASIA on the recently completed GATT and NAFTA trade agreements, particularly with regard to their possible impact on developing countries. Mr. Dawson noted as well the important initiative of Brazil, Uruguay, Argentina and Paraguay under the MERCOSUR Agreement to harmonize their national requirements with international standards. In closing, Mr. Dawson wished the Committee success with its deliberations.

ADOPTION OF THE AGENDA (Agenda Item 2)

10. The Committee **adopted** the Provisional Agenda (CX/NASWP 94/1) as the Agenda for the Session.

MATTERS OF INTEREST ARISING FROM THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES (Agenda Item 3 (a))

11. The Committee had for its consideration document CX/NASWP 94/2 when discussing this agenda item, which summarized matters of interest arising from the 20th Session of the Codex Alimentarius Commission. The Committee was informed that most of the items in the working paper were presented for information only or were scheduled for discussion elsewhere, and took note of the matters of interest presented in the working paper.

MATTERS OF INTEREST ARISING FROM FAO, WHO AND OTHER INTERNATIONAL ORGANIZATIONS (Agenda Item 3 (b))

12. The Committee had for its information documents CX/NASWP 94/3 and Conference Room Document 2 (WHO), which summarized matters of interest arising from FAO, WHO, PAHO and Joint FAO/WHO activities. The Committee took note of these activities as presented by the Secretary of the Codex Alimentarius Commission.

13. Upon request of the Committee, the Secretariat provided information concerning the establishment within FAO of a new Group - Food Quality Liaison Group - which had been set up to liaise with GATT/WTO and to provide advice and information on food quality and safety issues related to the international trade of food.

14. The Committee expressed its appreciation to FAO/WHO for their work being carried out related to food quality and safety and asked that this item be on the Agenda of the next Session of the Committee.

REPORT ON THE GATT URUGUAY ROUND TRADE NEGOTIATIONS ON AGRICULTURE
(Agenda Item 4)

15. The Secretariat introduced document CX/NASWP 94/4, which contained a brief reference to the texts of the Agreement on the Application of Sanitary and Phytosanitary Measures and the Agreement (1994) on Technical Barriers to Trade. The texts of these Agreements as adopted in the Final Act of the Uruguay Round in December 1993 had been circulated by the Codex Secretariat to Contact Points under cover of Circular Letter 1994/3-GEN. It was noted that these texts had been the subject of legal revisions, not affecting the substance of the Agreements, prior to the final signing of the Uruguay Round Final Act in Marrakesh in April 1994. The Committee did not discuss the implications of the Final Act Agreements in relation to the work of Codex, noting that this would be the subject of discussions at the Executive Committee's 41st Session and had, in any case, been thoroughly discussed previously.

16. The Chief of the Joint FAO/WHO Food Standards Programme reported that FAO was considering placing a person in Geneva to act as a liaison with the Geneva-based missions to GATT to explain the work of Codex and to canvass their opinions as to how the Codex would best respond to the needs of the respective World Trade Organization (WTO) Committees established to monitor the implementation of the two Agreements. He also reported that WHO had issued a formal Circular Letter (C.L.8.1994) supporting the fact that Codex Standards offered adequate health protection when applied under the Uruguay Round Agreements and that stricter standards did not imply better health protection. The Circular Letter exhorted Ministries of Health to become more closely involved in the Codex standards-setting process. It was noted that this WHO Circular Letter was similar to a Resolution of the World Health Assembly to the same effect.

REVIEW AND PROMOTION OF ACCEPTANCES OF CODEX STANDARDS AND CODEX MAXIMUM RESIDUE LIMITS FOR PESTICIDES BY COUNTRIES OF THE REGIONS
(Agenda Item 5)

17. Document CX/NASWP 94/5 contained a brief summary of notifications of acceptance made to the Secretariat up to and including notifications made at the 20th Session of the CAC. Further information in regard to acceptance was made as follows:

18. The Delegation of Australia informed the Committee that under the National Food Authority Act acceptance of Codex Standards and MRLs had to be considered as being consistent with, but subsidiary to, the principal objectives of the Act, which were, in priority order; to promote public health and food safety, provide consumers with an informed choice in their selection of foods, and the promotion of fair trade and the facilitation of trade and commerce in the food industry. Codex standards could only be accepted if they met these national considerations and if their acceptance did not result in a lowering of the national standard. It was expected that the GATT SPS and TBT Agreements would lead to more intense activity in focusing on pesticide MRLs in joint arrangements between the Federal Government, the States and Territories and with New Zealand. There were, however, difficulties in the legal framework in notifying acceptance of pesticide MRLs on the basis of "free distribution".

19. The Delegation of Canada reported that Canada would be reviewing its position in relation to all Codex standards in the light of the new acceptance procedures and as the revision of Codex Standards was systematically undertaken by the CAC. All of the recently finalized Draft Standards for Fish and Fishery Products would be incorporated as official standards by the Department of Fisheries and Oceans for use in domestic and international trade. Canada was also examining Codex MRLs and would be submitting a statement of acceptance prior to the 21st Session of the CAC. Many of the Codex MRLs were the same as those applied in Canada and Canada expected to indicate that 1180 MRLs could be accepted under the principle of "free distribution".

20. The Delegation of New Zealand informed the Committee that, in New Zealand, acceptance was determined by the need for the standards. Acceptance had already been notified for the Milk and Milk Product Standards. The Delegation noted that consequent to the Uruguay Round Agreements there would

need to be a more formal approach to acceptance and for consultations, especially with Australia. It was noted that all Codex MRLs for pesticides had been accepted by New Zealand under the principle of "free distribution".

21. The Delegation of the United States stated that it was committed to accepting Codex MRLs for pesticides provided that the Environmental Protection Agency (EPA) determined that the acceptance of the Codex Limit posed no significant risk to human health. EPA would estimate intake using the MRL as the basis for this calculation. Where differences in calculated intakes were small, the US was also committed to a process of harmonization which should lead to the ability to accept the Codex MRL. In regard to acceptance of other Codex Standards, the Delegation reported that the removal of non-essential detail from Codex Standards would greatly facilitate the possibility of acceptance.

NATIONAL REPORTS ON DEVELOPMENTS AND ISSUES OF CONCERN REGARDING FOOD STANDARDS, REGULATIONS AND CONTROL, AND HARMONIZATION WITH INTERNATIONAL STANDARDS (Agenda Item 6)

22. The Coordinating Committee was provided with reports by the Delegations of Australia, Canada, New Zealand and the United States on recent developments in food standards, regulations and control measures, and progress in relation to international harmonization. These reports are summarized below on the basis of information provided by these Delegations. More complete information was provided in documents circulated as CX/NASWP 94/6, CX/NASWP 94/6 - Add. 1 and CX/NASWP 94/6 - Add. 2.

New Zealand

23. The Delegation of New Zealand, speaking briefly to its report, provided an update on the review of New Zealand's food administration framework and noted that a number of options were currently under consideration. Referring to current discussions between Australia on harmonization of food standards, New Zealand noted that there were a number of issues that would need resolving before the two countries were in a position to have harmonized standards in place.

24. New Zealand and Australia were also working towards the harmonization of registration systems for agricultural and veterinary chemicals. These efforts would eventually create a single market for these products.

25. New Zealand also spoke about its experiences in dealing with the problems associated with the outbreak of algal bloom in its coastal waters in December 1992. This had been a new experience for New Zealand and put in jeopardy shellfish sales. Earlier in 1994 a Marine Biotoxin Surveillance Unit had been established for monitoring and surveillance of marine biotoxins.

The United States of America

26. The United States Delegation described a number of initiatives discussed more fully in CX/NASWP 94/6. These initiatives included the introduction of a proposed mandatory HACCP program for the seafood industry, which was expected to be fully implemented in early 1996; new nutritional labelling regulations for processed foods which would become effective in 1994; and a Model Food Code which provided a model set of regulations that could be used for retail food establishments by state and local governments.

27. Several initiatives aimed at reducing the levels of pathogenic bacteria on fresh meat and poultry, and efforts to strengthen quantitative risk assessment methodologies for microbial contamination of fresh meat and poultry were described. The Delegation noted that the USDA/FSIS authorized the use of irradiation to control bacterial pathogens on fresh poultry in 1992; however, industry and consumers had been slow to embrace this technology and only one facility was currently irradiating packages of poultry on a limited basis.

28. The Environmental Protection Agency (EPA) was currently working closely with the U.S. Congress to develop new food safety legislation. This legislative proposal, if acted upon, would change considerably the way EPA regulated pesticides. In June 1993, EPA announced a new initiative to reduce the use of pesticides nationwide. As part of this effort, EPA and USDA would promote sustainable agricultural and Integrated Pest Management (IPM) practices with the goal to develop IPM programs for 75 percent of the total crop acreage in the U.S. in the next seven years.

29. The Committee was updated on recent events concerning the Delaney Clause, a provision of U.S. food safety law which strictly prohibited the establishment of a food additive tolerance on processed foods for any chemical shown to cause cancer in laboratory animals. The EPA had published a list of all chemicals potentially affected by this Clause.

Canada

30. The Canadian Delegation briefed the Committee on a number of initiatives whose focus has been to provide for a more efficient and effective food inspection system and to provide for a more market-driven approach to food regulation, in keeping with broader government objectives. Food Regulatory responsibilities were recently restructured within the federal government and a major review of federal food regulations was now in process. Federal departments responsible for food regulation had been directed to publicly rejustify their particular regulatory programs.

31. The government was also developing a harmonized national inspection program for food establishments using HACCP principles. While the initial focus had been to harmonize the inspection activities of the three departments responsible for food safety, the federal government was also working cooperatively with provincial and municipal authorities to develop an integrated national system of food inspection.

32. A recently completed review of nutritional labelling requirements had concluded that Canada should retain a "made in Canada" system for nutrition labelling but should consider harmonizing with the U.S. definitions for nutrient claims in all areas except content claims for vitamins and minerals where U.S. and Canadian standards were markedly different.

33. Agriculture and Agri-Food Canada was developing a risk-based approach, using detailed scientific assessments, to the control of imports of food and agricultural products.

34. The Department of Fisheries and Oceans was successful in 1993 in being recognized as the competent authority for the inspection and certification of fishery products entering the European Union. In 1993, as well, Canada and Australia had concluded a mutual recognition agreement for the inspection of fishery products. Canada was currently negotiating with several other countries exporting fish products to Canada to provide for easier access of these products.

Australia

35. The Australian delegation provided the Committee with highlights of recent initiatives, details of which were provided in CX/NASWP 94/6 Add. 2. These highlights included the development of a Clean Food Export Strategy; progress on the negotiation of a veterinary agreement with the European Commission; the status of the development of a joint food standards-setting system with New Zealand based on New Zealand entering the Australian system; the development of national uniform food hygiene regulations; the establishment of a nil tolerance standard for listeria in certain high risk products; and the release of a manual for the control of listeria in high risk fish products.

36. In noting recent developments concerning the organization of food regulation in Australia, it was reported that the Australian Quarantine Inspection Service was undergoing a major reform program which would change its structure to focus on delivery of its services. The National Food Authority was carrying

forward with recommendations from the Final Report of the Policy Review released in May 1993; this Review provides a framework for the future work of the National Food Authority which included a review of all standards in the Food Standards Code.

37. Australia reported that the Australian Market Basket Survey, which was a total dietary survey of pesticides and contaminants conducted every two years, included for the first time an examination of natural toxins and herbicide residues. Among the foods examined, free-range eggs and organic breakfast cereals had been included to compare them with their conventional counterparts. The 1992 survey report, published in May 1994, showed all estimated dietary intakes of pesticides and contaminants were very low and well within international safe limits; there were no detectable herbicides in the foods tested and all levels showed a continued downward trend.

38. In the area of organic foods, it was noted that AQIS has started a program to audit organic industry organizations against a national standard for export purposes, and had applied to the National Food Authority for an amendment to the Australian Food Standards Code to make provisions for the labelling of organic foods. It was optimistic of receiving final listing from the European Union as an exporter of organic food.

PROGRESS REPORTS ON IMPLEMENTING THE CODEX CODE OF ETHICS FOR INTERNATIONAL TRADE IN FOODS AND ON THE PROMOTION OF CODEX ACTIVITIES, INCLUDING MEMBERSHIP, IN THE REGIONS (Agenda Item 7)

39. The Committee had before it document CX/NASWP 94/7 concerning the above subject. The Secretariat informed the Committee that the Code of Ethics for International Trade in Food had recently been published in booklet form and had been widely distributed.

40. The Secretariat advised the Committee of its efforts to increase the membership of Codex, including that related to those countries from the NASWP region who were not yet members of CAC. The Federated States of Micronesia had joined the CAC since the last meeting of CCNASWP.

41. The Committee recognized that only four countries of the region were participating in the current Session of the Committee; that the majority of the South-West Pacific Island countries who were members of the Committee were not present; that this lack of presence was most likely due to financial constraints; and that quite possibly these countries also lacked adequate information as to the importance of the CAC and thus needed additional technical assistance in this regard.

42. Several delegations suggested that consideration should be given to restructuring the membership of the Committee; that quite possibly a re-alignment of countries either into other existing Regional Committees or within the current Committee or both, should be considered.

43. The Committee agreed that the Executive Committee should be informed; i) of the concerns expressed as to whether the Committee was meeting the needs of the developing countries within the Regions and its advice was sought as to a possible realignment of regional membership; ii) that the entire membership of the CCNASWP be informed directly of these concerns through the record of this meeting and by means of a circular letter; and iii) that this item be included for discussion and consideration at the 4th Session of the Committee.

CONSUMER INVOLVEMENT IN DECISION-MAKING IN RELATION TO FOOD STANDARDS AND THE JOINT FAO/WHO FOOD STANDARDS PROGRAMME (Agenda Item 8)

44. The Delegation of the United States of America introduced document CX/NASWP 94/8 prepared in response to the CAC instruction that the Codex Regional Committees should consider means of encouraging more consumer participation in the Codex decision-making process. The Delegation noted the growing interest of consumers' groups in the Codex work, and also the criticism from several consumers' organizations that Codex was doing too little to respond to the concerns of citizens' and public interest

groups. The consumers' interest in Codex work had been intensified by the role foreseen for Codex in the Uruguay Round trade agreements. The Delegation of the United States indicated that mechanisms needed to be put in place which would enhance the role of consumers' in the Codex decision-making process. The Delegation noted that related issues had been raised by the United States at the recent 11th Session of the Codex Committee on General Principles.

45. The Committee noted that the Committee on General Principles had expressed its support for enhanced consumer participation in the Codex process, especially within the context of improving the transparency of Codex decision-making. Also, the Committee on General Principles had expressed support for the proposal that consideration should be given to establishing a reference and liaison point within the Joint FAO/WHO Food Standards Programme responsible for maintaining liaison with non-governmental organizations.

46. The Observer from IOCU expressed that organization's commitment to strengthening consumer participation in the Codex process. IOCU recognized that the goals of integrating consumers' interest into the decision-making process were admirable, but that they should be arrived at sooner rather than later. The Observer stressed the need to establish reputable broad-based consumer organizations in all countries (especially developing countries) and pointed to the variety of models available. It was pointed out that in involving consumer organizations at the national level consideration had to be given to the size of the organization, its accountability to its members and to its independence.

47. The Committee considered that there were a number of issues related to the participation of consumers in national delegations to Codex Committees. These included full participation during the formulation of national positions, and the funding of participation at meetings themselves. Also considered important was the need for general consumer information programmes and the need for broader public understanding of the issues before the Codex Commission. In the latter case, such outreach and education programmes should be in place before and during the discussion of the issues at hand rather than after decisions had been taken.

48. The Committee **concluded** that among the countries represented at the Session there were formal consultation mechanisms with respect to consumers. The Committee **encouraged** member countries to consider the suggestions in the paper as a means to strengthen the involvement of consumers. It was recognized that an artificial "balance" between consumers' and industry representations in country delegations was not a useful or practical approach but that more general consultation and liaison achieved good results.

IMPLICATIONS CONCERNING THE BROADER APPLICATION OF THE HAZARD ANALYSIS CRITICAL CONTROL POINT (HACCP) SYSTEM (Agenda Item 9)

49. The Delegation of Australia introduced document CX/NASWP 94/9, and pointed out that the issues outlined in the document related to the broad policy decisions confronting national authorities when they introduced HACCP-based systems into their regulatory processes. The following issues contained in the document were highlighted:

- the legal status of HACCP application by regulatory agencies, whether voluntary, mandatory or mixed systems;
- the extent to which regulatory agencies utilize HACCP as a regulatory tool and some of the areas where major input may be required by the regulatory agency;
- other issues which may impact on the application of HACCP programmes including:
 - legal issues - sanctions, etc.
 - scientific validation of programmes

- the management of cost factors, etc., and;
- the interrelationship between HACCP and ISO 9000 series standards.

50. The Committee noted the widespread use of the HACCP system in the countries represented at the session and the development of HACCP-based or similar systems in these countries for the purpose of control of food safety and basic quality factors. The Quality Management Program for fish and fishery products applied by Department of Fisheries and Oceans Canada was cited as an example. The Committee also recognized that HACCP or similar systems were likely to be the regulatory tools of choice for the future, although it was recognized that there had to be a clear distinction between the application of these systems for regulatory purposes and for other purposes.

51. The Delegation of the United States was of the opinion that the application of HACCP systems for regulatory purposes should be confined to issues of food safety. Other Delegations expressed misgivings about the mandatory implementation of HACCP programmes due to the potential conflict of government responsibilities. Some Delegations stressed the need for governments to provide advice on the regulatory application of HACCP systems through the development of manuals and training seminars.

52. It was also pointed out that HACCP-based systems were well developed and well applied to processed food, but that for fresh (raw) foods there were significant problems in application including cost considerations and the determination of control limits in regard to levels for minimizing risks to human health. In these cases, a pragmatic approach taking into consideration established Good Manufacturing Practices would have to be considered.

53. The Committee recognized that the issues referred to above needed to be developed further before determining whether they should be taken up by the appropriate Codex Committee(s). The Committee **recommended** that the Executive Committee consider the following proposals:

- (i) that the paper CX/NASWP 94/9 be circulated to all Codex member countries and interested organizations in order to invite comment on:
 - the mandatory components of introducing a HACCP system;
 - method of recognition and acceptance of the HACCP plan by the regulatory authority;
 - implementation strategies;
 - training;
 - legal issues for industry and national authorities;
 - ISO 9000 and HACCP; and
 - other related issues.
- (ii) that the paper be referred to both the Codex Committee on Food Hygiene and the Committee on Import and Export Food Inspection and Certification Systems for information and any comment that they may wish to make; and
- (iii) that the Regional Coordinating Committee take cognisance of comments received and develop the issues for further consideration at the next session of this Committee.

54. The Coordinating Committee also noted that FAO had scheduled an Expert Consultation on the Integration of HACCP into National Food Control Systems (late 1994) in which invited experts would be considering, among other matters, how the experience gained in the countries more advanced in the implementation of HACCP systems for food control could be made available to other countries.

HARMONIZATION OF RISK ASSESSMENT PROCEDURES BY COUNTRIES WITHIN THE REGIONS (Agenda Item 10)

55. Document CX/NASWP 94/10, which had been prepared by the Delegation of New Zealand, was introduced by that Delegation. It was pointed out that whereas risk assessment had been well established for chemical hazards relating to food safety, there was little information in regard to microbiological aspects. The Delegation drew attention to the distinction between risk assessment as a scientific estimation of risk in qualitative and quantitative terms, and risk management which involved the development and implementation of appropriate regulatory actions. It was noted that risk analysis was the overall discipline and involved risk assessment, risk management, and risk communication.

56. Reporting on the harmonization of risk assessment by the countries of the Regions, the Delegation of New Zealand pointed out that a Quadilateral Working Group (Australia, Canada, New Zealand, USA) had held a series of meetings and workshops and was developing a document for generic guidance on risk. The objectives of this work was similar to that of Codex, namely to protect public health and facilitate international trade in the countries concerned. It was noted that the GATT/WTO SPS Agreement stressed the importance of adequate risk assessment procedures to underpin standards for food safety used in international trade, and that such risk management decisions should be transparent, non-discriminatory, and based on an appropriate level of protection.

57. The Committee noted that there were strong pressures to develop uniform guidance on risk assessment and risk management procedures within Codex. It also noted that communication of the understanding of risk to the general public would be necessary.

58. The Committee requested that a comprehensive plan for risk assessment methodology and decision-making criteria be developed by Codex. It noted the development of similar plans by the Office Internationale des Epizooties (OIE) and suggested that the Codex plan take cognizance of, and be aligned with, that of OIE, where appropriate. Some Delegations also called for the development of Codex Guidelines on risk management. Emphasis was placed on the assessment and management of microbiological risks.

59. The Committee also requested that risk analysis be considered as part of the strategic planning exercise currently being undertaken by the Executive Committee, and suggested that the subject be considered by other Regional Coordinating Committees as well. It was agreed to maintain the topic of coordination of risk assessment procedures amongst the countries of the Region on the Agenda of its next Session.

REGULATORY CONTROLS ON THE SALE OF GENETICALLY ENGINEERED FOODS BY COUNTRIES IN THE REGIONS (Agenda Item 11)

60. The Committee had before it document CX/NASWP 94/11, prepared and introduced by the Delegation of Canada. The Delegation noted that the paper provided an historical perspective on the regulatory and safety assessment issues associated with the development of genetically engineered foods (GEFs). It was stressed that these were complex matters which would strain the ability of national regulatory agencies to handle individually. The paper, therefore, encouraged efforts to harmonize approaches on an international basis to best utilize available resources, increase confidence of consumers in the safety of these foods, and facilitate marketing internationally.

61. The Committee fully supported the position outlined in the paper and noted that the emergence of GEFs provided a unique opportunity to work towards broad international harmonization of national regulatory controls which were under development. In addition, an effective risk communication strategy was recognized as being important to address any consumer unease with these foods and permit the realization of the full benefits of this technology to the food supply. The Observer from IOCU advised that critical to consumer acceptance of GEFs was a fully transparent process for the establishment of regulatory

controls and safety assessment procedures in which consumers had full participation. Labelling of GEFs was also seen by the Observer from IOCU as vital to consumer interests. The Chair reminded delegations that the Committee on Food Labelling would be considering a paper on the labelling of GEFs at its 23rd Session (October 24-28, 1994).

62. The Committee expressed the view that Codex should be the focus of international harmonization initiatives with respect to GEFs. It was recognized, however, that with the exception of food additives and labelling, such activity did not fit within the responsibilities of current Codex committees. In this regard, the Committee took notice that the Executive Committee would be considering a paper on *Strategies for Achieving the Medium-Term Objectives of the Codex Alimentarius Commission* which included a recommendation that the mandate of the Committee on Nutrition and Foods for Special Dietary Uses be modified to "deal with emerging issues such as foods manufactured or produced through recombinant DNA" (CX/EXEC 94/41/7, para. 44). The Committee **agreed** that the Executive Committee should pursue a means to achieve an early consensus and international harmonization in this important area.

SALE OF POTENTIALLY HARMFUL HERBS AND BOTANICAL PREPARATIONS AS FOODS (Agenda Item 12)

63. The Committee had before it document CX/NASWP 94/12, which was prepared by Canada. The Delegation of Canada introduced the paper, which provided a summary of legal opinions and positions of countries concerning the regulation of these products. The Delegation pointed out that these substances often did not fit into the regulatory categories of foods and drugs, and, as a result, posed problems for national authorities.

64. To address this situation, the paper proposed the development of an international advisory list of toxic or adulterating substances (ie. a "negative" list). This list would identify substances which would be prohibited for sale as foods within member countries. Canada also proposed that Codex consider the establishment of a Code of Hygienic Practice applicable to the health foods industry to be used by member countries. The Delegation of Australia noted that a negative list had now been established in the Australian Food Standards Code.

65. In the discussions that followed, delegations supported the general principles put forward by Canada in this document and agreed that the development of an advisory list of toxic or adulterating substances would be beneficial.

66. The Observer from IOCU noted that work in this area would be a challenge for Codex since the use of botanical herbs and drugs remained closely tied to cultural practices in many countries. On the other hand, consumers were interested in safety, the use of Good Manufacturing Practices, informative labelling and the prevention of abusive practices in the marketing of these products.

67. It was noted during the discussions that further work on this subject could be handled by the Committee on Food Additives and Contaminants under its revised terms of reference, as well as other committees such as Food Labelling and Food Hygiene. There was an increasing number of these foods available and the interface between foods and medicines needed to be clarified.

68. The Committee **agreed** to forward to the Codex Executive Committee its recommendation that Codex undertake further work on this issue and to seek guidance from the Executive Committee on how this work would be carried out.

NOMINATION OF COORDINATOR (Agenda Item 13)

69. The Committee was informed that the current Regional Coordinator had been most pleased to serve in the post over the past period; however, consistent with the decision taken by the Committee at its First Session that the Coordinator should change for each session and rotate amongst members of the region,

Mrs. Gourlie advised that she would not seek a second term. In view of this decision, it was necessary for the Committee to propose a new Coordinator.

70. The Committee unanimously nominated Dr. P.J. O'Hara, New Zealand, as the proposed next Regional Coordinator of the Committee. Dr. O'Hara graciously accepted on the condition that he received his country's concurrence and approval by the 21st Session of the CAC.

71. The Committee expressed its high appreciation to the out-going Coordinator and Chairperson of the Committee for her stewardship over the previous two years, and for the planning, preparation and excellent conduct of the Committee's business, which advanced considerably the goals and principles of the Codex Alimentarius Commission.

OTHER BUSINESS (Agenda Item 14)

72. The Committee stressed the necessity of expediting the development within Codex of certain issues which it saw as being critical to the success of Codex work within the framework of the GATT/WTO Agreements on the Application of SPS Measures and on Technical Barriers to Trade. These included the development of guidelines for the application of HACCP within food control programmes and guidelines on risk analysis (see paras. 49-54 and 55-59 above). Other areas which were seen to be important for future work were provision of standards or guidelines covering the products of gene technology and extension of the work on enhancing consumer participation. Although the Committee recognized that aspects of all of these matters had been discussed at various times within the Codex structure, it called for a coordinated approach and expressed concern at the current procedures whereby such important topics were handled in a fragmented manner by several Committees.

73. It was suggested that for some of these matters, especially the emerging technologies, it might be appropriate to consider the establishment of a new Committee to concentrate the work of Codex in this area. The more frequent use of Expert Consultations was also proposed as a means to achieve more rapid progress on subjects of particular importance; however, the financial constraints on the parent organizations (which were responsible for the convening of expert meetings) were also noted. The Committee requested that its views on these matters be brought to the attention of the Executive Committee.

MEDIUM-TERM OBJECTIVES AND FUTURE WORK (Agenda Item 15)

74. The Committee took note of the Medium-Term Objectives adopted by the 20th Session of the CAC, as presented in document CX/NASWP 94/2, Appendix 1, and a paper prepared by the Delegation of Australia as a Conference Room Document, which recommended the prioritization of items on the CAC's Programme of Work. The Committee expressed its full support for the more formalized approach to the planning and prioritization of the Commission's work including the Medium Term Plan and the paper on *Strategies for Achieving the Medium Term Objectives* (CX/EXEC 94/41/7) under consideration by the 41st Session of the Executive Committee. It was suggested that the Commission's current Medium-Term Plan was somewhat modest as there were other topics which Committees should be capable of finalizing in the period up to 1997.

75. The Committee agreed that its priority objectives for the medium term would be to continue its work on information exchange and coordination of work within the countries of the Regions on risk analysis and HACCP and on food products derived from gene technologies, and the development of guidelines on the control of botanical and herbal preparations sold or used as foods. Much of this latter work would need to be considered ultimately by an appropriate world-wide Committee within the Codex Structure. Of particular concern was the emerging implications of the GATT/WTO SPS Agreement with respect to food standards elaborated by Codex and the availability of harmonized risk assessment procedures and risk assessment methodology that met the intent of the Agreement.

DATE AND PLACE OF NEXT SESSION (Agenda Item 16)

76. The Committee noted that its next Session would most likely be held in New Zealand in about two years' time; the precise date and place to be determined by the Secretariat and the Host Government.

SUMMARY STATUS OF WORK

Subject Matter	For Action By:	Document Reference
Review and Promotion of Acceptances of Codex Standards and Maximum Residue Limits for Pesticides by Countries of the Regions	Secretariat 4th CCNASWP	paras. 17-21, ALINORM 95/32
National Reports on Developments and Issues of Concern Regarding Food Standards, Regulations and Control, and Harmonization with International Standards	Governments 4th CCNASWP	paras. 22-38, ALINORM 95/32
Progress Reports on Implementing the Codex Code of Ethics for International Trade in Foods and on the Promotion of Codex Activities, Including Membership, in the Regions	41st CCEXEC Governments 4th CCNASWP	paras. 39-43, ALINORM 95/32
Broader Application of the Hazard Analysis Critical Control Point (HACCP) System	41st CCEXEC Governments 4th CCNASWP	paras. 49-54, ALINORM 95/32
Harmonization of Risk Assessment Procedures by Countries in the Regions	41st CCEXEC Governments 4th CCNASWP	paras. 55-59, ALINORM 95/32
Regulatory Controls on the Sale of Genetically Engineered Foods by Countries in the Regions	41st CCEXEC Governments 4th CCNASWP	paras. 60-62, ALINORM 95/32
Sale of Potentially Harmful Herbs and Botanical Preparations as Foods	41st CCEXEC Governments 4th CCNASWP	paras. 63-68, ALINORM 95/32

**ALINORM 95/32
APPENDIX I**

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LISTE DES PARTICIPANTS
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