

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD  
HEALTH  
ORGANIZATION



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**ALINORM 06/29/30**

## **JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

### **CODEX ALIMENTARIUS COMMISSION**

**Twenty-ninth Session**

**Geneva, Switzerland, 3 – 8 July 2006**

### **REPORT OF THE FOURTEENTH SESSION OF THE CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS**

*Melbourne, Australia, 28 November - 2 December 2005*

**Note:** This report includes Codex Circular Letter CL 2005/54-FICS

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**CL 2005/54-FICS**  
**December 2005**

**To:** Codex Contact Points  
Interested International Organizations

**From:** Secretary,  
Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme  
Viale delle Terme di Caracalla  
00100 Rome, Italy

**Subject:** **Distribution of the Report of the Fourteenth Session of the Codex Committee on Food Import and Export Inspection and Certification Systems (ALINORM 06/29/30)**

The report of the Fourteenth Session of the Codex Committee on Food Import and Export Inspection and Certification Systems will be considered by the 29<sup>th</sup> Session of the Codex Alimentarius Commission (Geneva, Switzerland, 3 – 8 July 2006).

## **MATTERS FOR ADOPTION BY THE 29<sup>TH</sup> SESSION OF THE CODEX ALIMENTARIUS COMMISSION**

**Proposed draft Principles and Guidelines for Imported Food Inspection Based on Risk, advanced to Steps 5/8 of the Codex Procedure, with the omission of Steps 6 and 7 (ALINORM 06/29/30, Appendix II).** See also para. 48 of this report.

**Proposed draft Principles for Traceability/Product Tracing as a Tool within a Food Import and Export Inspection and Certification System, advanced to Steps 5/8 of the Codex Procedure, with the omission of Steps 6 and 7 (ALINORM 06/29/30, Appendix III).** See also para. 80 of this report.

Governments and interested international organizations in observer status with Codex are invited to comment on the above documents and should do so in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts and the Guide to the Consideration of Standards at Step 8 of the Procedure for the Elaboration of Codex Standards including Consideration of any Statements relating to Economic Impact (see *Codex Alimentarius Procedural Manual*). Comments should be forwarded to the Secretary, Codex Alimentarius Commission, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax +39 06 57054593; e-mail codex@fao.org), ***preferably by e-mail, not later than 31 March 2006.***

## Contents

SUMMARY AND CONCLUSIONS	page iv
LIST OF ABBREVIATIONS	page v
REPORT OF THE 14 <sup>TH</sup> SESSION OF THE CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS	page 1
SUMMARY STATUS OF WORK	page 14
	<b>Paragraph</b>
INTRODUCTION	1
OPENING OF THE SESSION	2
ADOPTION OF THE AGENDA (Agenda Item 1)	3 - 5
MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES AND TASK FORCES (Agenda Item 2).	6 - 9
PROPOSED DRAFT STANDARDS AND RELATED TEXTS AT STEP 4	
PROPOSED DRAFT APPENDICES TO THE GUIDELINES ON THE JUDGEMENT OF EQUIVALENCE OF SANITARY MEASURES ASSOCIATED WITH FOOD INSPECTION AND CERTIFICATION (Agenda Item 3a)	10 - 17
PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR RISK-BASED INSPECTION OF IMPORTED FOODS (Agenda Item 3b)	18 - 49
PROPOSED DRAFT PRINCIPLES FOR THE APPLICATION OF TRACEABILITY/PRODUCT TRACING IN THE CONTEXT OF FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS (Agenda Item 3c)	50 - 80
PROPOSED DRAFT REVISION OF THE GUIDELINES FOR GENERIC OFFICIAL CERTIFICATE FORMATS AND THE PRODUCTION AND ISSUANCE OF CERTIFICATES (Agenda Item 3d)	81 - 86
DISCUSSION PAPER ON THE REVISION OF THE GUIDELINES FOR THE EXCHANGE OF INFORMATION BETWEEN COUNTRIES ON REJECTIONS OF IMPORTED FOODS (Agenda Item 4)	87 - 91
DISCUSSION PAPER ON THE DEVELOPMENT OF AN APPENDIX ON “INFORMATION RELATING TO THE NEED FOR TECHNICAL ASSISTANCE AND COOPERATION BETWEEN THE IMPORTING COUNTRIES TO EXPORTING COUNTRIES” TO THE CODEX GUIDELINES ON THE JUDGEMENT OF EQUIVALENCE OF SANITARY MEASURES ASSOCIATED WITH FOOD INSPECTION AND CERTIFICATION (Agenda Item 5)	92 - 94
OTHER BUSINESS AND FUTURE WORK (Agenda Item 6)	95
DATE AND PLACE OF NEXT SESSION (Agenda Item 7).	96
 <b><u>APPENDICES</u></b>	
<b>APPENDIX I</b> :LIST OF PARTICIPANTS	page 15
<b>APPENDIX II</b> : PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR IMPORTED FOOD INSPECTION BASED ON RISK (at Steps 5/8 of the Elaboration Procedure)	page 39
<b>APPENDIX III</b> : PROPOSED DRAFT PRINCIPLES FOR TRACEABILITY/PRODUCT TRACING AS A TOOL WITHIN A FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEM (at Steps 5/8 of the Elaboration Procedure)	page 43

## SUMMARY AND CONCLUSIONS

The Fourteenth Session of the Codex Committee on Food Import and Export Inspection and Certification Systems reached the following conclusions:

### **Matters for Adoption by the 29<sup>th</sup> Session of the Commission**

The Committee:

- Agreed to advance the renamed proposed draft Principles and Guidelines for Imported Food Inspection Based on Risk to Steps 5/8, with the omission of Steps 6 and 7, for adoption by the 29<sup>th</sup> Session of the Commission and to recommend the Commission to attach the Guidelines and Principles as an Appendix to the Codex *Guidelines for Food Import Inspection System* (CAC/GL 47-2003) (see para. 48 and Appendix II);
- Agreed to advance the proposed draft Principles for Traceability/Product Tracing as a Tool within a Food Inspection and Certification System to Steps 5/8, with the omission of Steps 6 and 7, for adoption by the 29<sup>th</sup> Session of the Commission (see para. 80 and Appendix III).

### **Matters of Interest to the 29<sup>th</sup> Session of the Commission**

The Committee:

- Agreed to return the proposed draft Appendices to the Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification to Step 2 for redrafting by a physical Working Group, led by the United States. The Committee agreed to progress work on all five appendices at the same time in a single appendix and to inform the 29<sup>th</sup> session of the Commission through the Executive Committee of this decision. The Working Group should also consider either including elements of technical assistance in the single Appendix or developing a separate Appendix on technical assistance (see paras 15-16 and para. 94);
- Agreed to return the renamed proposed draft Principles and Guidelines for Generic Official Certificate Formats and the Production and Issuance of Certificates to Step 2 for redrafting by a physical Working Group, led by the United States. The Committee further agreed that, when elaborating the document, the physical Working Group should take into account the written comments submitted and the comments made at this Session and should also take into account relevant issues highlighted in CRD 1 in relation to the fraudulent use of certificates. (see para. 86).

### **Matters of Interest to other Committees**

#### Codex Committee on General Principles

The Committee:

- Agreed to establish an electronic Working Group, led by Canada, to prepare a discussion paper to respond to the question of the 22<sup>nd</sup> Session of the Codex Committee on General Principles regarding the revision of the Codex *Code of Ethics in International Trade of Foods* (CAC/RCP 20-1979, Rev.1-1985) for consideration at its 15<sup>th</sup> Session (see para. 8).

### **Others Matters**

The Committee:

- Agreed to discontinue the discussion on the revision of the Codex *Guidelines for the Exchange of Information between Countries on Rejection of Imported Food* for the time being. It was also agreed that the issue of information exchange in case of fraudulent imports or false certificates would be considered by the physical Working Group on the revision of the Guidelines for Generic Official Certificates Formats and the Production and Issuance of Certificates (see para. 91).

**LIST OF ABBREVIATIONS USED IN THIS REPORT**

CAC/GL	Codex Alimentarius Commission / Guidelines
CCEURO	FAO/WHO Coordinating Committee for Europe
CCFICS	Codex Committee on Food Import and Export Inspection and Certification Systems
CCGP	Codex Committee on General Principles
CL	Circular Letter
CRD	Conference Room Document
FAO	Food and Agriculture Organization of the United Nations
ISO	International Organization for Standardization
OIE	World Organisation for Animal Health
SPS	Sanitary and Phytosanitary Measures (WTO Agreement)
WHO	World Health Organization
WTO	World Trade Organization

## INTRODUCTION

1. The 14<sup>th</sup> Session of the Codex Committee on Food Import and Export Inspection and Certification Systems was held from 28 November to 2 December 2005 in Melbourne, Australia, at the kind invitation of the Government of Australia. The Session was chaired by Mr Gregory Read, Executive Manager, Australian Quarantine and Inspection Service, Australian Government Department of Agriculture, Fisheries and Forestry. The Session was attended by delegates from 82 Member countries and 1 Member organization and Observers from 10 international organizations. The list of participants is attached to this report as Appendix I.

## OPENING OF THE SESSION

2. Mr Gregory Read opened the Session and welcomed the participants on behalf of the Government of Australia.

## ADOPTION OF THE AGENDA (Agenda Item 1)<sup>1</sup>

3. The Committee adopted the Provisional Agenda as its Agenda for the Session. The Committee agreed to discuss Agenda Item 3c “Proposed draft Principles for the Application of Traceability/Product Tracing in the Context of Food Import and Export Inspection and Certification Systems” and Agenda Item 3b “Proposed draft Principles and Guidelines for Risk-based Inspection of Imported Foods” immediately after Agenda Item 2 “Matters Referred by the Codex Alimentarius Commission and Other Codex Committees and Task Forces”. In addition, it agreed to discuss Agenda Item 5 “Discussion Paper on the Development of an Appendix on Information Relating to the Need for Technical Assistance and Cooperation Between the Importing Countries to Exporting Countries to the Codex *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification*” immediately after Agenda Item 3a “Proposed draft Appendices to the Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification”.

4. The Committee further agreed to consider:

- CRD 1 “Discussion Paper on Illegal Imports and Fraudulent Use of Certification and the Need for Appropriate Means to Tackle Frauds in the Context of Food Import and Export Inspection and Certification Systems”, submitted by the Delegations of the European Community and Australia, in conjunction with Agenda Item 3d “Proposed draft Revision of the Guidelines for Generic Official Certificate Formats and the Production and Issuance of Certificates”; and
- CRD 10 “ISO Submission to the 14<sup>th</sup> Session of the Codex Committee on Food Import and Export Inspection and Certification Systems” under Agenda Item 6 “Other Business and Future Work”.

5. The Delegation of the European Community presented CRD 3 on the division of competence between the European Community and its Member States according to Rule II.5 of the Rules of Procedure of the Codex Alimentarius Commission.

## MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES AND TASK FORCES (Agenda Item 2)<sup>2</sup>

### *Matters arising from the 28<sup>th</sup> Session of the Codex Alimentarius Commission*

6. The Committee noted the specific decisions of the 28<sup>th</sup> Session of the Codex Alimentarius Commission concerning the adoption of texts and recommendations and the approval of new work submitted by its 13<sup>th</sup> session, as contained in paragraphs 1-3 of working document CX/FICS 05/14/2.

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<sup>1</sup> CX/FICS 05/14/1, Amd. 1 (English version only) and CRD 3 (Division of Competence between the European Community and its Member States).

<sup>2</sup> CX/FICS 05/14/2; CRD 8 (Comments submitted by the European Community on Part. 2); Unnumbered document (Compilation of CRDs submitted at the 22<sup>nd</sup> Session of the Codex Committee on General Principles on the revision of the Codex Code of Ethics for International Trade in Food).

**Matters referred from the 22<sup>nd</sup> Session of the Codex Committee on General Principles<sup>3</sup>**

7. The Committee established an intra-session Working Group<sup>4</sup> to consider matters referred by the 22<sup>nd</sup> Session of the Codex Committee on General Principles (CCGP) regarding the revision of the Codex *Code of Ethics for International Trade of Foods* (CAC/RCP 20-1979, Rev.1-1985) and to recommend an approach to reply to the questions posed.

8. The Committee noted the report of the intra-session Working Group, as presented in CRD 17 and agreed to establish an electronic Working Group, led by Canada<sup>5</sup> to develop a discussion paper for consideration at its 15<sup>th</sup> Session. The discussion paper should:

- Review CCFICS terms of reference and advise if the request from CCGP falls within its mandate;
- Assess the existing CCFICS texts to determine if they respond to the question and, where appropriate, identify gaps where further guidance may be useful;
- Determine if the existing texts respond to the problems faced by countries with insufficient capacity to carry out imported food controls; indicate whether other organisations or agencies are better situated to address the problem; and
- Identify any other issues of relevance to the matter referred, where appropriate.

9. The Committee further agreed that in developing the discussion paper the electronic Working Group would take into consideration the comments included in the working document considered by the 22<sup>nd</sup> Session of the Codex Committee on General Principles and other relevant guidance. It was agreed that the electronic Working Group will work in English only.

**PROPOSED DRAFT STANDARDS AND RELATED TEXTS AT STEP 4 (Agenda Item 3)****PROPOSED DRAFT APPENDICES TO THE GUIDELINES ON THE JUDGEMENT OF EQUIVALENCE OF SANITARY MEASURES ASSOCIATED WITH FOOD INSPECTION AND CERTIFICATION (Agenda Item 3a)<sup>6</sup>**

10. The Chair of the Working Group, the Delegation of the United States, introduced the document representing the progress on the development of the proposed draft Appendices since the last session of the Committee. Draft texts for the three priority appendices were first circulated electronically to the Working Group for comment and then were substantially revised in a physical meeting of the Working Group held in Brussels, Belgium, from 5-7 September 2005, in which 32 delegations had participated.

11. The Delegation of the United States said that while good progress had been made on all three texts, a lot of work still remained to be done. While discussing the three appendices, the Working Group found that the approach of having individual appendices might not be the best and most logical one. It was suggested to consider progressing all the planned five appendices (or even six, including the appendix on technical assistance, see Agenda Item 5) at the same time in a single document. The single Appendix would better serve the purpose of providing guidance to specific sections of the Guidelines and would follow their logical flow.

<sup>3</sup> CRD 17 (Report of the intra session Working Group).

<sup>4</sup> Comprising Argentina, Canada, European Community, France, Guatemala, Norway, Spain, Switzerland, United Kingdom and United States.

<sup>5</sup> With the assistance of Angola, Antigua and Barbuda, Argentina, Austria, Barbados, Brazil, Chile, Ecuador, European Community, Finland, France, Guatemala, Iran, Malaysia, Norway, Spain, South Africa, Sweden, Thailand, United States, Zimbabwe, Consumers International, IDF and IIR.

<sup>6</sup> CX/FICS 05/14/3; CX/FICS 05/14/3-Add.1 (Comments submitted by Canada, India, Kenya, Malaysia, New Zealand and United States); CX/FICS 05/14/3-Add. 2 (Comments submitted by Argentina, Ecuador and Mexico); CRD 4 (Comments submitted by the European Community); CRD 13 (Comments submitted by Brazil, Dominica, Japan and Consumers International); CRD 15 (Comments submitted by Thailand); CRD 16 (Comments submitted by Australia and New Zealand).

12. Delegations in general expressed their support for having one combined appendix, which would outline the complete procedure, avoid duplications and be more flexible and user-friendly. It was suggested that such an appendix systematically tag the relevant paragraphs of the parent document. It was also recommended that the Appendix clearly distinguish procedures for the determination of equivalence of a single measure and of an inspection system.

13. In considering the proposed draft appendix on “Documentation for evaluation of submissions of requests for equivalence determinations”, delegations felt that its scope was too broad and more work was needed to ensure consistency with the terminology of the parent document without duplicating text and to clarify how the idea of experience, knowledge and confidence should be addressed.

14. The Observer of Consumers International suggested including in the document a procedure for appeal on denial of equivalence, an obligation for the importing country to lay out circumstances where equivalence might be withdrawn and an obligation for the granting agency to publish judgements for equivalence (public registry of equivalence agreements).

### **Status of the proposed draft Appendices to the Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification**

15. The Committee agreed to return the proposed draft Appendices to the Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification to Step 2 for redrafting by a physical Working Group, led by the United States<sup>7</sup>. The Committee agreed to progress work on all five appendices at the same time in a single appendix and to inform the 29<sup>th</sup> session of the Commission through the Executive Committee of this decision.

16. The Committee further agreed that, when elaborating the document, the physical Working Group should take into account the written comments submitted and the comments made at this Session as well as the draft structure contained in CRD 16. The Working Group should also consider either including elements of technical assistance in the single Appendix or developing a separate Appendix on technical assistance (see also para. 94). The Committee noted that the meeting of the physical Working Group was tentatively scheduled in April/May 2006. The Committee noted that the 28<sup>th</sup> session of the Commission adopted Guidelines for Physical Working Groups, which are included in 15<sup>th</sup> edition of the Codex Procedural Manual.

17. The Committee also noted that the FAO/WHO Project and Trust Fund for Enhanced Participation in Codex provided funds for attending intra-sessional Working Group meetings. To apply for such funding, developing countries should immediately communicate, through their Codex Contact Point to the Trust Fund Secretariat, any changes to their requests for 2006 (the deadline was 31 October) with the indication of priorities among different meetings selected.

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<sup>7</sup> With the assistance of Antigua and Barbuda, Australia, Argentina, Brazil, Burundi, Canada, Chile, Denmark, Ecuador, European Community, Finland, France, Guatemala, India, Iran, Italy, Japan, Kenya, Malaysia, Netherlands, New Zealand, Norway, Philippines, Republic of Korea, Romania, Rwanda, South Africa, Switzerland, , Thailand, Consumers International and IAFI.



**PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR RISK-BASED INSPECTION OF IMPORTED FOODS (Agenda Item 3b)<sup>8</sup>**

18. The Chair of the Working Group, the Delegation of the United States introduced the document. The Delegation noted that the 12<sup>th</sup> Session of the Committee had considered and approved a project document and that a draft document was considered at the 13<sup>th</sup> Session. A physical Working Group, including 25 countries and the European Community, met in Brussels from 8-9 September 2005, to review the document for presentation at this meeting. The Working Group agreed that the document should be an Annex to the Codex *Guidelines for Food Import Control Systems* (CAC/GL 47-2003) and revised the format of the document accordingly. The Working Group removed redundancies and made other technical changes. The Delegation noted that the 23<sup>rd</sup> Session of the Codex Committee on General Principles (10-14 April 2006) will be considering a discussion paper that New Zealand offered to prepare that will provide background to assist the Codex Committee on General Principles in deciding whether there is a need for new work on the definitions of “risk-based” and “science-based”. This was noted in the document and might provide guidance to the Committee at a future time.

19. The Committee acknowledged the progress made by the Working Group on the further development of the document. The Delegation of New Zealand stated that, in their opinion, the current draft document required further work to reduce the repetition of matters covered in the Codex *Guidelines for Food Import Control Systems* and to better address the concept of “risk-based” in the context of an imported food inspection programme. In this regard, the Delegation noted that the term “risk-based” was used frequently and some times imprecisely within the framework of Codex and that the document needed to be reconsidered in light of the discussion paper on the definition of “risk-based” and “science-based” at the upcoming session of the Codex Committee on General Principles.

**Specific comments**

20. In considering the document in detail, the Committee, in addition to some minor editorial changes, including amendments to the French and Spanish translations, agreed to the following changes:

**Title**

21. The Committee agreed to amend the title to refer to “based on risk” instead of “risk-based” in order to ensure conformity with the Codex mandate and paragraphs 22 – 26 of the Codex *Guidelines for Food Import Control Systems* and to substitute the terms throughout the text. A footnote was added to the term “risk” to refer to the definition of Risk Analysis Terms related to Food Safety, contained in the Codex Procedural Manual. In light of this decision and as the definition of “risk” referred to food safety, the Committee agreed to delete “food safety” and the square brackets from the title.

**Introduction**

22. The Committee deleted the second sentence of paragraph 1, which referred to other factors relevant to health protection and fair practices in the food trade, because it did not focus on the scope of the document (i.e. food safety) and was already covered by the Codex *Guidelines for Food Import Control Systems*. The Delegations of the European Community, Norway and Switzerland and the Observer from Consumers International expressed their opposition to this decision.

23. In paragraph 2, the words “enables resources to be better aligned with risk” were removed because their meaning was not clear. A sentence to indicate that “inspection may also cover feedingstuffs for food producing animals, where appropriate” was added to the footnote related to imported food. The Delegation of South Africa expressed objection to this decision.

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<sup>8</sup> CX/FICS 05/14/4; CX/FICS 05/14/4-Add. 1 (Comments submitted by Argentina, Australia, Canada, India, Kenya, Malaysia, Mexico, New Zealand, United States and Consumers International); CRD 11 (Comments submitted by Brazil, European Community, Japan and Paraguay); CRD 14 (Supplementary comments from New Zealand); CRD 15 (Comments submitted by Thailand).

24. The Committee deleted the entire paragraph 3 as its content was already covered in the Codex *Guidelines for Food Import Control Systems*. Paragraph 4 was deleted, with the exception of the last sentence which indicated that an imported food inspection programme based on risk allowed greater attention to be given to foods that present higher risks to human health, which was added to paragraph 2. The Delegation of New Zealand opposed this deletion and suggested that the footnote reference to the Codex Committee on General Principles consideration of risk-based be retained as they considered this was still relevant, but this was not supported by the Committee.

25. The footnote in paragraph 5 (renumbered 3) was deleted.

### **Objectives**

26. The words “presented by the product” were deleted at the end of paragraph 6 (renumbered 4) to make the sentence clearer.

### **Principles**

27. The first bullet of paragraph 7 (renumbered 5) was amended to reflect the wording of paragraph 10 (renumbered 8) and to more clearly delineate between the level of risk assigned to a food versus the food safety risk calculated according to a risk assessment procedure.

28. The Committee deleted the words “to the extent possible” at the end of the second bullet as it was thought to be contrary to the principle. The bullet was broadened to include the content of the sixth bullet that “a food inspection programme based on risk should not be applied arbitrarily or in a discriminatory manner and should not result in unjustified barriers to trade or unnecessary delays”. The Delegation of New Zealand expressed concern at the retention of this language, suggesting that the point was covered in the main text.

29. In the third bullet, the term “intensity” was replaced with “nature and frequency”, for consistency with the language used in the Codex *Guidelines for Food Import Control Systems*. The Committee agreed that the change would be applied throughout the text. A footnote was added to the term “nature” to include examples of the term, i.e. documentation check, visual examination, sampling and testing. The second part of the bullet, which listed the factors to be taken into account, was deleted and replaced with “all relevant factors”; a footnote was added to indicate that examples of relevant factors, where appropriate, were included in paragraph 22 of the Codex *Guidelines for Food Import Control Systems*.

30. In the fourth bullet, the Committee deleted the terms “as far as possible” and “where they exist” which were unnecessary. A footnote was added at the end of the bullet to state that “Statistical validation of sampling requirements should always be the aim but may not be practical where the consignment is not homogeneous”.

31. The fifth and sixth bullet were deleted and the content of the fifth bullet was merged with the second bullet (see para. 28). The Delegation of Barbados expressed concern because the principle in the sixth bullet did not take into account the specific needs of small scale economy countries, which relied heavily on food imports.

32. The Delegation of New Zealand expressed concern that the principles reflected the main text only and were not based on risk approach.

### **Designing a Risk-Based [Imported Food Inspection] Programme**

33. The Committee amended the title of the section, for consistency with the previous decision, as follows “Designing an Imported Food Inspection Programme Based on Risk”; it deleted paragraph 8, which repeated the principle in the second bullet.

34. In paragraph 9 (renumbered 6), the terms “evidence-based approach” was changed to “relevant information” because the “evidence-based” was not well understood and could create confusion. The term “food product” was changed to “food”. In this regard the Committee agreed to amend the entire text to refer to “food” only and not to “product” or “food product”. The last part of the second bullet was amended to read “as may be verified by audits and on-site visits by the competent authority of the importing country.” for clarity.

35. In the last bullet, the last dash point of the “third party inspection bodies” was removed and a new bullet inserted to refer to reports from officially recognised inspection and/or certification bodies.

36. The Committee clarified paragraph 10 (renumbered 7) by specifying that the scope of reviewing the level of risk assigned to a food was to maintain the proportionality between the frequency and the nature of inspection and the risk assessed.

37. The last bullet of paragraph 12 (renumbered 9) was moved into a new paragraph (numbered 10) as it was related to the information gathered by the importing country's competent authority and a new bullet on "other appropriate means acceptable between countries" was added in paragraph 12 (renumbered 9).

38. In paragraph 15 (renumbered 13) "those items listed in paragraph 6" was added after "or of the product itself" to emphasize the importance of considering not only the compliance history but all the items listed in paragraph 9 (renumbered 6).

39. The Committee added at the end of paragraph 16 (renumbered 14) "in proportion to the level of compliance verified" for clarity.

40. The Committee deleted "do its utmost to" from the footnote of paragraph 17 (renumbered 15) as it was redundant. A new paragraph (numbered 16) was added at the end of the Section to indicate that the level of adjustment/modification of the nature and frequency of the inspection should be proportional to the change in the level of the assessed risk of the food.

### ***Developing Requirements and Procedures***

41. The Committee deleted "where appropriate" in paragraph 18 (renumbered 17), as it was unnecessary and amended the last bullet of the paragraph to refer to official or officially accredited laboratories, for consistency with the language used in the *Codex Guidelines for Food Import Control Systems* (paragraph 26).

42. Paragraph 19 (renumbered 18) was clarified to indicate that the "range of procedures" was related to the nature of inspection. A new sentence was added to specify that consideration should be given to the proportionality of these procedures with the level of risk of the food. In the third bullet "only" was deleted as it was not appropriate.

### ***Implementing the Risk-Based Inspection Programme***

43. The entire paragraph 20 was deleted as redundant.

44. The Committee did not accept the suggestion of the Delegation of New Zealand that the entire section be deleted.

45. The Committee removed the square brackets in paragraph 22 (renumbered 20) and made the following changes:

- The last part of the first sentence was clarified by changing "trigger a change in level of food safety risk for the product concerned" with "trigger a change in the manner in which risk is managed by the importing country for the food concerned";
- The last part of the second sentence was deleted and a new sentence added to clarify that the enhanced sampling and testing might be applied to other establishments when there was evidence of a systemic problem;
- The term "hazard" in the third sentence was changed to "risk" as more appropriate and it was specified that the suspension of the importation of a product should be limited only to those situations involving a serious food safety risk that cannot be managed by other means.

46. The Committee did not accept the suggestions of the Delegation of India to add a sentence to indicate that the food should not be destroyed unless it has been agreed to by the exporting country and of the Observer of Consumers International to include a sentence to provide information on how to appeal the import prohibition and on how to satisfy the importing country's requirements for the prohibited food. The suggestion of the Delegation of Ghana to include language on the provision of information on the destruction of food consignments to be provided to the competent authority of the exporting country was not supported as this provision was already covered by the *Codex Guidelines for the Exchange of Information between Countries on Rejection of Imported Food* (CAC/GL 25-1997).

47. The last paragraph was amended to specifically refer to the competent authorities of the importing country.

### **Status of the proposed draft Principles and Guidelines for Risk-Based Inspection of Imported Foods**

48. The Committee agreed to advance the renamed proposed draft Principles and Guidelines for Imported Food Inspection Based on Risk to Steps 5/8, with the omission of Steps 6 and 7, for adoption by the 29<sup>th</sup> Session of the Commission (see Appendix II) and recommended that the Commission attach the Principles and Guidelines as an Appendix to the Codex *Guidelines for Food Import Control Systems* (CAC/GL 47-2003).

49. The Delegation of New Zealand did not support the decision to advance the text to Steps 5/8 as they felt that the document: did not properly address inspection based on risk; should wait for the results of the discussion at the 23<sup>rd</sup> Session of the Codex Committee on General Principles on the definition of “risk-based” and “science-based”; still contained repetition of matters covered in the Codex *Guidelines for Food Import Control Systems*; and, could be improved in the way it flowed. This concern was also supported by the Observer of Consumers International.

### **PROPOSED DRAFT PRINCIPLES FOR THE APPLICATION OF TRACEABILITY/PRODUCT TRACING IN THE CONTEXT OF FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS (Agenda Item 3c)<sup>9</sup>**

50. The Chairperson introduced the document representing the progress on the development of the proposed draft principles since the last session. These included the comments submitted in relation to the Circular Letter (CL 2005/6-FICS), the results of a physical Working Group meeting held in Brussels, Belgium from 12-14 September 2005. The Chairperson thanked the Vice-Chairs from Argentina and Norway for their assistance in the Working Group as well as the 38 delegations that had participated.

51. He said that the meeting had developed a consensus on a number of key themes which had then been applied throughout the drafting of the revised principles.

- Traceability/product tracing is a tool that does not in itself improve food safety and/or fair practice outcomes in the food trade unless it is combined with a relevant measure or requirement;
- Exporting countries should not have to replicate the traceability/product tracing tool of the importing country. They need only meet the objectives of the importing country’s food inspection and certification system;
- The concept of traceability/product tracing as a tool is that it should follow food one step forward and one step back;
- Importing countries should be prepared to explain to an exporting country what are the objectives and outcomes of its food inspection and certification system when they incorporate a traceability/ product tracing tool.

#### **General comments**

52. Many delegations commended the Working Group for the results reached and said that they were prepared to discuss the document paragraph by paragraph in order to be able to advance it in the step procedure.

53. Some delegations were of the opinion that the proposed draft principles should be more closely linked with food safety. The Chairperson advised caution when reopening debate on the extent to which the principles should make reference to both parts of the dual mandate of Codex. He said that the present text had been carefully drafted to reach a consensus in the Working Group.

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<sup>9</sup> CX/FICS 05/14/5; CX/FICS 05/14/5-Add. 1 (Comments submitted by Argentina, Australia, Bolivia, Canada, Colombia, Kenya, Mexico, New Zealand, Peru, United States, OIE, Consumers International and the 49<sup>th</sup> Parallel Biotechnology Consortium); CX/FICS 05/14/5-Add. 2 (Comments submitted by Ecuador and Honduras); CRD 5 (Comments submitted by the European Community); CRD 9 (Comments submitted by India); CRD 12 (Comments submitted by Brazil, Japan, Norway and Paraguay); CRD 15 (Comments submitted by Thailand).

54. The Delegation of Switzerland, as Coordinator of the FAO/WHO Regional Coordinating Committee for Europe informed the Committee of the conclusions of the CCEURO Seminar on traceability/product tracing (Brussels, 7 September 2005) and indicated that the Seminar agreed to a number of conclusions: traceability/product tracing is a tool which, within the context of a food control and certification system, can be applied to protect the health of consumers by securing food safety and to ensure fair practices in the food trade; traceability/product tracing is an information tool which allows the tracing of food products through the production and distribution chains, in this regard, it can be used to adopt focussed measures should a specific hazard be identified by facilitating the rapid withdrawal of food from the market place and thereby minimising the potential negative impact on the health of consumers, economic losses and the potential negative impact on food trade; a traceability/product tracing tool can reinforce the confidence in the food trade by ensuring the authenticity and accuracy of information provided on the products and their characteristics (e.g. origin, organic farming, animal welfare, religious concerns such as Kosher or Halal); traceability/product tracing principles apply equally to both food safety and fair practices in food trade; the traceability/product tracing tool does not replace food safety measures; traceability/product tracing should cover the entire food chain and cover feed when appropriate; traceability/product tracing systems should avoid any unnecessary trade restrictions and should be designed in terms of outcomes/performance rather than in prescriptive specifications about the system itself.

55. The Delegation of Chile expressed its concern that the Spanish text differed from the English text throughout the document using the term “management tool” (in Spanish “herramienta de gestión”) in the Spanish text rather than “tool” (in Spanish “herramienta”). The Committee amended the Spanish version by adapting it to the English version and noted that the French and Spanish translations should be based on the English text

#### **Specific comments**

56. The Committee considered the proposed draft Principles for the Application of Traceability/Product Tracing in the Context of Food Import and Export Inspection and Certification Systems in detail and in addition to some editorial changes, including minor amendments to the French and Spanish translations, agreed to the following changes:

#### ***Section 1 - Introduction***

57. The Committee changed the name of the Section to “Scope” to better reflect its contents. It deleted paragraph 1 because it did not add any relevant information and moved paragraph 3, as new paragraph 1 under this section as more appropriate. A footnote was added to paragraph 2 to refer to the Codex *Principles for Food Import and Export Inspection and Certification* (CAC/GL 20-1995).

58. The Representative of the OIE indicated that the OIE supported the proposed set of principles. The OIE believed that countries should be provided with guidance in setting up a traceability system that covers the entire food chain without gaps and duplications. Accordingly, the representative suggested that a reference to the standards of other international organisations, in particular OIE and IPPC, be added to paragraph 3. However, the Committee did not agree to this proposal.

#### ***Section 2 - Objective***

59. The section was deleted as the text had been included in section 1.

#### ***Section 3 - Definitions***

60. Some delegations expressed concern that the definition of “inspection” needed to be amended to refer also to “supplied products”. In this regard, it was noted that these definitions were taken from other texts and that it was not appropriate to consider amendments in this discussion.

#### ***Section 4 (renumbered 3) - Principles***

##### ***Context***

61. In paragraph 6 (renumbered 5), the Committee deleted “that in some cases it can be demonstrated” to strengthen the principle that a food inspection and certification system without traceability/product tracing tool might meet the same objective and produce the same outcomes as a food safety inspection and certification system with traceability/product tracing.

62. The Committee clarified the principle in paragraph 7 (renumbered 6) to indicate that, when applicable, it was not compulsory for an exporting country to establish the same traceability/product tracing tool as used by the importing country.

### ***Rationale***

63. The Committee agreed to delete “The purpose of” at the beginning of paragraph 8 (renumbered 7) in order to have a consistent application of a traceability/product tracing tool; it also added “and/or efficiency” after “effectiveness” for consistency with the language used in paragraph 9 (renumbered 8) and to emphasise that the application of a traceability/product tracing tool by a competent authority should improve either efficiency or effectiveness or both. The example at the end of the paragraph was put into a new footnote.

64. In paragraph 9 (renumbered 8), the Delegation of the United States noted that, while they supported the concept of traceability/product tracing as a tool, they also believed that, depending on its use, traceability/product tracing could either be a measure or a technical regulation. The Delegation observed that, in their view, the current wording of paragraph 9 excluded the possibility of traceability/product tracing being a measure or technical regulation and proposed to amend the paragraph to allow traceability/product tracing to be considered as a tool, measure or technical regulation according to its use. The Committee discussed the proposal but could not reach consensus, therefore it agreed to retain the existing text. For consistency the example at the end of the paragraph starting with the words “by reinforcing confidence...” was put into a new footnote.

65. In paragraph 10 (renumbered 9), the Committee discussed the usefulness of maintaining the example of the way a traceability/product tracing tool contributes to the protection of consumers against deceptive marketing practices and to the facilitation of trade. In noting that “Principles” documents should be concise and simple, that examples were more appropriate in “Guidelines” documents and that it was useful not to lose these concepts, the Committee agreed to move the example to a footnote. In the footnote, the reference to “country” was amended to read “country of origin” for clarity. For consistency, in paragraph 9 the example on how the traceability/product tracing tool could contribute to the effectiveness and/or efficiency of associated food safety measures was moved to a new footnote.

66. The Committee added a last sentence to paragraph 11 (renumbered 10) to include the notion that the scope and the extent of the application of traceability/product tracing tool should also be consistent with the described need.

### ***Design***

67. In paragraph 12 (renumbered 11) the word “cover” was replaced with “apply to”. In the footnote “should” was replaced with “could” and the reference to the ALINORM deleted, as it was more appropriate to refer only to other adopted texts. There was some discussion as to whether the footnote reference should be placed next to the word “production” in the definition of traceability/product tracing. This was not retained as the definition of traceability/product tracing is contained in the Procedural Manual and should not be altered.

68. Concerning paragraph 13 (renumbered 12) the Observer of Consumers International said that they believed that the minimum requirement for traceability/product tracing should be the recording of the movement of food and feed one step forward and one step back. However, where feasible, more information should be provided on the origin and destination in order to improve the effectiveness of traceability/product tracing and the timeliness of product recalls and withdrawals.

69. Several delegations commented that it had been fundamental in the outcome of previous discussions that if traceability/product tracing is required, each stakeholder in the food chain should only have to record from where they received (one step back) and where they sent the food (one step forward). The Committee left the text unchanged.

### ***Application***

70. The delegation of India proposed to add to paragraph 15 (renumbered 14) a sentence referring to the impossibility of applying traceability/ product tracing to primary production. The Chairperson said that the language used in the document had been built around the principle of addressing disparate production systems and therefore it was not necessary to repeat it in the text.

71. As agreed by the Working Group, the Delegation of Argentina proposed a revision of paragraph 15 (renumbered 14), which captured three areas on how the exporting country could be helped:

- By allowing a longer timeframe for compliance in order to maintain opportunities for exports;
- By allowing flexibility regarding the design of the traceability tool;
- By providing technical assistance.

72. After a long discussion the Committee agreed to the inclusion of a new paragraph to address these three areas of assistance. It was reaffirmed that flexibility and longer timeframes for compliance should not compromise the safety of exported food and should not be interpreted as the possibility to derogate from the importing countries' rules

73. The Observer of Consumers International suggested the deletion of paragraph 16, as they felt it was not within the Codex mandate to require that a traceability/product tracing tool "should not be more trade restrictive than necessary". The Committee did not agree to this proposal.

74. The Committee agreed to add a new Principles (paragraph 19) to state that a traceability/product tracing tool should be implemented, when and as appropriate on a case by case basis.

### **Other Discussion**

75. After concluding the detailed review of the proposed draft Principles the Committee considered whether they should be a standalone Codex document or an appendix to an existing Codex document.

76. A number of delegations stated that they would prefer the document to be a food inspection and certification standalone Codex text because this would avoid reopening existing Codex texts which would have to make reference to the Principles. This would also give more prominence to the Principles.

77. Other delegations felt that the Principles were closely related to the Codex *Principles for Food Import and Export Inspection and Certification*<sup>10</sup> and should thus become an appendix to these. Others felt that the document should become an appendix to the Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems<sup>11</sup>.

78. The Chairperson said that there was clearly no consensus on this matter but felt that either way would not impact significantly on the application of the Principles. He suggested moving the Principles forward as a standalone document. The Committee supported this suggestion. The delegations of Argentina, Brazil, Costa Rica, Chile, Cuba, Ecuador, Egypt, Guatemala and Mexico expressed their strong objection to this decision.

79. The Committee did not take any decision as to whether the document would be further developed into guidelines.

### **Status of the proposed draft Principles for Traceability/Product Tracing as a Tool within a Food Inspection and Certification System**

80. The Committee agreed to advance the proposed draft Principles to Steps 5/8, with the omission of Steps 6 and 7, for adoption by the 29<sup>th</sup> Session of the Commission (see Appendix III).

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<sup>10</sup> Codex *Principles for Food Import and Export Inspection and Certification* (CAC/GL 20-1995).

<sup>11</sup> Codex *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CAC/GL 26-1997).

**PROPOSED DRAFT REVISION OF THE GUIDELINES FOR GENERIC OFFICIAL CERTIFICATE FORMATS AND THE PRODUCTION AND ISSUANCE OF CERTIFICATES (Agenda Item 3d)<sup>12</sup>**

81. The Chair of the Working Group, the Delegation of the United States, introduced the document. The Delegation noted that the guidelines had been revised to make them more outcome focused, principles based, less prescriptive than the previous ones and to separate between mandatory and marketing requirements. In view of the inclusion of a new section on principles and in line with the names of other Codex food inspection and certification texts, they recommended changing the title of the Guidelines to “Guidelines and Principles for Generic Official Certificate Formats and the Production and Issuance of Certificates”.

82. In considering the numerous comments submitted and that it was not possible to review the document in detail at the present session due to time constraints, the Delegation of the United States recommended re-establishing the Working Group to further revise the document.

83. The Delegation of the European Community introduced CRD 1 and made a brief presentation to highlight the issues related to illegal imports and fraudulent use of certification. It was stressed that the cases presented were not the responsibilities of governments, but were linked to international criminal organisations. It was noted that these practices jeopardised measures put in place by importing countries to protect the health of consumers and to ensure fair practices in the food trade and had a negative impact on the food business of exporting countries by damaging their reputation. The Delegation stated that the purpose of the paper was to bring the Members’ attention to these problems and to consider whether guidance could be developed to protect countries against this type of practices.

84. The Committee in general supported the document prepared by the Working Group, which represented good progress, contained essential elements and allowed for adequate flexibility. It was suggested that further work be done to better align the text with the principles and to include a section on certificates that may be required for pre-clearance or pre-approval of imported products; the Annex on Principles for Electronic Certification in the main text; and text to address fraudulent certificates (e.g. use of heat sensitive paper and guidance to prevent frauds).

85. The Representative of OIE thanked the European Community for the informative presentation and noted that it reflected the experiences of the OIE Member Countries. He informed the Committee that the OIE was updating its standard on certification and that it was keen to coordinate its work with that of Codex to produce combined certificates, where possible, to maximise harmonisation. The Representative stated that the OIE supported the proposed revision of the document and the concept that a single certificate might contain information relating to animal and plant health and food safety.

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<sup>12</sup> CX/FICS 05/14/6; CX/FICS 05/14/6-Add. 1 (Comments submitted by Bolivia, Canada, Colombia, India, Kenya, Malaysia, New Zealand, United States, IDF and OIE); CRD 1 (Discussion Paper on Illegal Imports and Fraudulent Use of Certification and the Need for Appropriate Means to Tackle Frauds in the Context of Food Import and Export Inspection and Certification Systems); CRD 6 (Comments submitted by the European Community); CRD 15 (Comments submitted by Thailand).



**Status of the proposed draft Revision of the Guidelines for Generic Official Certificate Formats and the Production and Issuance of Certificates**

86. The Committee agreed to return the proposed draft revision of the renamed “Principles and Guidelines for Generic Official Certificate Formats and the Production and Issuance of Certificates” to Step 2 for redrafting by a physical Working Group, led by the United States<sup>13</sup>. It agreed that the meeting of the physical Working Group would be organised in conjunction with the meeting of the physical Working Group on the Appendix to the Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification (see para. 16), tentatively in April/May 2006. The Committee further agreed that, when elaborating the document, the physical Working Group should take into account the written comments submitted and the comments made at this Session and should also take into account relevant issues highlighted in CRD 1 in relation to the fraudulent use of certificates. The proposed draft revision of the Principles and Guidelines Appendices would then be circulated for comments at Step 3 and consideration by the next Session of the Committee.

**DISCUSSION PAPER ON THE REVISION OF THE GUIDELINES FOR THE EXCHANGE OF INFORMATION BETWEEN COUNTRIES ON REJECTIONS OF IMPORTED FOODS (Agenda Item 4)<sup>14</sup>**

87. The Chair of the Working Group, the Delegation of India, introduced the document, which provided justifications for the need to revise the *Codex Guidelines for the Exchange of Information between Countries on Rejection of Imported Foods* (CAC/GL 25-1997), as requested by the 13<sup>th</sup> Session of the Committee.

88. The Delegation stated that the reasons for the revision included among others the need:

- To add principles clarifying the condition under which information is to be exchanged to bring the document in line with the revised *Codex Principles and Guidelines for the Exchange of Information in Food Control Emergency Situations* (CAC/GL 19-1995, Rev.1-2004);
- To better specify the circumstances under which the food control authority of the exporting country should be informed of the rejection so that corrective action can be taken for future exports;
- To better address the issue of communication and specifically to add provisions for clear, relevant, factual and timely information between exporting and importing countries and to address the issue of language;
- To make the guidelines consistent with the annex as well as with the *Codex Principles and Guidelines for the Exchange of Information in Food Control Emergency Situations*.

89. The Working Group suggested various options to address these needs including a revision of both the content and structure of the document and the revision of the structure of the document only.

90. Some delegations supported new work of the revision of the guidelines, while others were of the opinion that the present guidelines were adequate and did not need to be revised. However, they found that it would have been useful to develop guidance on the issue of exchange of information with respect to certificates, in particular in case of fraudulent imports and use of false certificates.

91. In recognising that there was no adequate consensus to start new work on the revision of the Guidelines, the Committee agreed to discontinue the discussion of this matter for the time being. It was also agreed that the issue of information exchange in case of fraudulent imports or false certificates would be considered by the physical Working Group on the revision of the Guidelines for Generic Official Certificate Formats and the Production and Issuance of Certificates (see para. 86).

<sup>13</sup> With the assistance of Angola, Argentina, Australia, Belgium, Brazil, Burundi, Canada, Chile, Costa Rica, European Community, Finland, France, Ghana, India, Indonesia, Iran, Ireland, Italy, Japan, Kenya, Madagascar, Malaysia, Nepal, Netherlands, New Zealand, Norway, Philippines, Republic of Korea, Romania, Rwanda, Spain, South Africa, Sudan, Switzerland, Thailand, United Kingdom, Venezuela, IDF and OIE.

<sup>14</sup> CX/FICS 05/14/7; CRD 7 (Comments submitted by the European Community).

**DISCUSSION PAPER ON THE DEVELOPMENT OF AN APPENDIX ON “INFORMATION RELATING TO THE NEED FOR TECHNICAL ASSISTANCE AND COOPERATION BETWEEN THE IMPORTING COUNTRIES TO EXPORTING COUNTRIES” TO THE CODEX GUIDELINES ON THE JUDGEMENT OF EQUIVALENCE OF SANITARY MEASURES ASSOCIATED WITH FOOD INSPECTION AND CERTIFICATION (Agenda Item 5)<sup>15</sup>**

92. The Committee had a general discussion on the document prepared by the Delegation of the United States and on how to develop guidance on this matter. The Committee generally supported the points of guidance contained in para. 14 of CX/FICS 05/14/8.

93. Several delegations were in favour of including aspects of technical assistance in the single Appendix to the Codex *Guidelines on the Judgement of Equivalence of Sanitary Measures associated with Food Inspection and Certification* (see para. 15) and it was suggested that each component of the Appendix examine aspects of technical assistance. Also mentioned were the importance of considering the development of guidance for countries on how to access the resources necessary to meet the requirements for the determination of equivalence; the need to provide guidance without creating new obligations; the primary responsibility for technical assistance of FAO, WHO and WTO; and the specific provisions for technical assistance for the judgement of equivalence of Art. 4 of the SPS Agreement.

94. The Committee concluded the discussion on this Agenda item and agreed that the physical Working Group in charge of developing a single Appendix to the Guidelines on the Judgement of Equivalence (see para. 16) should on the basis of the discussion paper, the comments submitted and the discussion above, consider either the inclusion of elements of technical assistance in the single Appendix or the development of a separate Appendix on technical assistance.

**OTHER BUSINESS AND FUTURE WORK (Agenda Item 6)**

***ISO activities of interest to CCFICS***<sup>16</sup>

95. The Observer from ISO provided an overview of the organization, its work in food standardization and related work in conformity assessment. He described the intent of the new ISO 22000 series including requirements for a food safety management system (ISO 22000:2005); traceability (ISO/DIS 22005) and audit/certification of food safety management systems (draft ISO/TS 22003). The Observer also summarized the relevant work of ISO's Policy Committee on Conformity Assessment (CASCO) and highlighted the Committee's initiative to obtain regulator feedback on the use of conformity assessment documents by food safety regulators. The Committee thanked the Observer from ISO for the very useful information.

**DATE AND PLACE OF NEXT SESSION (Agenda Item 7)**

96. The Committee noted that its 15<sup>th</sup> Session was tentatively scheduled to be held from 13-17 November 2006, subject to further discussion between the Codex and Australian Secretariats.

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<sup>15</sup> CX/FICS 05/14/8; CRD 2 (Comments submitted by Colombia, European Community and India).

<sup>16</sup> CRD 10.

## SUMMARY STATUS OF WORK

<b>Subject Matter</b>	<b>Step</b>	<b>Action by:</b>	<b>Document Reference (ALINORM 06/29/30)</b>
Proposed draft Principles and Guidelines for Imported Food Inspection Based on Risk (N06-2004)	5/8	Comments 29 <sup>th</sup> CAC	Para. 48 and Appendix II
Proposed draft Principles for Traceability/Product Tracing as a Tool within a Food Inspection and Certification System (N04-2005)	5/8	Comments 29 <sup>th</sup> CAC	Para. 80 and Appendix III
Proposed draft Appendix to the Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification (N04-2004)	2/3	Physical Working Group Comments 15 <sup>th</sup> CCFICS	Paras 15-16 and para. 94
Proposed draft Principles and Guidelines for Generic Official Certificate Formats and the Production and Issuance of Certificates (N05-2005)	2/3	Physical Working Group Comments 15 <sup>th</sup> CCFICS	Para. 86
Discussion Paper on the Revision of the Guidelines for the Exchange of Information Between Countries on Rejections of Imported Foods	discontinu ed		Para. 91
Discussion Paper on the development of an Appendix on “Information relating to the need for technical assistance and cooperation between the importing countries to exporting countries” to the Codex Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification	discontinu ed		Para. 94
Discussion Paper on the reply to the question raised by the 22 <sup>nd</sup> Session of the Codex Committee on general Principles regarding the revision of the Codex <i>Code of Ethics for International Trade of Foods</i> (CAC/RCP 20-1979, Rev.1-1985)	-	Electronic Working Group 15 <sup>th</sup> CCFICS	Para. 9

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**PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR IMPORTED FOOD INSPECTION  
BASED ON RISK<sup>1</sup>****(N06-2004)****(at Steps 5/8 of the Elaboration Procedure)****SECTION 1 - INTRODUCTION**

1. This Annex elaborates on paragraphs 22-26 of the main text (CAC/GL 47-2003).
2. The implementation of an imported food inspection programme based on risk provides a more effective means for addressing the food safety risks that are associated with imported food<sup>2</sup>, ensuring compliance of imported foods with importing countries' food safety requirements and allows greater attention to be given to foods that present a higher level of risk to human health.
3. This document should be read in conjunction with all relevant Codex guidelines.

**SECTION 2 - OBJECTIVE**

4. This annex is intended to provide competent authorities with information to assist them with the design and implementation of inspection programmes for imported food, based on the food safety risks.

**SECTION 3 - PRINCIPLES**

5. The following principles apply to the development and implementation of an imported food inspection programme based on risk.
  - In determining the level of risk assigned to an imported food an importing country should consider the assessed food safety risk to human health the food presents or is likely to present based on available scientific information in relation to the consumption of the food.
  - Requirements for an imported food inspection programme based on risk should be developed using a risk analysis approach, and should not be applied arbitrarily or in a discriminatory manner, and should not result in unjustified barriers to trade or unnecessary delays.
  - The nature<sup>3</sup> and frequency of inspection of a specific imported food should be proportionate to the level of risk attributed to it and take into account, all relevant factors.<sup>4</sup>
  - Sampling plans<sup>5</sup> and methods of analysis should, be based on Codex standards, guidelines, and recommendations. In the absence of Codex sampling plans, reference should be made to internationally accepted or scientifically based sampling plans when practically feasible.<sup>6</sup>
  - Information regarding a country's imported food inspection programme based on risk should be transparent, easily accessible, and up to date.

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<sup>1</sup> A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food. Definition of Risk Analysis Terms Related to Food Safety, Codex Alimentarius Procedural Manual 14<sup>th</sup> Edition.

<sup>2</sup> Imported food in this annex also includes food ingredients. Inspection may also cover feeding stuffs for food producing animals where appropriate.

<sup>3</sup> Examples of the nature of inspection could include documentation check, visual examination, sampling and testing.

<sup>4</sup> Examples of relevant factors where appropriate are included in paragraph 22 of CAC/GL 47/2003.

<sup>5</sup> *Principles for the Establishment or Selection of Codex Sampling Procedures*, Codex Alimentarius Procedural Manual, 14<sup>th</sup> Edition, Page 82.

<sup>6</sup> Statistical validation of sampling requirements should always be the aim but may not be practical where the consignment is not homogenous.

## Appendix II

**SECTION 4 - DESIGNING AN IMPORTED FOOD INSPECTION PROGRAMME BASED ON RISK**

6. The competent authority should use relevant information to assess the level of risk associated with the imported food. This information could include, *inter alia*:

- The scientific determination of the food safety risk to the extent possible<sup>7</sup>.
- The adequacy of processing controls in place in the exporting country as evidenced by its laws, regulations, and other policies; its infrastructure; and its ability to effectively enforce food safety requirements, as may be verified by audits and on-site visits by the competent authority of the importing country.<sup>8</sup>
- The compliance history of the food generally, irrespective of the source of the food;
- The compliance history of the food with respect to the source of the food including, where available, the compliance history of:
  - the exporting country or region/area within an exporting country;
  - the producer and manufacturer;
  - the exporter;
  - the shipper; and
  - the importer.
- reports from officially recognized inspection and/or certification bodies.

7. The level of risk assigned to a food should be reviewed periodically or when new information that may affect the food safety risk associated with the food becomes known in order to maintain the proportionality between the nature and frequency of inspection and the risk assessed.

8. The competent food safety authority may establish levels of inspection based on the above factors in order to determine the nature and frequency of inspections at the border/point of control of a given food from a given country, producer/manufacturer, exporter, shipper, and importer. The nature and frequency of inspection may then be adjusted according to the demonstrated compliance to food safety requirements. The nature and frequency of inspection should be fully documented.

9. The importing country should adjust the nature and frequency of inspection of the imported food based on information from competent authorities in the exporting country regarding the exported foods. This information may include:

- certificates;
- equivalence determinations;
- memoranda of understanding;
- mutual recognition agreements; or
- other appropriate means acceptable between countries.

10. The importing country may also adapt/alter the nature and frequency of inspection of the imported food based on an assessment by the importing country's competent authority of controls its importers exercise over their suppliers.

11. Exporting countries can provide information on the control systems in place in their country and, as appropriate, may provide assurance to the importing country that a particular food complies with the food safety requirements of the importing country.

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<sup>7</sup> Risk assessments, foodborne illness outbreak and epidemiological findings/history, contaminant and/or residue information can be key components of this information.

<sup>8</sup> Laboratory sampling programmes and results may provide this type of information. Audits are another way of gaining information.

12. Audits by the importing country may, where appropriate, verify an exporting country's inspection controls, and the information gained from these audits could be used as part of the review of the level of risk assigned to the food from that country.

13. When an importing country does not have prior knowledge of an exporting country's processing controls or of the food itself, that is those items listed in paragraph 6, a compliance history is lacking or such information cannot be readily obtained, an importing country may, until there is such knowledge, initially establish inspections of a more comprehensive nature and of a higher frequency than that which it might assign to the food when such information is available.

14. Sustained conformance with the importing country's requirements, as demonstrated, for example, by audit results and results of border/point of control checks, provides an opportunity for importing countries to adjust the nature and frequency of inspection at the border/point of control, in proportion to the level of compliance verified.

15. Foodborne illness outbreaks; epidemiological findings; results of audits conducted in the exporting country; the detection of non-compliances with food safety requirements at the point of import and detection of pathogens, contaminants and harmful residues in imported food; and the results of border/point of control checks, may lead an importing country to adjust the nature and frequency of inspection, or in extreme cases, to suspend the trade in that food until it is confirmed that corrective measures have been introduced and are being implemented effectively<sup>9</sup>. An importing country may work with an exporting country to prevent the occurrence of further outbreaks.

16. The level of adjustment/modification of the nature and frequency of inspection applied to a food should be proportional to the changes in the level of assessed risk for the food in question.

## **SECTION 5 - DEVELOPING REQUIREMENTS AND PROCEDURES**

17. Competent authorities should take into account Codex standards, recommendations, and guidelines, in developing requirements for border/point of control checks of imported food and make use, when available, of:

- Relevant information from risk assessments conducted according to internationally recognized protocols for the biological, chemical, and physical hazards associated with the type of food.
- Internationally accepted or scientifically based sampling plans, to the extent possible.
- Appropriate inspection procedures, appropriate sampling techniques, and official or officially accredited laboratories using validated analytical methods.

18. The nature of inspection may consist of a range of procedures to ensure that imported foods meet the importing country's food safety requirements. When defining these procedures to verify compliance with safety requirements, the proportionality of these measures with the level of risk of the food or group of foods should be considered. These procedures may include for example:

- Checking the documentation and/or the general condition of the shipment;
- Checking documentation plus periodic food sampling (e.g., 1 in 20 or 1 in 40 shipments) to confirm the accuracy of the documentation;
- Sensory examination ;
- Random or targeted sampling and testing of, or within, shipments according to a sampling plan;  
or
- Lot-by-lot inspection, sampling, and testing, which, in general, should be reserved for those foods that present, or have the potential to present, the highest food safety risk.

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<sup>9</sup> In such cases, the importing country will ensure that corrective measures put in place by the exporting country are evaluated in a reasonable interval.

**SECTION 6 - IMPLEMENTING THE IMPORT INSPECTION PROGRAMME BASED ON RISK**

19. Competent authorities with responsibility for imported food inspection programs based on risk should ensure that relevant policies and procedures are implemented in a transparent, coordinated, and consistent manner. Personnel should be appropriately trained to enable such coordination, and information should be shared among competent authorities.

20. A failure of food shipments to meet importing country food safety requirements might, besides other actions, trigger a change in the manner in which risk is managed by the importing country for the food concerned. The response could include food being held pending final judgment combined with enhanced sampling and testing from the establishment involved. These actions may also be applied to other exporting establishments from the same country producing similar foods where there is evidence of a systemic problem. The suspension of the importation of a food by an importing country should be reserved only for those situations involving a serious food safety risk that has not been managed by other means. Procedures should provide for appeal.

21. When the results of border/point of control checks indicate failure of a shipment to meet the requirements of the importing country, competent authorities of the importing countries should consider action as described in the *Codex Guidelines for the Exchange of Information Between Countries on Rejection of Imported Food* (CAC/GL 25-1997) or in the *Codex Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations* (CAC/GL 19-1995, Rev 1-2004).

22. Competent authorities of the importing country should ensure adequate laboratory competency, capability and capacity is available to conduct the testing of imported food.

**PROPOSED DRAFT PRINCIPLES FOR TRACEABILITY / PRODUCT TRACING AS A TOOL  
WITHIN A FOOD INSPECTION AND CERTIFICATION SYSTEM**

**(N04-2005)**

**(at Steps 5/8 of the Elaboration Procedure)**

## **SECTION 1 - SCOPE**

1. This document elaborates a set of principles to assist competent authorities in utilising traceability/product tracing as a tool within their food inspection and certification system. This document should be read in conjunction with all relevant Codex texts.

2. Recognising the dual mandate of the Codex Alimentarius, traceability/product tracing is a tool that may be applied, when and as appropriate, within a food inspection and certification system in order to contribute to the protection of consumers against food-borne hazards and deceptive marketing practices and the facilitation of trade on the basis of accurate product description.<sup>1</sup>

## **SECTION 2 - DEFINITIONS**

*Inspection*<sup>2</sup>: is the examination of food or systems for control of food, raw materials, processing and distribution, including in-process and finished product testing, in order to verify that they conform to requirements.

*Certification*<sup>2</sup>: is the procedure by which official certification bodies and officially recognized bodies provide written or equivalent assurance that foods or food control systems conform to requirements. Certification of food may be, as appropriate, based on a range of inspection activities which may include continuous on-line inspection, auditing of quality assurance systems, and examination of finished products.

*Equivalence*<sup>3</sup>: is the capability of different inspection and certification systems to meet the same objectives.

*Traceability/product tracing*<sup>4</sup>: the ability to follow the movement of a food through specified stage(s) of production, processing and distribution.

## **SECTION 3 - PRINCIPLES**

3. These principles cover the context, rationale, design and application of traceability/product tracing as a tool for use by a competent authority within a food inspection and certification system.

### **Context**

4. Traceability/product tracing, as defined above, is one of a number of tools that may be utilised by a competent authority within its food inspection and certification system.

5. An importing country should consider that a food inspection and certification system without a traceability/product tracing tool may meet the same objective and produce the same outcomes (e.g. regarding food safety, provide the same level of protection) as a food inspection and certification system with traceability/product tracing<sup>5</sup>.

6. It should not be mandatory for an exporting country to replicate (i.e. establish the same) the traceability/product tracing tool as used by the importing country, when applicable.

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<sup>1</sup> Codex Principles for Food Import and Export Inspection and Certification (CAC/GL 20 – 1995) (para 5).

<sup>2</sup> Codex Principles for Food Import and Export Inspection and Certification (CAC/GL 20 – 1995).

<sup>3</sup> Codex Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems. (CAC/GL 26 – 1997).

<sup>4</sup> Codex Procedural Manual, 14<sup>th</sup> Edition.

<sup>5</sup> Codex Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems (CAC/GL 34-1999); Codex Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems (CAC/GL 53-2003)



## Appendix III

**Rationale**

7. The application of a traceability/product tracing tool by a competent authority should improve the effectiveness and/or efficiency of the actions that may be necessary regarding its measures or requirements within its food inspection and certification system.
8. Traceability/product tracing is a tool that when applied in a food safety context does not in itself improve food safety outcomes unless it is combined with appropriate measures and requirements. It can contribute to the effectiveness and/or efficiency of associated food safety measures<sup>6</sup>.
9. Traceability/product tracing is a tool that when applied in a food inspection and certification system can contribute to the protection of consumers against deceptive marketing practices and facilitation of trade on the basis of accurate product description<sup>7</sup>.
10. In every case a traceability/product tracing tool should be justified within the context of the food inspection and certification system and the purpose, objectives and specifications of the traceability/product tracing tool clearly described. The scope and extent of application of the tool should also be consistent with the described need.

**Design**

11. The traceability/product tracing tool may apply to all or specified stages of the food chain (from production<sup>8</sup> to distribution), as appropriate to the objectives of the food inspection and certification system.
12. The traceability/product tracing tool should be able to identify at any specified stage of the food chain (from production to distribution) from where the food came (one step back) and to where the food went (one step forward), as appropriate to the objectives of the food inspection and certification system.
13. The objectives, scope and related procedures of a food inspection and certification system that includes a traceability/product tracing tool should be transparent and made available to competent authorities of the exporting country upon request.

**Application**

14. The application of traceability/product tracing should take into account the capabilities of developing countries.
15. If in the context of a traceability/product tracing tool an importing country has objectives or outcomes of their food inspection and certification system which cannot be met by an exporting country, the importing country should consider the provision of assistance to the exporting country, and especially in the case of a developing country. Assistance may include longer time frames for implementation, flexibility of design and technical assistance, so that the objectives or outcomes of the food inspection and certification system of the importing country can be met.
16. A food inspection and certification system within which a traceability/product tracing tool is applied should not be more trade restrictive than necessary.
17. The application of the traceability/product tracing tool should be practical, technically feasible and economically viable within a food inspection and certification system.
18. In deciding whether and how to apply the traceability/product tracing tool, in the context of a food inspection and certification system the competent authority should take account of the assessed food safety risks and/or the characteristics of the potential deceptive marketing practices being addressed.
19. Traceability/product tracing tool within the context of a food inspection and certification system should be implemented when and as appropriate on a case by case basis.

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<sup>6</sup> For example, by providing information on suppliers or customers involved in potential food safety issues so enabling targeted product recall/withdrawal.

<sup>7</sup> For example, by reinforcing confidence in the authenticity of the product and the accuracy of information provided on the products (e.g. country of origin, organic farming, religious concerns such as kosher or halal).

<sup>8</sup> Production could be interpreted in such a broad manner as to cover food producing animals, feed, fertilizers, pesticides, veterinary drugs and any input of plant or animal origin, etc. if relevant for specific applications of traceability/product tracing to food..