

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
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ALINORM 03/30A

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Twenty-sixth Session
Rome, Italy 30 June – 5 July 2003

REPORT OF THE ELEVENTH SESSION OF THE CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS

Adelaide, Australia, 2-6 December 2002

Note: This report includes Codex Circular Letter CL 2002/54-FICS

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CX 4/70.2

CL 2002/54-FICS
December 2002

TO: Codex Contact Points
Interested International Organizations

FROM: Secretary, Joint FAO/WHO Food Standards Programme, FAO
Viale delle Terme di Caracalla, 00100 Rome, Italy

SUBJECT: **Distribution of the Report of the Eleventh Session of the Codex Committee on Food Import and Export Inspection and Certification Systems (ALINORM 03/30A)**

The report of the Eleventh Session of the Codex Committee on Food Import and Export Inspection and Certification Systems will be considered by the 26th Session of the Codex Alimentarius Commission (Rome, Italy, 30 June–05 July 2003).

PART A: MATTERS FOR ADOPTION BY THE 26TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION

Draft Standards and Related Texts at Step 8

- Draft Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems** (para. 16 and Appendix II).

Governments wishing to submit written proposals for amendments at Step 8 on the draft Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems should do so in writing in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts (at Step 8) (*Codex Alimentarius Procedural Manual*, Twelfth Edition, pages 19-21) to the Secretary, Codex Alimentarius Commission, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (telefax: +39.06.5705.4593; E-mail: codex@fao.org) **not later than 31 March 2003**.

PART B: REQUEST FOR COMMENTS AND INFORMATION

Governments and international organizations wishing to submit comments on the following subject matter are invited to do so **no later than 1 September 2003** to: Codex Australia, Agriculture Fisheries and Forestry - Australia GPO Box 858, Canberra ACT, 2601 (fax: 61.2.6272.3103; E-mail: codex.contact@affa.gov.au), with a copy to the Secretary, Joint FAO/WHO Food Standards Programme, FAO, Via delle Terme di Caracalla, 00100 Rome, Italy (Fax No + 39.06.5705.4593; E-mail: codex@fao.org).

- Discussion Paper on the Judgement of Equivalence of Technical Regulations Associated with Food Inspection and Certification Systems** (para. 45).

The Committee agreed to request comments on specific or potential examples of problems in trade that were or could be solved through the application of equivalence and mutual recognition agreements.

2. Other Business and Future Work (para. 54).

The Committee agreed to request comments on suggested subjects for future work and the prioritization of such work.

SUMMARY AND CONCLUSIONS

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

- Agreed to consider at its next Session the request of the 24th Session of the Codex Committee on Methods of Analysis and Sampling related to the use of analytical results in inspection and certification systems (para. 7);
- Forwarded the draft Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems to the Commission for final adoption (para. 16);
- Agreed to discontinue work on the elaboration of proposed draft Guidelines for the Utilization and Promotion of Quality Assurance Systems to Meet Requirements in Relation to Food, with the understanding that the Executive Committee would be informed of this decision (para. 20);
- Agreed to return the proposed draft Guidelines for the Exchange of Information in Food Control Emergency Situations for revision by a drafting group led by Australia for circulation, comment and further consideration at its next meeting (para. 39);
- Agreed that a drafting group led by Australia would revise the Discussion Paper on the Judgement of Equivalence of Technical Regulations Associated with Food Inspection and Certification Systems for circulation, comment and further consideration at its next meeting. (para. 45);
- Agreed to request comments on specific or potential examples of problems in trade that were or could be solved through the application of equivalence and mutual recognition agreements (para. 45);
- Agreed that clarification would be sought from the WTO/TBT Committee, through the Codex Secretariat, on the operation of equivalence and mutual recognition within the TBT Agreement (para. 45);
- Agreed to reconvene the Working Group on Traceability under the Chairmanship of Switzerland to prepare a Discussion Paper on Traceability/Product Tracing for circulation, comment and further consideration at its next meeting (para. 53), and;
- Agreed to request comments on suggested subjects for future work and the prioritization of such work (para. 55).

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OPENING OF THE SESSION

1. The eleventh Session of the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) was held in Adelaide, Australia from 2-6 December 2002 at the kind invitation of the Government of the Commonwealth of Australia. The Session was chaired by Mr. Gregory Read, Executive Manager, Australian Quarantine and Inspection Service, Department of Agriculture, Fisheries and Forestry – Australia. The Session was attended by 143 participants from 35 Member countries and 13 International organizations. A complete List of Participants is attached at Appendix I.

ADOPTION OF THE AGENDA (Agenda Item 1)²

2. The Committee noted that no written proposals had been received for revisions or amendments to the Provisional Agenda and therefore, the Committee adopted the Provisional Agenda as the Agenda for the Session.

3. However, the Committee agreed to discuss agenda item 7, Discussion Paper on Traceability in the Context of Food Inspection Systems, immediately after agenda item 3 and to consider agenda item 5, proposed draft Revision to the Codex Guidelines for the Exchange of Information in Food Control Emergency Situations immediately thereafter.

MATTERS REFERRED FROM THE EXECUTIVE COMMITTEE OF THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES (Agenda Item 2)³

4. The Committee noted matters arising from the 49th (September 2001) and 50th (June 2002) Sessions of the Executive Committee of the Codex Alimentarius Commission and other Codex Committees related to the *Preparation of the Medium-Term Plan 2003-2007 and Discussions Concerning Traceability/Product Tracing in Other Codex Committees and International Organizations*. The Committee agreed that the information provided on the activities of other Codex Committees related to Traceability/Product Tracing be considered under agenda item 7.

5. The Committee noted that activities relevant to its work under the Medium – Term Plan Objective 1: Promoting Sound Regulatory Frameworks, had been revised and retained, namely under *Activity 22 - Traceability* and *Activity 27 – Judgement of Equivalence*. In particular, the 50th Session of the Executive Committee agreed to add the term “product tracing” to the title of Activity 22.⁴

6. It was also noted that *Activity 2 – Review of Codex Standards to Provide Risk Management Options to Achieve National Appropriate Levels of Protection (ALOPs)*, was deleted from Objective 2 of the Medium-Term Plan as it was felt the determination of ALOP was the responsibility of Member States and might be better addressed through capacity building at the national level.⁵

7. The Committee also noted the request of the 24th Session (November 2002) of the Codex Committee on Methods of Analysis and Sampling to provide advice insofar as inspection issues were involved in the use of analytical results.⁶ The CCFICS agreed to consider this issue in detail at its next Session pending the provision of further clarification and depending on future progress within the Codex Committee on Methods of Analysis and Sampling.

² CX/FICS 02/11/1

³ CX/FICS 02/11/2

⁴ ALINORM 03/3A, paras. 41-42

⁵ ALINORM 03/3A, para. 46

⁶ ALINORM 03/23, paras. 109-117

DRAFT GUIDELINES ON THE JUDGEMENT OF EQUIVALENCE OF SANITARY MEASURES ASSOCIATED WITH FOOD INSPECTION AND CERTIFICATION SYSTEMS (Agenda Item 3)⁷

8. The 10th CCFICS appended the draft Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems (ALINORM 03/30, Appendix III) to its report for comments under CL 2002/8-FICS. The Committee agreed that subsequent to this step, a drafting group led by New Zealand would prepare a revised version of the draft Guidelines for circulation, additional comment at Step 6 and further consideration at its next meeting.⁸

9. The Committee noted the results of the drafting group meeting held in Oakland, California, from 26-28 August 2002 and the revised draft Guidelines were presented under CX/FICS 02/11/3 by the Delegation of New Zealand. New Zealand noted in particular that the text had been reordered for clarity, Section 5 had been renamed in order to better reflect its content; a new Section 6 “Objective Basis of Comparison” had been added to give guidance on possible information to be provided for the establishment of an objective basis of comparison of sanitary measures; and paragraph 15 of the new section 6 had been square bracketed as the drafting group did not have adequate time to finalize the revision of the proposed draft.

General Comments

10. The Committee congratulated the drafting group for the excellent work, which had substantially improved the previous text, and agreed to remove the square brackets in paragraph 15 while retaining the text as drafted.

11. The representative of IACFO recommended that the Committee consider in the future the development of appendices to the Guidelines that would address documentation requirements, outline the terms for onsite visits by importing country officials, and address the specific type of technical assistance to be provided by importing countries to exporting countries, especially developing countries.

Section 1 – Preamble

12. The Committee agreed to delete the reference to Article 2 of the WTO SPS Agreement in the footnote to the text as the interpretation of the WTO Agreement was outside the mandate of Codex.

Section 3 – Definitions

13. Notwithstanding the opinion of the delegation of Switzerland that the phrase “risks arising from diseases carried by foods which are animals, plants or products thereof” would go beyond the purview of the CCFICS and that the definition should be revised on the basis of the Codex definition for “food”, the Committee agreed to leave the definition of Sanitary Measure as drafted.

Section 4 – General principles for the Determination of Equivalence

14. The Committee agreed to add in paragraph 7 (j) “and past experience” after “taking into account any knowledge” in order to be consistent with paragraph 11. For the same reason, the Committee added to paragraph 20 (a) “and confidence”.

Figure 1

15. The figure was revised in order to correct references to the main body of the text and to more accurately reflect the steps necessary for the determination of equivalence.

⁷ CX/FICS 02/11/3 and comments submitted by Bangladesh, Brazil, Canada, Egypt, Mexico, New Zealand, United States, European Community, Consumers International (CX/FICS 02/11/3-Add. 1), Argentina, India, International Association of Consumer Food Organizations (CX/FIC 02/11/3-Add.2), Colombia, Philippines and World Trade Organization (CRD 1).

⁸ ALINORM 03/30, paras 50-51

Status of the Draft Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems

16. The Committee forwarded the draft Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems (see Appendix II) to the 26th Session of the Codex Alimentarius Commission for final adoption at Step 8.

PROPOSED DRAFT GUIDELINES FOR THE UTILIZATION AND PROMOTION OF QUALITY ASSURANCE SYSTEMS TO MEET REQUIREMENTS IN RELATION TO FOOD (Agenda Item 4)⁹

17. The 10th CCFICS returned the proposed draft Guidelines for the Utilization and Promotion of Quality Assurance Systems to Meet Requirements in Relation to Food to Step 2 for reformulating by a drafting group under the direction of Australia to reflect appropriate principles.¹⁰

18. In introducing the proposed draft Guidelines, the delegation of Australia explained that the working group, as instructed by the 10th CCFICS, had elaborated a stand-alone principles document, while noting that the principles may be incorporated into a detailed guidelines document at a later stage. It was also explained that the document was primarily intended for Governments, and was complementary to the ongoing work undertaken by the International Organization for Standardization (ISO) which was primarily directed to industry. The draft ISO document also emphasized the importance of the application of HACCP system.

19. The Committee considered the recommendations contained in the CX/FICS 02/11/4 and in particular the need for CCFICS to further advance the Proposed Draft Principles within the Codex Step Procedure and to resume the work on the development of detailed guidelines. Notwithstanding the mandate of the CCFICS to elaborate on quality assurance systems, it was noted that these programs were intended for voluntary application only. It was stated that Codex texts on General Principles of Food Hygiene and HACCP provided adequate guidance to ensure the safety of food products and that existing Codex texts developed by CCFICS, such as Principles for Food Import and Export Inspection and Certification (CAC/GL 20-1995), Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (CAC/GL 26-1997) provided adequate guidance on quality assurance. The Committee therefore agreed that the CCFICS should discontinue work on these Guidelines.

Status of the Proposed Draft Guidelines for the Utilization and Promotion of Quality Assurance Systems to Meet Requirements in Relation to Food

20. The Committee agreed to discontinue work on the elaboration of proposed draft Guidelines for the Utilization and Promotion of Quality Assurance Systems to meet Requirements in Relation to Food, with the understanding that the Executive Committee would be informed of this decision.

PROPOSED DRAFT REVISION TO THE CODEX GUIDELINES FOR THE EXCHANGE OF INFORMATION IN FOOD CONTROL EMERGENCY SITUATIONS (Agenda Item 5)¹¹

21. The 9th CCFICS reached general agreement that the elaboration of guidelines for food control emergency situations involving international trade should be undertaken in the context of the *Codex Guidelines for the Exchange of Information in Food Control Emergency Situations*.¹² It was suggested that guidelines concerning food control emergency situations should include the consideration of:

⁹ CX/FICS 02/11/4 and comments submitted by Argentina, Bangladesh, Canada, India, Mexico, New Zealand, United States, European Community, (CX/FIC 02/11/4-Add.1) and Colombia (CRD 2).

¹⁰ ALINORM 03/30, para. 84

¹¹ CX/FICS 02/11/5 and comments submitted by Argentina, Bangladesh, Canada, Egypt, Japan, Mexico, New Zealand, United States (CX/FICS 02/11/5-Add. 1), Cuba, European Community, International Association of Consumer Food Organizations (CX/FIC 02/11/5-Add.2), Colombia, Philippines and European Community (CRD 3).

¹² CAC/GL 19-1995

- The development of a specific food emergency control plan or alternatively, generic guidance;
- The difficulty in applying sound risk management and risk communication practices to food control emergency situations due to the inherent lack of information and timely risk assessments;
- The need to expand on the application of risk communication, including a framework for feedback, in the process;
- Differences and similarities between importing and exporting control measures to be taken;
- Final disposition of food products, including the concept of traceability and third country exports;
- Texts and other documentation elaborated by international governmental and non-governmental organizations, including the future elaboration of the FAO Rapid Alert System, and;
- A revised definition for food control emergency situations.

22. The Committee accepted the offer of Australia, with the assistance of Japan, the Netherlands, the United States and the European Commission, to draft a revision of the *Codex Guidelines for the Exchange of Information in Food Control Emergency Situations* for consideration at its next Session to include elements related to generic guidance and/or specific food emergency control plans on the basis of the Committee's discussions and written comments submitted with the understanding that this revision was subject to approval as new work by the 24th Session of the Codex Alimentarius Commission.¹³ The extraordinary 49th Session of the Executive Committee of the Codex Alimentarius Commission approved the revision of the Guidelines as new work.¹⁴

23. The 10th CCFICS agreed to return the proposed draft *Guidelines for the Exchange of Information in Food Control Emergency Situations* to Step 2 for revision by a drafting group led by Australia and with the assistance of Germany, Japan, Netherlands, Papua New Guinea, the United States and the European Commission. The Committee agreed that the text would be redrafted based on the Committee's discussions and written comments submitted and would take account of the revision currently being undertaken on the Codex Code of Ethics for International Trade in Foods.¹⁵

24. In introducing document CX/FICS 02/11/5, the delegation of Australia indicated that specific comments on the redefinition of the scope of the guidelines and on the issue of re-exported food were being sought. It was noted that the Title of the Guidelines was revised by the drafting group to read as proposed draft Guidelines for Food Safety Emergency Situations Involving International Trade.

25. The Committee considered the proposed draft revised guidelines and focussed on the Title, Preamble, and Scope as well as the first paragraphs of the Section "Considerations Relating to Food Safety Emergency Situations". However, in view of divergent opinions expressed on different aspects of the scope of the Guidelines, the Committee agreed to maintain the proposed draft Guidelines as currently drafted in document CX/FICS 02/11/5.

26. The Committee discussed the scope of the revised Guidelines and in particular whether it should focus on risk communication/exchange of information issues related to emergency situations or should also consider risk management measures and the development of an action plan. Some of the delegations were of the opinion that the revision should only focus on communication aspects that were not adequately addressed by the current guidelines. Some delegations pointed out that this was the reason for amending the existing Guidelines. Other delegations were of the opinion that the scope of the Guidelines should be expanded to include risk management measures as suggested by the 9th CCFICS. In this regard, some delegations suggested retaining the original Title of the Guidelines so as to better reflect the focus on communication/information exchange in emergency situations.

27. With regard to the communication aspects, it was noted that the current *Codex Guidelines for the Exchange of Information in Food Control Emergency Situations* addressed only communication between importing and exporting countries (i.e., bilateral communication). It was suggested that the revised Guidelines should include aspects related to multilateral communication and consider communication of

¹³ ALINORM 01/30A, paras 104-105

¹⁴ ALINORM 03/3, para. 24 and Appendix III

¹⁵ ALINORM 03/30, para. 94

findings, nature of the problem (including risk assessments where available) and measures taken as well as the development of an international food alert system. Therefore, it was suggested that the revised guidelines should emphasize the need for both importing and exporting countries to provide and to obtain all relevant information through official contact points and to verify the accuracy of anecdotal information.

28. Some delegations stressed that the revision should not conflict with the objectives of the *Guidelines for the Exchange of Information Between Countries on Rejections of Imported Foods* (CAC/GL 25-1997) in respect of the rejection of food consignments.

29. With regard to risk management measures, the Committee noted the on-going work of the Codex Committee on General Principles (CCGP) and the Codex Committee on Food Hygiene (CCFH) on the development of draft General Principles of Risk Analysis, draft General Principles and Guidelines for the Conduct of Microbiological Risk Management and on the management of specific commodity/pathogen combinations.

30. Some delegations stressed that the revised guidelines should highlight the provisional aspect of risk management measures in food emergency situations as well as scientific uncertainty and the need to adjust provisional measures in the light of new information. Some delegations were of the opinion that the inclusion of risk assessment and management aspects in the revised Guidelines was not duplicating the ongoing work in other Codex Committees while others were of the opinion that it was premature to embark on new work before the completion of texts being undertaken by these committees.

31. With regard to the suggestion that risk management decisions in emergency situations should be based on risk assessment, some delegations expressed concerns that urgent responses to emergency situations may not permit extensive risk assessments to be carried out. Some countries may have difficulties with limited resources to carry out extensive risk assessments.

32. It was also suggested that the revised Guidelines should consider and define the role of the food industry, should be expanded to cover emergency situations that can arise from bio-terrorism, and should develop an international alert system that will include provisions to maintain updated information of food emergency contact points.

33. The Committee decided that the Guidelines should be further considered by the drafting group (see below) on the basis of the following title, definition and principles:

Principles for the Exchange of Information in Food Safety Emergency Situations

Definition

34. A food safety emergency situation, whether accidental or intentional, exists when a competent authority identifies a serious and unacceptable risk or threat to the health of consumers associated with the consumption of a food or foods that requires urgent action. A food safety emergency situation usually occurs where the risk is not contained or its extent is unknown at the time of detection.

35. Some countries expressed concern as to the meaning of the term “threat”. One delegation also proposed to delete “not contained or its extent” by replacing it with “not clearly identified” in the second sentence of the definition.

Principles

36. In the event that a food safety emergency is identified the following principles apply.

- i. All relevant information should be shared to enable potentially affected countries to make informed risk management decisions.

- ii. An importing country detecting a food safety emergency should inform the exporting country without delay. Similarly, an exporting country should inform potentially affected trading partners and all other official contact points without delay.
- iii. Information flow should be transparent and continue during all phases of the risk analysis process (risk assessment as appropriate to the circumstances, risk management and risk communication) to enable continuous evaluation and development of the emergency response.
- iv. The exchange of information on food safety emergencies should be between the competent authorities and occur through official contact points.
- v. Competent authorities should provide clear, relevant, factual and timely information to industry, consumers, other relevant stakeholders and the media on the status of the food safety emergency.
- vi. [In order to implement the above principles, countries should incorporate appropriate provisions in their food safety emergency action plans where these exist]
[To enable the exchange of information, countries should have a food safety emergency action plan]

37. One delegation proposed that it is only within the mandate of the CCFICS that the Principles should only refer to emergency situations involving international trade. However, it was noted that the Guidelines might also apply to national emergency situations that might be of interest to other countries.

38. The Committee suggested that the drafting group should consider the inclusion of principle 6 in the body of the Guidelines as it was felt to be linked the implementation of the text. It was also noted that principles 5 and 6 concerned national prerogatives and therefore, might not be within the mandate of a text intended to be applied between governments. The Committee also suggested that the drafting group should consider the inclusion of or the development of a separate text concerning an action plan for food control emergency situations.

Status of the Proposed Draft Revision of the Codex Guidelines for the Exchange of Information in Food Control Emergency Situations

39. The Committee agreed to return the proposed draft *Guidelines* to Step 2 for revision by a drafting group led by Australia with the assistance of Germany, Netherlands, New Zealand, Sweden, the United States, the European Commission and the International Association of Consumer Food Organizations (IACFO). The Committee agreed that the drafting group should consider the above discussion, definition and principles; the initial mandate given at the 9th CCFICS; the current Guidelines (CAC/GL 19-1995) and other Codex guidelines and texts as appropriate. It was agreed that the revised document would be circulated for comments and further consideration at its next meeting.

DISCUSSION PAPER ON THE JUDGEMENT OF EQUIVALENCE OF TECHNICAL REGULATIONS ASSOCIATED WITH FOOD INSPECTION AND CERTIFICATION SYSTEMS (Agenda Item 6)¹⁶

40. The 10th Session of the CCFICS agreed to defer further drafting of the proposed draft Guidelines on the Judgement of Equivalence of Technical Regulations Associated with Food Inspection and Certification Systems within the Codex Step Procedure. The Committee agreed that a drafting group led by Australia should prepare a discussion paper for circulation, comment and further consideration at its current meeting. The Committee agreed that the paper should examine the need for the elaboration of guidelines on the judgement of equivalence of technical regulations to ensure conformity with essential quality requirements

¹⁶ CX/FICS 02/11/6 and comments submitted by Argentina, Canada, Mexico, New Zealand, United States, European Community, International Association of Consumer Food Organizations (CX/FICS 02/11/6-Add. 1) and the Philippines (CRD 4).

and presenting pertinent examples for consideration and recommendations relating to the elements for inclusion in a draft guideline.¹⁷

41. The Committee was informed that Objective 1: Promoting Sound Regulatory Frameworks, of the Revised Draft Medium-Term Plan 2003-2007 included Activity 27 related to *Standards Development*, which included the “Development of guidelines on the judgement of equivalence for specific purposes such as equivalence of measures to ensure food hygiene or measures to ensure conformity with essential quality requirements”.

42. In introducing the Discussion Paper, the delegation of Australia stated that the drafting group noted a lack of actual examples where the application of equivalence of technical regulations or conformity assessment procedures may have had a role in ensuring fair trade practices. It was further noted that the document interpreted the World Trade Organization Agreement on Technical Barriers to Trade (TBT Agreement) and that it should quote the TBT text directly, if reference to such text is needed. The discussion focussed on how technical regulations and conformity assessment procedures in relation to food inspection and certification would be applied in the context of TBT equivalence.

43. Some delegations noted that the Committee’s mandate appeared to be limited to the potential establishment of guidelines to ensure conformity with essential quality requirements, including the judgement of equivalence of inspection and certification systems in this regard. The delegation of Norway presented a document¹⁸ which focussed on equivalence as well as mutual recognition as trade facilitating tools in relation to technical measures, including illustrating examples in actual agreements involving these issues. The delegation noted that the concept of mutual recognition (conformity assessment) was only treated in the TBT Agreement, whereas the recognition of equivalence (technical regulations) was included in both the SPS and TBT Agreements. Delegates from other countries supported the view that trade could be facilitated by the application of equivalence to technical regulations and that work should be undertaken on this subject by the Committee. It was noted that the discussion paper should help differentiate and define the differences in the recognition of equivalence between the SPS and TBT Agreements, and that the WTO Committee on Technical Barriers to Trade might be consulted on the operation of and understanding of equivalence and mutual recognition within the TBT Agreement.

44. Other delegations were of the opinion that in view of the lack of actual or realistic examples of where trade could have been facilitated by the application of equivalence to technical regulations or by conformity assessment procedures, further work on this document should not be undertaken at this time.

45. The Committee decided that a drafting group under the direction of Australia, with the assistance of Brazil, Canada, France, Norway, Switzerland and the United States, would revise the Discussion Paper on the Judgement of Equivalence of Technical Regulations Associated with Food Inspection and Certification Systems for circulation, comment and further consideration at its next meeting. It was agreed that the paper would be revised on the basis of written comments submitted at the current meeting and comments to be submitted in response to a request for specific or potential examples of problems in trade that were or could be solved through the application of equivalence and mutual recognition agreements. Furthermore, clarification would be sought from the WTO/TBT Committee, through the Codex Secretariat, on the operation of equivalence and mutual recognition within the TBT Agreement. It was noted that the Discussion Paper should be prepared so as to facilitate the Committee’s discussions related to the potential elaboration of Guidelines in the future.

¹⁷ ALINORM 03/30, paras. 73-75

¹⁸ Working Paper on Equivalence and Mutual Recognition Agreements in Relation to Technical Measures; Norwegian Agricultural Economics Research Institute; No. 2002-36.

DISCUSSION PAPER ON TRACEABILITY/PRODUCT TRACING IN THE CONTEXT OF FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS (Agenda Item 7)¹⁹

46. The 10th Session of the CCFICS agreed that a working group led by Switzerland would prepare a Discussion Paper on Traceability/Product Tracing in the Context of Food Inspection and Certification Systems for further consideration at its next Session.²⁰ The CCFICS noted discussions on Traceability/Product Tracing in other Codex Committees as summarized in document CX/FICS 02/11/2 (agenda item 2).

47. The 49th (Extraordinary) Session of the Executive Committee of the Codex Alimentarius Commission (September 2001) discussed the general issue of traceability/product tracing in the framework of Codex and pointed out that any measures requiring traceability/product tracing should be justified as having a food safety objective as an SPS measure or having a legitimate objective as a TBT measure. The Executive Committee recommended that the Codex Committee on General Principles consider these two aspects of traceability/product tracing and was of the opinion that first consideration should be given to the use of traceability/product tracing as a risk management option in the Working Principles for Risk Analysis. The Executive Committee agreed that it should be for the Committees concerned to undertake work as they deemed appropriate within their respective mandates.²¹ The Executive Committee also noted the role of the CCFICS in relation to the development of procedures for the application of traceability/product tracing in food import and export inspection and certification systems.

48. The Committee noted that the 50th Session of the Executive Committee of the Codex Alimentarius Commission (June 2002) agreed²² to retain both aspects of traceability/product tracing without mentioning priorities and to indicate that first consideration should be given to the use of traceability/product tracing as a food safety risk management option as already agreed by the 49th Session.

49. In introducing the Discussion Paper, the delegation of Switzerland noted that the Working Group on Traceability²³ (Fribourg, Switzerland, 19-20 August 2002) had prepared the document on the basis of specific instructions provided by the 10th CCFICS and written comments submitted. It was noted that the elements identified by the Working Group related to traceability/product tracing were the ability to identify a food (product identification), how it was changed (if appropriate), where it came from and where it was sent (one step backward and one step forward) (product information) and the linkages between product identification and product information, while also noting that the applicability of these elements would depend on the objectives being pursued by the individual texts. In consideration that the Working Group had not had the opportunity to examine all of the CCFICS texts related to traceability/product tracing in detail, the Group also agreed on a specific framework for the continued examination of such texts for their adequacy and applicability within the CCFICS.

50. The Committee thanked the Working Group for their efforts, and generally supported the analysis and approach outlined in the Discussion Paper as a basis for continued discussions on traceability/product tracing within the CCFICS. However, it was felt that the elaboration of specific Guidelines at this stage was premature. The Committee also recognized that the primary responsibility for the development of a

¹⁹ CX/FICS 02/11/7 and comments submitted by Canada, Mexico, New Zealand, United States, Consumers International (CX/FICS 02/11/7-Add. 1), Philippines and the European Community (CRD 5).

²⁰ ALINORM 03/30, para. 67

²¹ ALINORM 03/3, paras. 29-33.

²² ALINORM 03/3A, para. 42

²³ Argentina, Australia, Belgium, Bolivia, Brazil, Canada, Chile, France, Germany, India, Ireland, Italy, Japan, Kenya, The Republic of Korea, The Netherlands, Norway, Papua New Guinea, Paraguay, Peru, Philippines, Sweden, Thailand, United Kingdom, United States of America, European Commission, World Health Organisation, World Trade Organisation, Biotechnology Industry Organization (BIO), Comité Européen des Fariquantes de Sucre (CEFS), Consumers International (CI), Commission Internationale des Industries Agricoles et Alimentaires (CIAA), Council on Responsible Nutrition (CRN), European Association for Bioindustries (EuropaBio), Croplife International (GCPF), International Council of Grocery Manufacturers Association (ICGMA), International Dairy Federation (IDF) and International Federation for Animal Health (IFAH)

definition for traceability/product tracing rested with the Codex Committee on General Principles but that the CCFICS might wish to further expand on the elements required for such a definition.

51. The Committee reached general agreement with the opinion of the Executive Committee that any measures requiring traceability/product tracing should be justified as having a food safety objective as an SPS measure or having a legitimate objective as a TBT measure. However, some delegations were of the opinion that traceability/product tracing should focus on food safety measures only as a priority while other delegations felt that both food safety and other matters necessary for ensuring fair practices in the food trade, as covered by the mandate of the Codex Alimentarius Commission, should be examined at the same time. It was also stated that guidelines or principles related to traceability/product tracing would more than likely relate to both aspects regardless of efforts to theoretically separate the two concepts.

52. The Committee noted and agreed that:

- Responsibility for the development of a definition for traceability/product tracing rested with the CCGP;
- CCFICS was responsible for traceability/product tracing related to food inspection and certification systems, and;
- Existing Codex texts related to food inspection and certification as well as discussions in CCFICS and other Codex Committees and written comments submitted should be taken into account in the determination of the current adequacy and applicability of CCFICS texts related to traceability/product tracing and the need for further work in this area.

53. In order to carry out the above review and to complete the mandate assigned by the 10th CCFICS, the Committee decided to reconvene the Working Group on Traceability under the Chairmanship of Switzerland and with the participation of Argentina, Australia, Belgium, Brazil, Canada, Chile, France, Germany, India, Italy, Japan, Kenya, Netherlands, New Zealand, Norway, Philippines, Republic of Korea, Sweden, Thailand, United Kingdom, United States, BIO, EC, Greenpeace, ICGMA, IDF and WHO. The Chairman expressed the view that the analysis of existing CCFICS texts should be completed according to the Framework prior to the Working Group meeting so that the Working Group could review the results of this analysis at the meeting. The Working Group should take into account discussions on traceability/product tracing in other relevant Codex committees. The Working Group should prepare a discussion paper with a complete analysis of the issues involved for circulation, additional comment and further consideration at its next Session. It was reiterated that this review should analyze the appropriateness and need for CCFICS to develop specific guidance on the practical implementation of traceability/product tracing and how it is to be progressed. It was also agreed that the Committee's discussions on this issue would be forwarded to the Executive Committee and other Codex Committees for information and potential action.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 8)

54. The representative of the International Atomic Energy Agency (IAEA) informed the Committee that the Revised Guidelines for Certification of Foods Irradiated for Non-Phytosanitary Purposes,²⁴ which was developed and finalized by the Joint FAO/WHO/IAEA International Consultative Group on Food Irradiation, would be made available on the ICGFI website in the near future.

55. The Committee agreed that a request for comments on suggested subjects for future work and the prioritization of such work would be requested by Circular Letter to this report. In this regard, the Committee noted the comments²⁵ of Consumers International that suggested the development of three appendices or references to Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems, namely, documentation requirements for the submission of a request for a judgement of equivalence, terms for onsite visits by importing country authorities to verify inspection and certification systems and technical assistance to be provided by importing countries to

²⁴ Conference Room Document 6

²⁵ CX/FICS 02/11/3-Add. 1

exporting developing countries. Some delegations noted the need for further work in this area whether or not within the CCFICS.

56. The Committee noted that the Draft Medium-Term Plan 2003-2007 included an activity to “Establish systematic procedures for review of existing standards to ensure their continued relevance and application including revision where necessary and removal of overly prescriptive or unnecessarily stringent provisions”. In this regard, it was suggested that previously adopted texts related to inspection and certification systems might require updating in the future to reflect updated terminology and/or to ensure consistency in scope between similar texts (e.g., Guidelines for the Exchange of Information Between Countries on Rejections of Imported Food and Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems).

DATE AND PLACE OF NEXT SESSION (Agenda Item 9)

57. The Committee noted that its 12th Session was tentatively scheduled to be held from 1 – 5 December 2003 in Australia, subject to further discussions between the Codex and Australian Secretariats and confirmation by the Codex Alimentarius Commission. It was noted that the scheduling and frequency of additional meetings of the Committee would depend in part on the identification of future work priorities.

SUMMARY STATUS OF WORK

SUBJECT MATTER	STEP	ACTION BY:	DOCUMENT REFERENCE IN ALINORM 03/30A
Draft Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems	8	Comments 26 th CAC	Paras. 8 - 16 and Appendix II
Proposed Draft Guidelines for the Exchange of Information in Food Control Emergency Situations	2	Drafting Group Comments 12 th CCFICS	Paras. 21 - 39
Proposed Draft Guidelines for the Utilization and Promotion of Quality Assurance Systems to meet Requirements in Relation to Food	-----	52 nd CCEXEC	Paras. 17 - 20
Discussion Paper on the Judgement of Equivalence of Technical Regulations Associated with Food Inspection and Certification Systems	-----	Drafting Group Comments 12 th CCFICS	Paras. 40 - 45
Discussion Paper on Traceability/Product Tracing in the Context of Food Import and Export Inspection and Certification Systems	-----	Working Group Comments 12 th CCFICS	Paras. 46 - 53

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**DRAFT GUIDELINES ON THE JUDGEMENT OF EQUIVALENCE OF SANITARY MEASURES
ASSOCIATED WITH FOOD INSPECTION AND CERTIFICATION SYSTEMS¹
(Advanced to Step 8)**

SECTION 1 – PREAMBLE

1. It is often the case that importing and exporting countries operate different food inspection and certification systems. The reasons for such differences include differences in prevalence of particular food safety hazards, national choice about management of food safety risks and differences in the historical development of food control systems.
2. In such circumstances, and in order to facilitate trade while protecting the health of consumers, an exporting and an importing country may work together to consider the effectiveness of sanitary measures of the exporting country in achieving the appropriate level of sanitary protection of the importing country, consistent with the principle of equivalence as provided for in the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (WTO SPS Agreement).²
3. Application of the principle of equivalence has mutual benefits for both exporting and importing countries. While protecting the health of consumers, it serves to facilitate trade, and minimize the costs of regulation to governments, industry, producers, and consumers by allowing the exporting country to employ the most convenient means in its circumstances to achieve the appropriate level of protection of the importing country.³
4. Importing countries should avoid the application of unnecessary measures when they have already been carried out by the exporting country. Importing countries may be able to reduce the frequency and extent of verification measures following a judgment of equivalence of measures applied in the exporting country.

SECTION 2 – SCOPE

5. This document provides guidelines on the judgement of the equivalence of sanitary measures associated with food inspection and certification systems. For the purpose of determining equivalence, these measures can be broadly characterized as infrastructure; programme design, implementation and monitoring; and/or specific requirements (refer paragraph 13).

SECTION 3 – DEFINITIONS

6. The definitions presented in this document are derived from and consistent with those of the Codex Alimentarius Commission and the WTO SPS Agreement.

Sanitary measure: Any measure applied to protect human life or health within the territory of the country from risks arising from additives, contaminants, toxins or disease-causing organisms in food or feedstuffs, or from risks arising from diseases carried by foods which are animals, plants or products thereof or from risks arising from any other hazards in foods.

¹ These guidelines should be read in conjunction with other relevant Codex texts, including in particular the Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems – CAC/GL 34-1999.

² Consistent with the definition of *equivalence* in Section 3, measures that are *equivalent* (i.e., are different from the measures used by the importing country but nonetheless achieve the importing country's appropriate level of protection) should be distinguished from measures that are the same as the measures of the importing country.

³ The benefits to an exporting country of application of the principle of equivalence would be offset or negated if a request for an equivalence determination were, by itself, used as a pretext for the disruption of established trade. Such action by an importing country would be contrary to the principles of international trade.

Note: Sanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, *inter alia*, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labeling requirements directly related to food safety.

Hazard: A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.⁴

Risk: A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.⁴

Risk Assessment: A scientifically-based process consisting of the following steps: (i) hazard identification; (ii) hazard characterization; (iii) exposure assessment; and (iv) risk characterisation.⁴

Appropriate level of sanitary protection (ALOP): The level of protection deemed appropriate by the country establishing a sanitary measure to protect human life or health within its territory. (This concept may otherwise be referred to as the “acceptable level of risk”.)

Equivalence of sanitary measures:⁵ Equivalence is the state wherein sanitary measures applied in an exporting country, though different from the measures applied in an importing country, achieve, as demonstrated by the exporting country, the importing country’s appropriate level of sanitary protection.

SECTION 4 - GENERAL PRINCIPLES FOR THE DETERMINATION OF EQUIVALENCE

7. Determination of the equivalence of sanitary measures associated with food inspection and certification systems should be based on application of the following principles:
- a) An importing country has the right to set a level of sanitary protection it deems appropriate in relation to the protection of human life and health.⁶ The ALOP may be expressed in qualitative or quantitative terms.
 - b) The sanitary measure⁷ applied in an importing country should in practice achieve the ALOP of the importing country and be applied consistent with article 2.3 of the SPS agreement.⁸
 - c) An importing country should describe how its own sanitary measure achieves its ALOP.
 - d) An importing country should recognize that sanitary measures different from its own may be capable of achieving its ALOP, and can therefore be found to be equivalent.
 - e) The sanitary measure that the exporting country proposes as equivalent must be capable of achieving the importing country’s ALOP.
 - f) An importing country should, upon request by an exporting country, promptly enter into consultations with the aim of determining the equivalence of specified sanitary measures within a reasonable period of time.⁹
 - g) It is the responsibility of the exporting country to objectively demonstrate that its sanitary measure can achieve the importing country’s ALOP.
 - h) The comparison of countries’ sanitary measures should be carried out in an objective manner.

⁴ Codex Alimentarius Commission: Procedural Manual (12th Edition), pages 43-44.

⁵ Equivalence is defined in CAC/GL 26-1997 as “the capability of different inspection and certification systems to meet the same objectives”.

⁶ The SPS Agreement sets out the rights and obligations of WTO Members in relation to the determination of an appropriate level of sanitary protection.

⁷ Where this guideline refers to ‘measure’ in the singular it may also be taken to refer to ‘measures’ or ‘a set of measures’, as appropriate to the circumstances.

⁸ Equivalent measures may achieve the ALOP of the importing country or, in combination with other measures, they may contribute to the achievement of the importing country’s ALOP. In the remainder of this guideline any reference to the former should be taken to include the latter possibility.

⁹ Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems - CAC/GL 26- 1997.

- i) Where risk assessment is used in the demonstration of equivalence, countries should strive to achieve consistency in the techniques applied, using internationally accepted methodology where available and taking into account relevant Codex texts.
- j) The importing country should take into account any knowledge and past experience it has of the food inspection and certification systems in the exporting country to make the determination as efficiently and quickly as possible.
- k) The exporting country should provide access to enable the inspection and certification systems which are the subject of the equivalence determination to be examined and evaluated upon request of the food control authorities of the importing country.
- l) All judgments of equivalence should consider the means by which that equivalence will be maintained.
- m) Countries should ensure transparency in both the demonstration and judgment of equivalence, consulting all interested parties to the extent practicable and reasonable. The exporting and importing countries should approach an equivalence determination procedure in a cooperative way.
- n) An importing country should give positive consideration to a request by an exporting developing country for appropriate technical assistance that would facilitate the successful completion of an equivalency determination.

SECTION 5 - THE CONTEXT OF AN EQUIVALENCE DETERMINATION

- 8. To facilitate judgement of equivalence between countries and promote harmonisation of food safety standards, Codex members should base their sanitary measures on Codex standards and related texts.¹⁰
- 9. An equivalence determination can be sought for any sanitary measure or set of measures relevant to a food product or group of food products. Relevant sanitary measures making up a food control system in the exporting country that are not the subject of an equivalence determination should meet importing country requirements.
- 10. The extent of the equivalence determination will depend on the prior experience, knowledge, and confidence that the importing country has regarding the food control measures of the exporting country.
- 11. When an importing country has prior experience, knowledge, and confidence in food control measures relevant to those being evaluated for equivalence and the countries agree that import requirements are being fully met, e.g. where trade experience exists, determination of the equivalence of sanitary measures may be made without further consideration of those other relevant measures making up the food control system.
- 12. When an importing country does not have prior experience, knowledge, and confidence in food control measures relevant to those being evaluated for equivalence and the countries have not determined that import requirements are being fully met, e.g., where trade in a food product or group of food products is being proposed for the first time, determination of the equivalence of sanitary measures will require further consideration of those other relevant measures making up the food control system.
- 13. For the purposes of determining equivalence, the sanitary measures associated with a food inspection and certification system can be broadly categorised as:
 - a) infrastructure; including the legislative base (e.g., food and enforcement law), and administrative systems (e.g., organization of national and regional authorities, enforcement systems, etc.);
 - b) programme design, implementation and monitoring; including documentation of systems, monitoring, performance, decision criteria and action, laboratory capability, transportation infrastructure and provisions for certification and audit; and/or

¹⁰ Article 3 of the WTO SPS Agreement states, *inter alia*, that WTO Members may introduce or maintain sanitary measures which result in a higher level of sanitary protection than would be achieved based on Codex standards, if there is a scientific justification, or as a consequence of the member's chosen level of protection. Such measures must be based on a risk assessment appropriate to the circumstances.

- c) specific requirements; including requirements applicable to individual facilities (e.g., premises design), equipment (e.g., design of food contact machinery), processes (e.g., HACCP plans), procedures (e.g., ante- and post-mortem inspection), tests (e.g., laboratory tests for microbiological and chemical hazards) and methods of sampling and inspection.
14. Categorization in this manner is likely to facilitate agreement between countries on the basis for comparison of sanitary measures subject to an equivalence determination (see section 6). Further, allocation of measures to a particular category may assist countries in simplifying the extent of the equivalence determination relative to other sanitary measures making up the food control system.

SECTION 6 - OBJECTIVE BASIS OF COMPARISON

15. Since the sanitary measures applied by an importing country have the purpose of achieving its ALOP, an exporting country may demonstrate achievement of the importing country's ALOP by demonstrating that the measures it proposes as equivalent have the same effect, relative to the achievement of the importing country's ALOP, as the corresponding sanitary measures applied by the importing country by using an objective basis of comparison.
16. The importing country should, at the request of the exporting country, specify as precisely as possible an objective basis for comparison of the sanitary measures proposed by the exporting country and its own measures.¹¹ Dialogue between the exporting and importing country will assist in the development of understanding and, desirably, agreement on the objective basis for comparison. Supporting information to be provided by the importing country may include:
- a) the reason/purpose for the sanitary measure, including identification of the specific risks that the measure is intended to address;
 - b) the relationship of the sanitary measure to the ALOP, i.e., how the sanitary measure achieves the ALOP;
 - c) where appropriate, an expression of the level of control of the hazard in a food that is achieved by the sanitary measure;
 - d) the scientific basis for the sanitary measure under consideration, including risk assessment where appropriate;
 - e) any additional information that may assist the exporting country in presenting an objective demonstration of equivalence.

SECTION 7 - PROCEDURE FOR THE DETERMINATION OF EQUIVALENCE

17. The importing country should make available details of its sanitary measures to the exporting country on request. The exporting country should review all applicable sanitary measures of the importing country for the food involved and identify those it will meet and those for which it seeks determination of equivalence. The importing and exporting countries should then use an agreed process for exchange of the relevant information to facilitate the determination of equivalence. This information should be limited to that which is necessary for this purpose.
18. The determination of equivalence is facilitated by both exporting and importing countries following a sequence of steps, such as those described below and illustrated in Figure 1. The parties should work through these steps in a cooperative manner with the aim of reaching agreement:

¹¹ The objective basis for comparison of sanitary measures categorized as "Infrastructure" is likely to be of a qualitative nature, e.g., the ability of food control legislation to achieve broad food safety goals. The objective basis of comparison of sanitary measures categorized as "Specific Requirements" is likely to be quantitative in nature e.g., a comparison of levels of hazard control achieved by the measure. The objective basis of comparison of sanitary measures categorized as "Programme" is likely to contain a mixture of qualitative and quantitative elements e.g., correct application of principles, and establishment of appropriate critical limits, in HACCP food control systems.

- a) The exporting country identifies the sanitary measure of the importing country for which it wishes to apply a different measure, and requests the reason/purpose for the measure.
- b) The importing country provides the reason/purpose for the identified sanitary measure and other relevant information in accordance with section 6.
- c) In accordance with section 6 the importing country should specify as precisely as possible an objective basis for comparison of the sanitary measures proposed by the exporting country and its own measures. On the initiative of the exporting country, the importing and exporting countries should enter into a dialogue concerning this objective basis for comparison with a view to reaching agreement.
- d) The exporting country develops a submission using risk assessment or other relevant methodology as appropriate, to demonstrate that the application of the different sanitary measure achieves the ALOP of the importing country, and presents it to the importing country.
- e) The importing country reviews the submission and, if adequate, uses the submission to determine whether the exporting country's measure achieves the importing country's ALOP.
- f) If the importing country has any concerns with the submission as presented, it should notify them to the exporting country at the earliest opportunity and should detail the reasons for concern. If possible, the importing country should suggest how the concerns might be addressed.
- g) The exporting country should respond to such concerns by providing further information, modifying its proposal or taking other action as appropriate.
- h) The importing country notifies the exporting country of its judgement within a reasonable period of time and provides the reasoning for its decision, should the judgement be that the sanitary measure is not equivalent, i.e., does not achieve the importing country's ALOP.
- i) An attempt should be made to resolve any differences of opinion over judgement of a submission, either interim or final.

SECTION 8 – JUDGEMENT

19. Judgement of equivalence by the importing country should be based on a transparent analytical process that is objective and consistent, and includes consultation with all interested parties to the extent practicable and reasonable.
20. Judgement of the equivalence of sanitary measures should take into account:
 - a) experience, knowledge and confidence of an exporting country's food inspection and certification systems (see section 5);
 - b) supporting data submitted by the exporting country;
 - c) analysis of the strength of the relationship between the exporting country's specified sanitary measure, and the achievement of the ALOP of the importing country as reflected in the objective basis for comparison (see section 6);
 - d) that parameters should be stated in quantitative terms to the extent possible;
 - e) adequacy of qualitative descriptions where the level of control of hazards in foods ~~is~~ is not quantified;
 - f) consideration of variability and other sources of uncertainty in data;
 - g) consideration of all expected human health outcomes of the exporting country's identified sanitary measure;
 - h) those Codex texts relevant to the food safety matters under consideration.

Following any judgment of equivalence, exporting and importing countries should promptly advise each other of significant changes in their supporting programmes and infrastructure that may affect the original determination of equivalence.

**Figure I: Simplified flow chart for the determination of equivalence
(individual steps may be iterated)**

