

codex alimentarius commission



FOOD AND AGRICULTURE
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Agenda Item 4

CX/FICS 03/4
September 2003

JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS

Twelfth Session

Brisbane, Australia, 1 – 5 December 2003

DISCUSSION PAPER ON TRACEABILITY/PRODUCT TRACING IN THE CONTEXT OF FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS

Governments and international organizations wishing to submit comments on the following subject matter are invited to do so **no later than 7 November 2003** to: Codex Australia, Australian Government Department of Agriculture Fisheries and Forestry GPO Box 858, Canberra ACT, 2601 (fax: 61.2.6272.3103; E-mail: codex.contact@affa.gov.au), with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Via delle Terme di Caracalla, 00100 Rome, Italy (Fax No + 39.06.5705.4593; E-mail: codex@fao.org).

Background

1. The Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) decided at its 11th session held in Adelaide, Australia (December 2002), to reconvene the Working Group¹ on Traceability/Product Tracing under the Chairmanship of Switzerland, in order to complete the mandate assigned by the 10th session of the CCFICS².

Information Letter and Request for Comments (February 2003)

2. Switzerland, as Chair of the Working Group, sent an Information Letter and Request for comments (dated February 2003) to all members of the Working Group. The following members of the Working Group submitted comments: Australia, Canada, Germany, the Netherlands, New Zealand, Norway, United States of America, European Commission, Biotechnology Industry Organization (BIO), Consumers International (CI) and the 49th Parallel Biotechnology Consortium (49P).

¹ Switzerland (Chair), Argentina, Australia, Belgium, Bolivia, Brazil, Canada, Chile, France, Germany, India, Ireland, Italy, Japan, Kenya, Republic of Korea, The Netherlands, Norway, Papua New Guinea, Paraguay, Philippines, Sweden, Thailand, United Kingdom, United States of America, European Commission, Food and Agriculture Organization, World Health Organisation, World Trade Organisation, Biotechnology Industry Organization, Comité Européen Des Fabricantes De Sucre, Consumers International, Confédération des Industries Agro-Alimentaires de l'UE, Council on Responsible Nutrition, CropLife International, EuropaBio, Greenpeace, International Council of Grocery Manufacturers Association, International Dairy Federation, International Federation for Animal Health, 49th Parallel Biotechnology Consortium

² ALINORM 03/30 Para. 67, ALINORM 03/30a Para. 53

Request for Comments on the Draft Analysis Document (June 2003)

3. Based on the comments received from several Working Group Members to the Information Letter mentioned above, Switzerland prepared a Draft Analysis Document, which reviewed the adequacy and applicability of CCFICS texts as related to traceability/product tracing and the need for further work in this area. The Draft Analysis Document was submitted to all Working Group Members for review and comments (6th June 2003).

4. Switzerland amended the Draft Discussion Paper based on the comments received³ and submitted it to the members of the Working Group (4th August 2003).

2nd Meeting of the CCFICS Working Group on Traceability/Product Tracing

5. The Working Group met in Fribourg, Switzerland, from 3rd to 5th September 2003 at the invitation of the Government of Switzerland. Sixty delegates attended the 2nd Meeting of the Working Group.

Mandate of the Working Group

6. The Working Group recalled the mandate that it had been assigned by the 10th and 11th sessions of the CCFICS (ALINORM 03/30A, paragraph 53), which is as follows: “The Working Group should prepare a Discussion paper with a complete analysis of the issues involved for circulation, additional comment and further consideration at the 12th session of the CCFICS (December 2003). This review should analyse the appropriateness and need for CCFICS to develop specific guidance on the practical implementation of traceability/product tracing and how the issue is to be progressed”.

7. The Draft Discussion Paper (4th August 2003) prepared by Switzerland formed the basis for the discussions at the 2nd Working Group Meeting.

8. The Working Group took note of the discussions held within other Codex Committees and in particular Regional Coordinating Committees, and acknowledged that these discussions should be kept under consideration while discussing traceability/product tracing within CCFICS. The Working Group also noted that the Codex Committee on General Principles had decided at its 18th session (Paris, France, 7th –11th April 2003) to develop a definition for traceability/product tracing for consideration at its 20th session due to be held in Paris in May 2004. However, it was noted by some delegations that the current lack of an agreed definition made it difficult for them to determine whether there was a common understanding of the entire concept of traceability/product tracing, especially its application, scope and coverage.

9. It was recalled, however, that at its 49th session, the Codex Executive Committee had agreed that it should be for the Codex Committees concerned to undertake work on traceability/product tracing, as they deemed appropriate within their respective mandates. The Executive Committee had 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 systems⁴.

10. Some delegations expressed their concern that the implementation of a traceability/product tracing system could be very costly and should, therefore, be limited to cases where there were no alternative instruments available to achieve the intended purpose. Other delegations expressed concern on the costs, particularly with regard to food safety, of not implementing a traceability/product tracing system. Several delegations stressed that the work undertaken by Codex was closely interlinked with WTO disciplines and that consequently, any guidance on the application of traceability/product tracing should not conflict with WTO obligations. Other delegations expressed the view that the Codex and the WTO had different mandates and therefore, the CCFICS should proceed with the examination of traceability/product tracing within the Codex mandate and within the Terms of reference of the CCFICS. The delegation of 49P drew the attention of the Working Group to the fact that the Cartagena Protocol on Biosafety would be coming into force on 11th September 2003 and that it contained a provision (Article 18), which relates to the issue of traceability/product tracing for some food products.

³ Argentina, Australia, Canada, New Zealand, United Kingdom, United States of America, 49 Parallel Biotechnology Consortium, and International Federation for Animal Health.

⁴ ALINORM 03/3, paras. 29-33

11. The Working Group recognised that traceability/product tracing was not an objective in itself but rather a tool, which may assist countries to demonstrate that imported and/or exported foods meet quality and/or safety requirements. It was noted that in order to strengthen the confidence in the information contained in the export certificate for example, there was a need to ensure the authenticity of the information contained therein and that traceability/product tracing might also provide some assistance in this regard. It was, therefore, recognised that the CCFICS could consider how to use the traceability/product tracing tool within food import and export inspection and certification systems.

Analysis of CCFICS Texts

12. The Working Group undertook the analysis of the CCFICS texts listed below based on the framework and on the elements of traceability/product tracing, which had been approved by the CCFICS at its 11th Session⁵.

13. The *elements* of traceability/product tracing utilized for this analysis were:

- i. Product identification: Ability to identify a food;
- ii. Product information: Where it came from, how it was changed (if appropriate) and where it was sent (one step back and one step forward); and
- iii. The linkages between product identification and product information.

14. The following *framework* was used in the review of the CCFICS texts, with a view to examining the adequacy and applicability of traceability/product tracing within CCFICS:

- i. Does the text address elements of traceability/product tracing?
- ii. Does the existing text adequately cover the elements of traceability/product tracing with respect to the objectives of the text?
- iii. Would these objectives be met even more adequately, if traceability/product tracing elements were included/strengthened?
- iv. Are there other methods that would be more appropriate?
- v. Are there gaps in the text with regards to traceability/product tracing?
- vi. What are the options, if gaps are identified?

15. The following CCFICS *texts* were subject to the analysis:

- i. Principles for Food Import and Export Inspection and Certification (CAC/GL 20-1995)
- ii. Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (CAC/GL 26-1997)
- iii. Guidelines for the Development of Equivalence of Agreements Regarding Food Import and Export Inspection and Certification Systems (CAC/GL 34-1999)
- iv. Guidelines for the Exchange of Information in Food Control Emergency Situations (CAC/GL 19-1995)
- v. Guidelines for the Exchange of Information between Countries on Rejections of Imported Food (CAC/GL 25-1997)
- vi. Guidelines for Generic Official Certificate Formats and the Production and Issuance of Certificates (ALINORM 01/30A Appendix II adopted at Step 8-CAC 2001)
- vii. Guidelines for Food Import Control Systems (ALINORM 03/30 Appendix II, adopted at Step 8, CAC 2003)
- viii. Guidelines on the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems (ALINORM 03/30A Appendix II, adopted at Step 8, CAC 2003)

⁵ ALINORM 03/30A, paragraphs 49 and 53

16. The Working Group undertook a thorough analysis of the above-mentioned existing CCFICS texts with regard to their appropriateness and applicability with respect to traceability/product tracing. The members of the Working Group were entirely satisfied with the thorough review undertaken, and decided to append the full text of the Analysis of the CCFICS documents to this Discussion paper (**Appendix I**).

17. The analysis of the CCFICS texts that was undertaken by the Working Group considered whether existing CCFICS texts have gaps with respect to their reference to and consideration of traceability/product tracing and the specific objectives of each text and whether any consequential action should be taken.

18. The Working Group noted that existing CCFICS texts do not provide specific guidance on traceability/product tracing per se, as each CCFICS text was developed in order to address specific objectives. However, it was noted that most texts do contain individual elements of traceability/product tracing, such as product identification or product information, which are relevant considering the objectives pursued by each text. Since the examined texts were developed for reasons other than providing guidance on the application of traceability/product tracing, there was no consistent presentation of what principles or guidance provisions ought to apply to the concept of traceability/product tracing within the context of food import and export inspection and certification systems.

19. The Working Group, therefore, reached the conclusion that CCFICS texts do not provide a consistent set of principles on traceability/product tracing, although they sometimes reference individual elements of traceability/product tracing. Hence, the Working Group considered whether existing CCFICS texts would need to be complemented by specific principles and/or guidance on traceability/product tracing in order to provide additional information to help protect the health of consumers and ensure fair practices in food trade. The Working Group concluded that the objectives of most of the examined texts would not be met more adequately if traceability/product tracing elements in most of those texts were included or strengthened.

20. The Working Group noted that according to Codex Regional Committee comments, developing countries were concerned as to whether they had sufficient capacity to meet any proposed requirements in the area of traceability/product tracing particularly the cost of implementation of these systems. Furthermore, it was considered by some delegations that the whole concept of traceability/product tracing was of concern, especially as the terms traceability/product tracing has not yet been defined. However, many members stated that traceability/ product tracing principles for the purposes of food safety and for other applications were important. Other members suggested that traceability/product tracing be managed on a case-by-case basis.

21. The Working Group recognized that it would be helpful that workshops or seminars be organized to address the application, scope and coverage of traceability/ product tracing among member countries.

22. Some delegations concluded that both food safety and fair trading practices were relevant with respect to the need for guidance concerning traceability/product tracing. They recognized the importance of developing guidance that linked both product identification and product information, and that enabled relevant information to accompany the products in order to assist ensure the accuracy of the certification with respect to the fact that the product met food safety standards and/or technical requirements.

23. Other delegations noted their concern with respect to the impact of Codex work on traceability/product tracing on WTO obligations. The Working Group however recognized the views expressed by the Codex Executive Committee at its 49th Session (September 2001) in that any measures requiring traceability/product tracing should be justified as having a food safety objective as an SPS measure or as having a legitimate objective as a TBT measure⁶. Furthermore, it was recalled that at its 11th session, the CCFICS had reached a general agreement on the opinion expressed by the Executive Committee in this regard⁷.

⁶ ALINORM 03/3, paras. 29-33

⁷ ALINORM 03/30A, para. 51

Appropriateness and Need for CCFICS to Develop Specific Guidance on Traceability/Product Tracing

24. In their written comments, several members of the Working Group had expressed their support for the development by CCFICS, of a set of principles on traceability/product tracing. The CCFICS would follow a horizontal approach and proceed to develop a new text, which would contain the set of general principles on traceability/product tracing. It was proposed that the outcome of the Codex Regional Committees discussions on traceability/product tracing, serve as a starting point for discussions on a set of general principles on traceability/product tracing within the CCFICS. In their written comments, Members of the Working Group stated that the principles document should acknowledge the importance of traceability/product tracing for food safety purposes (i.e., as an SPS measure), as well as for ensuring the protection of consumers from unfair trade practices (i.e. as a TBT measure). The principles on traceability/product tracing would need to be flexible and set targets for performance. They would, furthermore need to be clear, simple and pragmatic in order to ensure that they can be implemented and that they adequately support existing CCFICS texts.

25. In view of the current international developments (a number of countries have developed and already implement traceability/product tracing systems), it was suggested that the CCFICS could play an important role by developing principles or guidelines for the application of traceability/product tracing for food import and export inspection and certification systems with a view to harmonizing methods and procedures which protect the health of consumers, ensure fair trading practices and facilitate international trade in foodstuffs (letter a, Terms of reference for the CCFICS).

Options for Future Work on Traceability/Product Tracing Within CCFICS

26. The Working Group had an exchange of views regarding the two Options which were presented in the Draft Discussion Paper prepared by Switzerland: Option 1: Revision of relevant CCFICS texts and Option 2: Overarching CCFICS principles on traceability/product tracing. Several countries agreed that the two Options were adequate, whilst others expressed the opinion that the Working Group should develop a large array of Options which would be presented to the CCFICS for consideration.

27. The Working Group therefore decided to develop a broad set of Options, which could be considered by the CCFICS as a possible way forward in the examination of traceability/product tracing within the CCFICS. The Working Group also listed the advantages and disadvantages of each Option in the following Table. The Options as well as the advantages and disadvantages listed in the Table are intended to facilitate the discussions which will be held at the forthcoming 12th session of CCFICS. It should be noted, however, that this Table does not reflect a consensual position reached by the Working Group on the different Options presented. The Table simply presents the results of a brief brainstorming exercise carried out within the Working Group as well as a characterization of the advantages and disadvantages of the various Options by the Sub-Working Groups which had been set up to that effect. The contents of the Table should therefore not be considered as recommendations resulting from consensus.

28. Furthermore, it should be noted that: the list of Options is illustrative, therefore, more Options may exist; the advantages and disadvantages of the Options may be subject to different opinions among the members of the Working Group; and, that the Options are not mutually exclusive therefore different combinations of two or more Options may be possible. It was also proposed by a delegation that variations of the given Options may be considered, in order to take into account the following modalities: the audience (Codex and its subsidiary bodies or National Governments) as well as the purpose of the Option under consideration (food safety purposes only, non-food safety purposes only or a combination of both food safety as well as non-food safety purposes).

29. The Working Group fully acknowledged that it is the responsibility of the CCFICS to take the final decision on the action it would consider appropriate with respect to traceability/product tracing within its mandate.

OPTION 1: SUSPENSION OF WORK

Option 1A: Decision not to pursue work on Traceability / Product Tracing within CCFICS. The existing CCFICS texts are kept as they are (no revision).

Option 1B: The CCFICS awaits further guidance from other Codex Committees (in particular CCGP) and decides on further action, as appropriate, at a later stage.

OPTION 2: REVISION OF (ONE OR MORE) RELEVANT CCFICS TEXTS

Option 2A: Revision of specific existing CCFICS texts in order to strengthen their reference to traceability / product tracing.

Option 2B: Revision of the Principles for Food Import and Export Inspection and Certification (CAC/GL 20-1995) in order to include horizontal principles/ guidelines on the application of traceability / product tracing within CCFICS.

OPTION 3: NEW WORK

Option 3A: Develop a new horizontal document, containing “principles for the application of traceability / product tracing” within CCFICS.

Option 3B: Develop a new horizontal document containing “guidelines for the application of traceability / product tracing” within CCFICS.

Option 3C: Develop a new horizontal document, containing both, “principles and guidelines for the application of traceability / product tracing” within CCFICS.

Option 3D: Develop two separate documents, one containing horizontal “principles”, another containing “guidelines”. These two documents could be developed in parallel or sequentially.

Option 3E: Develop a reference text that lists criteria that may be used by an importing and an exporting country on a case-by-case basis.

OPTION 4: OTHER

Option 4A: Combination of Options 2B and 3B.

(*Option 2B*: Revision of the Principles for Food Import and Export Inspection and Certification (CAC/GL 20-1995) in order to include horizontal principles / guidelines on the application of traceability / product tracing within CCFICS **and** *Option 3B*: Development of a new horizontal document containing “guidelines for the practical implementation of traceability / product tracing” within CCFICS in an Annex or separate document).

LIST OF OPTIONS TABLE

Option	Advantages	Disadvantages
<p>Option 1A: Decision not to pursue work on Traceability / Product Tracing within CCFICS. The existing CCFICS texts are kept as they are (no revision).</p>	<ul style="list-style-type: none"> - No further work needed 	<ul style="list-style-type: none"> - Not sustainable - Against the mandate of the Working Group
<p>Option 1B: The CCFICS awaits further guidance from other Codex Committees (in particular CCGP) and decides on further action, as appropriate, at a later stage.</p>	<ul style="list-style-type: none"> - More clarity on definition and scope - Practical experience and knowledge from countries will provide a better basis for work on traceability / product tracing 	<ul style="list-style-type: none"> - Traceability/product tracing is an important and actual issue - The Option is not consistent with the Working Group's mandate and is not in-line with the decisions taken by other Codex Committees (e.g. CCEXEC) - No progress - Waiting for a definition and the scope can be an advantage but it is not necessary in order to start work on the subject (risk to be behind the international developments) - Divergence in national systems - Countries' and consumers' opinions indicate not to postpone the debate - Potential for food safety crisis
<p>Option 2A: Revision of specific existing CCFICS texts in order to strengthen their reference to traceability / product tracing.</p>	<ul style="list-style-type: none"> - Would allow for the more appropriate modification of "Guidelines for Food Import Control Systems" (ALINORM 03-30 Appendix II) as this document has most of the elements of traceability/ product tracing and therefore it might be the best document to strengthen with respect to traceability/ product tracing 	<ul style="list-style-type: none"> - Not feasible to do a formal review and revision of all of the CCFICS texts - It may be premature to recommended modifications to CCFICS texts until CCGP gets to a more advanced stage regarding its deliberations on traceability/ product tracing, e.g., develops a definition. - Not consistent with the analysis as performed by the CCFICS Working Group (paragraph 16) where it is indicated that the objectives of the current texts would not be met more adequately if traceability/product tracing elements were included or strengthened. Therefore, there is no value in initiating this work.

Option	Advantages	Disadvantages
<p>Option 2B: Revision of the Principles for Food Import and Export Inspection and Certification (CAC/GL 20-1995) in order to include horizontal principles/ guidelines on the application of traceability / product tracing within CCFICS.</p>	<ul style="list-style-type: none"> - It is more feasible to revise one but not all of the current CCFICS texts - Paragraph 20 in the current CAC/GL 20 - 1995 text would be a reasonable link for traceability/ product tracing. - It would be an expedient activity for CCFICS to consider - i.e. progress could be made. - It would bring more clarity to the role of traceability/ product tracing in import/export inspection and certification systems - It would add some validity to, and is a more logical progression of, this work within CCFICS by establishing the “principle” first and then determining how the addition of this text might impact on existing and future CCFICS text. - It would give CCFICS a starting point and the momentum to carry this concept forward in CCFICS, i.e., in systems for inspection and certification. - Through the development and consideration of such modifications within CCFICS, it would provide an opportunity for greater discussion and hence bring clarity to the subject among member countries. 	<ul style="list-style-type: none"> - Traceability/ product tracing is too specific a tool to be referenced in CAC/GL 20-1995 as this is a broad principles document - it would be more appropriate to reflect this concept as procedural guidance in ALINORM 03-30 Annex II - Guidelines for Food Import Control Systems. - It may be premature to recommended modifications to this text until CCGP gets to a more advanced stage regarding its deliberations on traceability/ product tracing, e.g., develops a definition. - Addressing traceability/ product tracing in this document as a unique factor would give traceability/ product tracing undue prominence in CCFICS. - Guidelines in the Codex context are not appropriate for this document - the Working Group should consider using a “horizontal principles approach” instead. - There is a wide divergence of understanding of the use of traceability/ product tracing systems within CCFICS - developing appropriate text will be difficult until such understanding is advanced. - We (members of the Working Group) still do not have agreement regarding where we want to go, hence recommending work in this area may not be appropriate.
<p>Option 3A: Develop a new horizontal document, containing “principles for the application of traceability / product tracing” within CCFICS.</p>	<ul style="list-style-type: none"> - Provide rationale for approach undertaking traceability - Establish a policy basis that countries should use for developing their own guidelines - Give consistency to measures applied by different countries - In accordance with paragraph a and b of the Terms of reference of CCFICS - Give freedom to Governments to develop different Guidelines or no Guidelines at all 	<ul style="list-style-type: none"> - Could be taken as overarching principles applicable in general to all products and situations - Some countries believe that these principles without guidelines are not sufficient to achieve complete consistency between Governments.

Option	Advantages	Disadvantages
<p>Option 3B: Develop a new horizontal document containing “guidelines for the application of traceability / product tracing” within CCFICS.</p>	<ul style="list-style-type: none"> - Some countries indicated that consistency and trade facilitation will be improved. - Provide a basis for comparison with alternative measures in view of reaching an agreement on equivalence. - In accordance with paragraphs a and b of the Terms of reference of CCFICS. - CCFICS has the most appropriate expertise to develop guidance for traceability/product tracing in food import and export inspection and certification systems. 	<ul style="list-style-type: none"> - Difficult to develop without Codex policy basis for principles. - Not applicable to every case and to every situation. - No technical expertise and knowledge in the absence of a FAO/WHO Expert consultation.
<p>Option 3C: Develop a new horizontal document, containing both, “principles and guidelines for the application of traceability / product tracing” within CCFICS.</p>	<ul style="list-style-type: none"> - Save time (in the long term) - May be more efficient than Option 2D (allows discussion of both at the same time) - Likelihood to have consistency within document. - Principles and guidance will work together (synergy). 	<ul style="list-style-type: none"> - May take longer time than Option 2D to get to a final result - Presumption that guidance is necessary and can be constructed
<p>Option 3D: Develop two separate documents, one containing horizontal “principles”, another containing “guidelines”. These two documents could be developed in parallel or sequentially.</p>	<ul style="list-style-type: none"> - Principles can be achieved before implementing guidance (sequential approach possible). - Greater potential for an early result (principles) and therefore a foundation for the guidance. - Allows for better understanding of the subject and of the feasibility for preparation of guidance. 	<ul style="list-style-type: none"> - Potentially less consistency between the documents.

Option	Advantages	Disadvantages
<p>Option 3E: Develop a reference text that lists criteria that may be used by an importing and an exporting country on a case-by-case basis.</p>	<ul style="list-style-type: none"> - Flexibility of utilising some or all of the criteria as appropriate to the product (result). - Full list of criteria agreed by CCFICS. - Voluntary application of the criteria by mutual agreement of the countries concerned. 	<ul style="list-style-type: none"> - Individual bilateral agreements may vary because of differences in the criterion utilised from the list (lack of harmonisation). - Industry may have difficulty in meeting the different criteria associated with agreements between different countries (lack of uniformity). - Strong negotiators may have an advantage in bilateral negotiations. - Difficulties may arise where a product is further processed in another country or in other countries before re-export elsewhere. - The meaning of the word “criteria” may be different for different countries. - This option may assume that consumers are subject to different levels of protection because of differences in agreements (inequality).
<p>Option 4A: Combination of Options 2B and 3B.</p> <p><i>(Option 2B: Revision of the Principles for Food Import and Export Inspection and Certification (CAC/GL 20-1995) in order to include horizontal principles / guidelines on the application of traceability / product tracing within CCFICS and Option 3B: Development of a new horizontal document containing “guidelines for the practical implementation of traceability / product tracing” within CCFICS in an Annex or separate document).</i></p>	<ul style="list-style-type: none"> - Consistency between the 2 documents if developed in parallel and in close association. 	<ul style="list-style-type: none"> - Duplication / inconsistency if the 2 documents are developed in parallel but in isolation.

30. During the discussion on the Options, the delegation of Argentina, supported by some other delegations, expressed the opinion that traceability/product tracing should only be dealt with by CCFICS after an assessment of the economic implications of possible Guidelines on traceability/product tracing has been carried out. In the view of this delegation, this Option could be included as a variant under Option 1. Several other delegations did not agree with this opinion, and referring to the Codex Alimentarius Procedural Manual “Procedures for the Elaboration of Codex Standards and Related Texts⁸,” pointed out that possible implications of the Codex draft texts on the economic interests of Codex Members and interested international organizations were considered at Steps 5 and 6 of the Codex Procedure. They also drew the attention of the Working Group to the fact that it would not be possible to conduct an economic impact assessment before the contents of the principles or guidelines had been specified further. While agreeing that economic aspects were important, these delegations reminded the Working group that the work of Codex should primarily focus on protecting the health of consumers and ensuring fair practices in food trade.

31. In addition to the Options provided for discussion, it was also suggested that maintaining the “status quo” with respect to CCFICS’ management of traceability/product tracing may also be appropriate, that is, that elements of traceability/product tracing relevant to the objectives of CCFICS existing texts be included in new CCFICS texts or the revision of existing text.

Recommendations

32. Based on the discussions held at its Second Meeting, the CCFICS Working Group on Traceability/Product Tracing recommends that

- the Committee consider the outcome of the Analysis and the Options outlined in the Discussion Paper as a basis for its decision on the further steps to be taken with respect to traceability/product tracing;
- Codex Member countries and International Observer Organizations submit written comments to the CCFICS on the listed Options, in which they may wish to include an indication of their preferred Option or Options, for consideration at the forthcoming 12th session of the CCFICS;
- in their written comments on the Discussion Paper, Codex Member countries and International Observer Organizations should bear in mind that the listed Options may not be mutually exclusive and that there may be an opportunity to combine them.

33. As the discussion revealed that there was no common understanding of the practical application, scope and coverage of traceability/product tracing within CCFICS, the Working Group further recommends

- that the CCFICS encourages discussion on the application, scope and coverage of traceability/product tracing within its mandate in order to enhance the common understanding on traceability/product tracing and consider mechanisms by which this discussion may be realized. To this end, CCFICS should invite members that have experience with the application of traceability/product tracing systems to share this experience with other members within the CCFICS.

34. The CCFICS should continue taking into consideration the results of the discussions on the application, scope and coverage of traceability/product tracing in relevant Codex Committees.

⁸ Codex Alimentarius Procedural Manual, 13th Edition, page 21

ANALYSIS OF CCFICS TEXTS

The Working Group undertook the analysis of the CCFICS texts listed below based on the framework and on the elements of traceability/product tracing, which had been approved by the CCFICS at its 11th Session⁹.

The *elements* of traceability/product tracing utilised for this analysis were:

1. **Product identification** : Ability to identify a food;
2. **Product information**: Where it came from, how it was changed (if appropriate) and where it was sent (one step back and one step forward); and
3. **The linkages between product identification and product information.**

Framework for the analysis

The following framework was used in the review of the CCFICS texts, with a view to examining the adequacy and applicability of traceability/product tracing within CCFICS:

1. Does the text address elements of traceability/product tracing?
2. Does the existing text adequately cover the elements of traceability/product tracing with respect to the objectives of the text?
3. Would these objectives be met even more adequately, if traceability/product tracing elements were included/strengthened?
4. Are there other methods that would be more appropriate?
5. Are there gaps in the text with regards to traceability/product tracing?
6. What are the options, if gaps are identified?

Analysed texts:

1. Principles for Food Import and Export Inspection and Certification (CAC/GL 20-1995)
2. Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (CAC/GL 26-1997)
3. Guidelines for the Development of Equivalence of Agreements Regarding Food Import and Export Inspection and Certification Systems (CAC/GL 34-1999)
4. Guidelines for the Exchange of Information in Food Control Emergency Situations (CAC/GL 19-1995)
5. Guidelines for the Exchange of Information between Countries on Rejections of Imported Food (CAC/GL 25-1997)
6. Guidelines for Generic Official Certificate Formats and the Production and Issuance of Certificates (ALINORM 01/30A Appendix II adopted at Step 8-CAC 2001)
7. Guidelines for Food Import Control Systems (ALINORM 03-30 Appendix II, adopted at Step 8, CAC 2003)
8. Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems (ALINORM 03-30A Appendix II, adopted at Step 8, CAC 2003)

Texts which were not analysed:

9. Proposed Draft Guidelines on the Judgement of Equivalence of Technical Regulations Associated with Food Inspection and Certification Systems (CX/FICS 02/11/6)

⁹ ALINORM 03/30A, paragraphs 49 and 53.

10. Proposed Draft Revision to the Codex Guidelines for the Exchange of Information in Food Control Emergency Situations (CX/FICS 02/11/4)

1. **PRINCIPLES FOR FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION (CAC/GL 20-1995)**

Objectives of the text:

This text sets out some principles whose objective is to ensure that food inspection and certification systems are used to ensure that foods, and their production systems, meet requirements in order to protect consumers against food-borne hazards and deceptive market practices and to facilitate trade on the basis of accurate product description.

In paragraph 1 of Section 1 of the text, it is acknowledged that inspection and certification systems are fundamentally important and very widely used means of food control that should be governed by a number of principles which will ensure an optimal outcome consistent with consumer protection and facilitation of trade. Section 1 also states that confidence of consumers in the quality (including safety) of their food supply depends in part on their perception as to the effectiveness of food control measures.

Paragraph 2 specifies that inspection of food may occur at any stage in the production and distribution process. For some foods, the most appropriate way of ensuring their safety is generally by carrying out checks on harvesting, processing, storage, transport, and other handling of products. According to the methods of preservation used, it may be necessary to maintain inspection checks on a continuous basis up to the time of retail sale. It further indicates that inspection systems may be focused on the foodstuffs themselves, on the procedures and facilities employed in the production and distribution chain, on the substance and materials which can be incorporated into or contaminate foodstuffs.

Section 3 highlights 10 principles for food inspection and certification systems, which should be used wherever appropriate to ensure that foods, and their production systems, meet requirements in order to protect consumers against food-borne hazards and deceptive marketing practices and to facilitate trade on the basis of accurate product description. These principles are: Fitness for purpose; Risk Assessment; Non-Discrimination; Efficiency; Harmonisation; Equivalence; Transparency; Special and Differential Treatment; Control and Inspection Procedures; and Certification and Validity.

Paragraph 20 states that the countries that certify exports of food and those importing countries which rely on export certificates should take measures to assure the validity of certification. Validation measures by exporting countries may include achieving confidence that official or officially recognised inspection systems have verified that the product or process referred to in the certificate conforms to requirements. Measures by importing countries may include point of entry inspection systems, audit of exporting inspections systems, and ensuring that certificates themselves are authentic and accurate.

1. **Does the text address elements of traceability/product tracing?**

As a principles guideline, this text does not provide specific references or guidance regarding traceability/product tracing. However, certain principles (e.g. fitness for purpose, use of objective risk assessment, efficiency, transparency, completion without delay of procedures needed to assess compliance with requirements) are entirely applicable to traceability/product tracing systems developed and operated by competent authorities.

The text recognises the need to submit the food chain to the requirements for quality and safety. This checking is based on the necessary flow of information that has to accompany the ingredients and foodstuffs in order to ensure that the final inspector in charge of the certification draws up a document in accordance with the regulations of Section 7 – Certification systems – of the Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (CAC/GL 26-1997) and in particular paragraph 48 which states that “Certification procedures should include procedures to ensure the authenticity and validity of certificates at all the relevant stages and to prevent fraudulent certification. In particular, personnel: should not certify matters without their personal knowledge or that cannot be ascertained by them; and they should not sign blank or incomplete certificates, or certificates for products which have not been produced under appropriate control programmes. Where a certificate is signed on the basis of another supporting document, the person signing the certificate should be in possession of that document”.

2. Does the existing text adequately cover the elements of traceability/ product tracing, with respect to the objectives of the text?

Not applicable since the objectives of the text do not require specific mention of traceability/product tracing.

3. Would these objectives be met even more adequately, if traceability/product tracing elements were included/strengthened?

This document describes in a general manner principles for food import and export inspection and certification. However, control and inspection procedures as well as certification validity have elements relating to traceability/product tracing. Thus, this general text does not need to focus specifically on traceability/product tracing since all other aspects are also very general and some of them have been considered in greater detail in specific CCFICS texts (e.g. equivalence, control programmes and operations, etc).

4. Are there other methods that would be more appropriate? No.

5. Are there any gaps in the text with regards to traceability/product tracing? No.

6. What are the options if gaps are identified? Not applicable.

2. GUIDELINES FOR THE DESIGN, OPERATION, ASSESSMENT AND ACCREDITATION OF FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS (CAC/GL 26-1997)

Objectives of the text:

These guidelines provide a framework for the development of import and export inspection and certification systems consistent with the Principles for Food Import and Export Inspection and Certification (CAC/GL 20-1995). They are intended to assist countries in the application of requirements and the determination of equivalency, thereby protecting consumers and facilitating trade in foodstuffs.

These guidelines deal with the recognition of equivalence of inspection and/or certification systems and not with standards related to specific food products or their components (e.g., food hygiene, additives and contaminants, labelling and quality requirements).

Paragraph 5 provides guidance for the recognition of a Hazard Analysis Critical Control Point (HACCP) approach as a fundamental tool for improving the safety of foodstuffs. Paragraph 6 further states that if safety and/or quality assurance tools are used by food businesses, the official inspection and certification systems should take them into account in particular through the adaptation of their control methodologies.

Paragraph 26, 4th bullet point, refers to the examination of written and other records. Paragraph 28 provides guidance on the elements that should be covered by controls. These include: raw materials, ingredients, technological aids and other products used for the preparation and production of foodstuffs (2nd bullet point); semi-finished and finished products (3rd bullet point) as well as the labelling integrity and claims (9th bullet point).

Paragraphs 32, 33, 34 and 35 provide guidance on the decision criteria of control programmes which should be targeted at the most appropriate stages and operations, depending on the specific objectives, including the history of non-conformity for the product, processor, importer or country. Paragraph 40 provides guidance on communication facilities including the provisions to ensure adequate compliance action and to address potential recalls.

1. Does the text address elements of traceability/product tracing?

Both product identification and product information elements are referenced in this document. The examination of written and other records, controls related to labelling integrity and claims, and the exchange of information related to rejections of imported foods are mentioned in the text.

2. Does the existing text adequately cover the elements of traceability/product tracing with respect to the objectives of the text?

These guidelines provide a framework for the development of import and export inspection and certification systems consistent with the Principles for Food Import and Export Inspection and Certification. Elements of traceability/product tracing are adequately addressed with respect to the objectives of this text.

3. Would these objectives be met even more adequately, if traceability/product tracing elements were included/strengthened? No.

4. Are there other methods that would be more appropriate? Not applicable.

5. Are there gaps in the text with regards to traceability/product tracing? No gaps have been identified.

6. What are the options, if gaps are identified? Not applicable

3. GUIDELINES FOR THE DEVELOPMENT OF EQUIVALENCE OF AGREEMENTS REGARDING FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS (CAC/GL 34-1999)

Objectives of the text:

These guidelines provide practical guidance for governments desiring to enter into bilateral or multilateral equivalence agreements concerning food import and export inspection and certification systems. They provide guidance for consideration of such agreements including purpose, scope, and types of equivalence agreements.

Section 7 refers to the consultative process for equivalence agreements and states that the importing country should make readily available the texts of its relevant control measures and identify the objectives of these measures.

1. Does the text address traceability/product tracing?

The guidelines do not refer specifically to traceability/product tracing. However, Section 7, states “participants in the agreement should agree to procedures for information exchange in the event of a food emergency control situation”.

Several other references to elements of traceability/product tracing are made, specifically product identification. Reference is made to a listing of establishments for the purpose of monitoring imported shipments which implies that establishment markings on imported product may be used to determine eligibility for importation of a particular product.

2. Does the existing text adequately cover the elements of traceability/product tracing with respect to the objectives of the text?

The objectives of the text are to provide guidance for countries wishing to enter into bilateral or multilateral equivalence agreements. As such, the indirect references made to traceability/product tracing elements are adequate to address these objectives.

3. Would these objectives be met even more adequately, if traceability/product tracing elements were included/strengthened? No.

4. Are there other methods that would be more appropriate? Not applicable.

5. Are there gaps in the text with regards to traceability/product tracing? No

6. What are the options, if gaps are identified? Not applicable.

4. GUIDELINES FOR THE EXCHANGE OF INFORMATION IN FOOD CONTROL EMERGENCY SITUATIONS (CAC/GL 19-1995)

Objectives of the text:

The objective of this text is to ensure the rapid exchange of information between importing and exporting countries, in cases where there is a clearly identified risk of serious untoward health effects associated with the consumption of certain foods, in this way, risks to human health can be minimised and the foodstuffs concerned can be rapidly identified and removed from the market.

The role of traceability/product tracing in assisting the achievement of this objective is mentioned in Paragraphs 6 and 9 which specifically reference information elements to be exchanged, based on the Annex to the guidelines (Standard Format for Information Exchange in Food Control Emergency Situations). These information elements include description and quantity of the product(s); type and size of package; lot identification; other identification marks/stamps including container and shipping details; and, the name and address of the producer, manufacturer seller, or importer as appropriate.

1. Does the text address elements of traceability/product tracing?

Both product identification and product information are referenced in this document. The text highlights specific details related to the description and quantity of product in question, as well as details regarding importation. Indirectly, there is an implied ability to link this data for the purpose of investigation and appropriate action. This document thus contains information that could be incorporated into a traceability/product tracing system.

2. Does the existing text adequately cover the elements of traceability/product tracing with respect to the objectives of the text?

The objectives of the text are to provide guidance regarding the rapid exchange of information related to situations in both exporting and importing countries that may represent food control emergencies. As such, there is significant focus on the type of information related to the food concerned as well as details related to its export or import.

3. Would these objectives be met even more adequately, if traceability/product tracing elements were included/strengthened?

This document relates to information exchange rather than response to emergencies identified internally or externally. Specific guidance on traceability/product tracing could be contained in a separate document.

4. Are there other methods that would be more appropriate? See 3 above.

5. Are there gaps in the text with regards to traceability/product tracing?

Additional guidance regarding traceability/product tracing within this document might not contribute further towards the realisation of the objectives of this text.

6. What are the options, if gaps are identified? See 3 above.

NOTE: This document is currently under revision. However, its status with respect to traceability/product tracing might not change.

5. GUIDELINES FOR THE EXCHANGE OF INFORMATION BETWEEN COUNTRIES ON REJECTIONS OF IMPORTED FOOD (CAC/GL 25-1997)

Objectives of the text:

The objective of this text is to provide the basis for structured information exchange on import rejections caused by failure to comply with importing country requirements.

Paragraphs 11 and 12 provide guidance on information required in order to be able to identify the consignment or lot of food concerned, as well as importation details, including a description of the nature and quantity of the food, any lot identification or other identification stamps, marks or numbers and the name and address of the exporter and/or food producer, manufacturer, importers or sellers. Other important elements are the place and date of entry. Additional information in relation to these factors is contained in the Annex to CAC/GL 25-1997 (Standard Format for Exchange of Information between Countries on Rejection of Imported Food).

1. Does the text address elements of traceability/product tracing?

The text provides information on product identification and product information related to rejected consignments or lots of imported food¹⁰. Paragraphs 6, 11 and 12 reference the need for an investigation in the exporting country upon the rejection of a lot of imported food, which implies traceability/product tracing using information related to the product itself (paragraph 11) and information regarding the importation (paragraph 12). The specific information to be provided by countries in relation to rejections is further elaborated in the Annex to the Guidelines. (Standard Format for Exchange of Information between Countries on Rejection of Imported Food).

The linkages between product identification and product information are implicitly given. Explicit guidance could be more appropriate as this could avoid confusions and/or misunderstanding between the involved countries, especially in the case of mixed shipments.

However, no specific provisions relating to traceability/product tracing are given.

2. Does the existing text adequately cover the elements of traceability/product tracing with respect to the objectives of the text?

All three elements of traceability/product tracing are covered with respect to the objectives of the text although certain aspects could be completed as mentioned above. Product identification, product information and a means to linking this information are referenced directly or indirectly in the text.

3. Would these objectives be met even more adequately, if traceability/product tracing elements were included/strengthened?

As mentioned in 1 above, information about the destination of lots/shipments can be useful in order to trace products similar to those rejected. This is especially relevant if the rejection is due to food safety reasons. Furthermore, a better linkage between product identification and product information can prevent misunderstanding and limit the size of the rejected shipment. It could thus be concluded that the objectives of the text could be met even more adequately if traceability/product tracing elements were strengthened.

4. Are there other methods that would be more appropriate? No

5. Are there gaps in the text with regards to traceability/product tracing? Yes, see 3 above.

6. What are the options, if gaps are identified?

An option would be to complete the guidelines with information about the intended destination of rejected foods and about the linkages between product identification and product information. The other option would be the elaboration of a general guidelines document on traceability/product tracing.

¹⁰ There is adequate information on where the product came from and on the reasons for the rejection. However, the text provides limited guidance on information regarding where the product was sent to, or was supposed to be sent to. This last information would be useful to have when considering the action to be taken regarding similar products from previous shipments.

6. GUIDELINES FOR GENERIC OFFICIAL CERTIFICATE FORMATS AND THE PRODUCTION AND ISSUANCE OF CERTIFICATES (ALINORM 01/30A, APPENDIX II, ADOPTED AT STEP 8-CAC 2001)

Objectives of the text

These guidelines concern the design and use of official and officially recognised certificates that attest to attributes of food presented for international trade.

Paragraph 2 states that certificates should be required only where declarations are necessary relating to product safety or suitability for consumption, or to otherwise facilitate fair trade. Paragraph 4 mentions both, the use of paper or electronic forms of certification. Paragraph 6 outlines principles which determine the necessity for certificates. It is further stated that certificates should be designed and used in a manner that provides for accurate identification of the consignments being certified. Paragraph 16 outlines the information which should be included in the details of the consignment. The details of the product being certified should at least contain the following information: nature of the food; name of the product; quantity; lot identifier or date coding; identity and location of the production establishment; name and contact details of both the importer or consignee and exporter or consignor; the country of dispatch and the country of destination.

Paragraph 17 also provides guidance on the exceptional cases, justified by immediate public health concerns, where a statement of origin may be justified. Paragraph 18 outlines particular attestations, such as health status and product conformity with particular standards, production or processing requirements that should be clearly identified in the text of the certificate.

1. Does the text address elements of traceability/product tracing?

The text makes direct reference to product identification elements and indirectly references elements of product information, e.g., statement of origin, conformity to particular standards.

2. Does the existing text adequately cover the elements of traceability/product tracing with respect to the objectives of the text?

Yes. The objectives of the text relate to the provision of essential information relating to food safety and facilitation of trade, without imposing unnecessary burdens on the exporting country or exporter. As such, the product identification and information elements are adequately covered for the purpose of this document.

3. Would these objectives be met even more adequately, if traceability/product tracing elements were included/strengthened? No

4. Are there other methods that would be more appropriate? Not applicable.

5. Are there gaps in the text with regards to traceability/product tracing? No

6. What are the options, if gaps are identified? Not applicable.

7. GUIDELINES FOR FOOD IMPORT CONTROL SYSTEMS (ALINORM 03-30 APPENDIX II, ADOPTED AT STEP 8, CAC 2003)

Objectives of the text:

The objective of these Guidelines is to provide a framework for the development and operation of an import control system to protect consumers and facilitate fair practices in food trade while ensuring that unjustified technical barriers to trade are not introduced.

Paragraph 9 states that the object of legislation is to provide the basis and the authority for operating a food import control system. The legal framework allows for the establishment of the competent authority(ies) and the processes and procedures required to verify the conformity of imported products against requirements.

Paragraph 21 provides guidance on the information required concerning the food to be imported. Details of the consignments that may be obtained include: the date and point of entry; the mode of transport; a comprehensive description of the commodity (including for example product description, amount, means of preservation, country of origin and/or of dispatch, identifying marks such as lot identifier or seal identification numbers, etc.); exporter's and importer's name and address; manufacturer and/or producer, including establishment registration number; destination; and, other information. Paragraph 38 states that a clear rationale should exist if a product registration system exists or is implemented.

1. Does the text address elements of traceability/product tracing?

All elements of traceability/ product tracing are addressed in the text either directly, as per the product identification and product information elements in paragraph 21, or indirectly, as per the linkage of this information to permit recall of consignments following importation (paragraph 10, 9th bullet point). While some elements are considered important to contribute to the efficacy of the control programme, other elements, e.g., the product registration system mentioned in paragraph 38, are considered optional and a clear rationale for their existence is required.

2. Does the existing text adequately cover the elements of traceability/product tracing with respect to the objectives of the text?

Yes. The objectives of the text are to provide guidance on the development and operation of an import control system to protect consumers and to facilitate fair practices in the food trade, while ensuring that unjustified technical barriers to trade are not introduced. As such, there is adequate mention of those elements of traceability/ product tracing considered necessary for an effective and efficient system without being prescriptive regarding any particular traceability/product tracing system.

3. Would these objectives be met even more adequately, if traceability/product tracing elements were included/strengthened? No

4. Are there other methods that would be more appropriate? Not applicable.

5. Are there gaps in the text with regards to traceability/product tracing? No

6. What are the options, if gaps are identified? Not applicable.

**8. GUIDELINES ON THE JUDGEMENT OF EQUIVALENCE OF SANITARY MEASURES ASSOCIATED WITH FOOD INSPECTION AND CERTIFICATION SYSTEMS
(ALINORM 03/30A APPENDIX II, ADOPTED AT STEP 8, CAC 2003)**

Objectives of the text:

The objective of this text is to provide guidelines on the judgement of the equivalence of sanitary measures associated with food inspection and certification systems, in cases where the systems operated by importing and exporting countries are different.

Paragraph 5 provides guidance on the information required by authorities to assess equivalence of sanitary measures associated with food inspection and certification systems.

Paragraph 13 states that for the purpose of determining equivalence, the sanitary measures associated with a food inspection and certification system can be broadly characterized as infrastructure; including the legislative base (e.g., food and enforcement law), and administrative systems; programme design, implementation and monitoring including documentation of systems, monitoring, provisions for certification and audit; etc., and specific requirements; including requirements applicable to individual facilities, equipment, processes, (e.g. HACCP plans), procedures (e.g. ante- and post-mortem inspection), tests and methods of sampling and inspection).

1. Does the text address elements of traceability/product tracing?

The text does not directly or indirectly address elements of traceability/ product tracing. It may be assumed that within the three broad categories of sanitary measures (refer to notes on paragraph 13 above) that are being examined, there may well be different elements of traceability/product tracing, however, this document deals strictly with guidelines to judge equivalence.

2. Does the existing text adequately cover the elements of traceability/product tracing with respect to the objectives of the text?

Yes. As a general text dealing with how sanitary measures might be judged for equivalence, there is no need for specific reference to elements of traceability/ product tracing. Hence, with respect to the objectives of the text, the lack of reference to traceability/ product tracing does not impact on the text.

3. Would these objectives be met even more adequately, if traceability/product tracing elements were included/strengthened? No

4. Are there other methods that would be more appropriate? Not applicable.

5. Are there gaps in the text with regards to traceability/product tracing? No

6. What are the options, if gaps are identified? Not applicable

The following CCFICS draft texts **were not** analysed:

9. PROPOSED DRAFT GUIDELINES ON THE JUDGEMENT OF EQUIVALENCE OF TECHNICAL REGULATIONS ASSOCIATED WITH FOOD INSPECTION AND CERTIFICATION SYSTEMS (CX/FICS 02/11/6)**Status of the document:**

“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” paragraph 45, ALINORM 03/30A.

10. PROPOSED DRAFT REVISION OF THE CODEX GUIDELINES FOR THE EXCHANGE OF INFORMATION IN FOOD CONTROL EMERGENCY SITUATIONS (CX/FICS 02/11/4).**Status of the document:**

“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 Organisations (IACFO)” paragraph 39, ALINORM 03/30A.