codex alimentarius commission



FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS WORLD HEALTH ORGANIZATION



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Agenda Item 7

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS Eleventh Session Adelaide, Australia, 2 – 6 December 2002

DISCUSSION PAPER ON TRACEABILITY/PRODUCT TRACING IN THE CONTEXT OF FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS (Prepared by the CCFICS Working Group on Traceability)

Governments and international organizations are invited to consider the recommendations in the attached discussion paper and provide written comments to the Australian Secretariat no later than <u>30 October 2002</u>. This information should be sent to the Manager, Codex Australia, Agriculture, Fisheries and Forestry - Australia, GPO Box 858, Canberra ACT 2601, Australia (Telefax No. +61 2 6272.3103 or E-mail: codex.contact@affa.gov.au), with a copy to the Secretary of the Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy.

BACKGROUND

1. At its 10th Session (February 2002) the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) agreed to the establishment of a Working Group whose mandate would be to draft a discussion paper on traceability for circulation, comment and further consideration at its next meeting. The Committee agreed that the discussion paper should specifically address:

- the adequacy and applicability of traceability in existing or pending texts under elaboration by the CCFICS;
- on the basis of the above review, the appropriateness for CCFICS to develop specific guidance on the practical implementation of traceability with respect to food import and export inspection and certification systems, with priorities to be developed in the light of above discussion;
- the outcome of the Chairpersons meeting from the relevant Codex Committees that was scheduled to meet prior to the 17th Session of the Codex Committee on General Principles (CCGP) on traceability;
- a time-frame for any new work that CCFICS might undertake with the understanding that this work should not duplicate the work being undertaken by other Committees.¹

2. The following Codex Member Countries and International Observer Organisations are members of the Working Group: Switzerland (Chair), 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

¹ ALINORM 03/30; Paragraph 67

(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).

3. Switzerland, in its capacity as Chair of the Working Group, sent an information letter and request for comments (dated 3rd April 2002) to all members of the Working Group.

4. The following members of the Working Group submitted comments: Argentina, Australia, Brazil, Canada, France, Ireland, The Netherlands, Switzerland, United Kingdom, United States of America, Biotechnology Industry Organisation (BIO) and Council for Responsible Nutrition (CRN).

5. Switzerland prepared a draft discussion paper based on the comments submitted by the Working Group members mentioned above.

MEETING OF THE CCFICS-WORKING GROUP ON TRACEABILITY

6. The Working Group met in Fribourg, Switzerland, from 19 to 20 August 2002 at the invitation of the Government of Switzerland. 60 delegates attended the meeting of the Working Group.

7. The draft discussion paper prepared by Switzerland formed the basis for the discussions at the Working Group meeting. The Working Group also took note of the written comments submitted to the Swiss Secretariat after the circulation of the initial discussion paper. Additional comments were received from India, Japan, Papua New Guinea, Peru, Republic of Korea, Biotechnology Industry Organisation (BIO), Consumers International (CI), International Council of Grocery Manufacturers Associations (ICGMA) and the International Federation for Animal Health (IFAH).

8. The 11th Session of the CCFICS is invited to consider the framework, outlined in the discussion paper, as a basis for further analysis of CCFICS texts and to consider the merit of circulating the agreed framework to other Codex committees for consideration/information.

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

Scope

1. [The scope of this discussion paper relates to the application of "traceability/product tracing" within the mandate and objectives of the Codex Alimentarius Commission, that is the protection of the health of consumers and ensuring fair practices in the food trade. Both of these objectives are considered within the specific mandate of the Codex Committee on Food Import and Export Inspection and Certification Systems.]

1. [The scope of this discussion paper relates to the adequacy and application of "traceability/product tracing" in existing or pending texts under elaboration by the Codex Committee on Food Import and Export Inspection and Certification Systems and, on the basis of this review, the appropriateness for CCFICS to develop specific guidance on the practical implementation of traceability with respect to food import and export inspection and certification systems.]

Background on Terminology

2. The term "traceability" is specifically referenced in the terms of reference and mandate given to the CCFICS Working Group on Traceability by CCFICS at its 10th Session (Paragraph 67, ALINORM 03/30). Due account has been given to the agreement reached by the Executive Committee at its 50th Session (Paragraph 41, ALINORM 03/3A) to add the term "product tracing" alongside the term "traceability" and to the comments submitted by Working Group members in favour of the term product tracing. Therefore, the **working terminology** used in this discussion paper is "**traceability/product tracing**".

Discussion on the Working Definition of Traceability/ Product Tracing

3. There is no agreed Codex definition for "traceability/product tracing". The Codex Executive Committee recognised this in their discussion of "traceability/product tracing" and expressed the view that any measure requiring "traceability/product tracing" should be either justified as an SPS measure having a food safety objective or a legitimate objective consistent with the TBT Agreement². However, the Codex Alimentarius has yet to develop a definition for "traceability/product tracing" which could be applied within the whole Codex System. This task should be undertaken by the Codex Committee on General Principles (CCGP).

4. At its last session held in Paris France, April 2002, the CCGP requested the Codex Secretariat to prepare a discussion paper considering how the Committee could best contribute to the consideration of "traceability/product tracing" in Codex, taking into account the work of other relevant Committees. The Secretariat was also asked to provide a draft definition for Codex use³. [In reply to a question on the role of Regional Co-ordinating Committees, the Secretariat recalled that these Committees might wish to contribute to the debate, as agreed by the Executive Committee, and they would therefore be invited to discuss this question. The results of these discussions would be integrated into the document prepared for the Committee].

5. [The Working Group used a provisional working definition for "traceability/product tracing" for the sole purpose of discharging its mandate.]

6. The International Organisation for Standardisation (ISO 9000: 2000) defines traceability as the "*ability* to trace the history, application or location of that which is under consideration.

Note 1 When considering product (3.4.2.), traceability can relate to

- the origin of materials and parts,
- the processing history, and
- the distribution and location of the product after delivery".

² ALINORM 03/3, Paragraphs 29-33

³ ALINORM 03/33, Paragraph 12

7. Taking into account the decision by the Executive Committee to assign the responsibility for developing a definition for "traceability/product tracing" to CCGP, and in order to guide its review of the adequacy and applicability of "traceability/product tracing" in existing or pending texts under elaboration by CCFICS, the Working Group considered the following possible elements with regard to "traceability/product tracing": 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 will depend on the objectives being pursued by the individual texts.

Adequacy and Applicability of Traceability/Product Tracing within CCFICS

8. The Codex Alimentarius Commission has adopted the following definitions⁴ which relate to the mandate of CCFICS:

Inspection is the examination of food or systems for control of food, raw materials, processing and distribution, including in process and finished product testing, in order to verify that they conform to requirements.

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

Requirements are the criteria set down by the competent authorities relating to trade in foodstuffs covering the protection of public health, the protection of consumers and conditions of fair trading.

9. [In terms of the above-given definitions, "traceability/product tracing" may have a key contribution to make in relation to effective implementation of these requirements.]

Traceability/Product Tracing in Adopted Codex (CCFICS) Texts

10. Below are examples of provisions contained in adopted Codex texts, elaborated by CCFICS, for which "traceability/product tracing" may assist in implementation:

A. **Principles for Food Import and Export Inspection and Certification (CAC/GL 20-1995)**: This text sets out some principles whose objective is to ensure that food inspection and certification systems 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.

Section 1 of the text recognises 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. 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 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

⁴ CAC/GL 20-1995, Principles for Food Import and Export Inspection and Certification, Section 2-Definitions.

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 with requirements. Measures by importing countries may include point of entry inspection systems, audit of exporting inspection systems, and ensuring that certificates themselves are authentic and accurate.

B. Guidelines for the Exchange of Information between Countries on Rejections of Imported Food (CAC/GL 25-1997): 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 to identify the food concerned and importation details, including a description of the nature and quantity of food, lot identification, other identification stamps, marks or numbers, name and address of the exporter and/or food producer, manufacturer, importers or sellers and date and place of entry. Additional information in relation to these factors is contained in the Annex to CAC/GL 25-1997.

C. Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (CAC/GL 26-1997): The objective of this text is to 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. They are intended to assist countries in the application of requirements and the determination of equivalency, thereby protecting consumers and facilitating trade in foodstuffs.

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 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 including raw materials, ingredients, technological aids and other products used for the preparation and production of foodstuffs; labelling integrity and claims. Paragraphs 32, 33, 34 and 35 provide guidance on the decision criteria of control programmes 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.

D. Guidelines for the Development of Equivalence of Agreements Regarding Food Import and Export Inspection and Certification Systems (CAC/GL 34-1999): The objective of this text is to provide practical guidance to governments that desire to enter into bilateral or multilateral equivalence agreements with respect to food import and export inspection and certification systems and it provides 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. The guidance does not refer specifically to "traceability/product tracing". The text does state however, that participants in an equivalence agreement should agree to procedures for information exchange in the event of a food emergency control situation.

E. Guidelines for the Exchange of Information in Food Control Emergency Situations (CAC/GL 19-1995): The objective of this text is to ensure the rapid exchange of information to minimise impacts on human health and to rapidly identify and remove concerned foodstuffs from the market through prompt notification of appropriate authorities about identified risks of serious untoward health effects associated with the consumption of certain foods.

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, as listed in the Annex to these Guidelines which is entitled "Standard Format for Information Exchange in Food Control Emergency Situations". These information elements include description and quantity of products; type and size of package; lot identification; other identification marks/stamps including container and shipping details; and, name and address of producer, manufacturer seller, or importer as appropriate.

F. Guidelines for Generic Official Certificate Formats and the Production and Issuance of Certificates (ALINORM 01/30A adopted at Step 8-CAC 2001): The objective of this text is to provide a basis for certifications for the food trade.

Paragraph 2 refers to the scope, which includes 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 of requirements, specifically stating that certificates should be designed and used in a manner that provides for accurate identification of the consignments being certified. The details of the product being certified should at least contain the following information (Paragraph 16): nature of the food; name of product; quantity; lot identifier or date coding; identity and location of the production establishment; name and contact details of both, the importer and exporter or consignee and consignor; country of dispatch and country of destination. Paragraph 17 also provides guidance on statement of origin. 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.

Traceability/Product Tracing in Draft CCFICS Texts which are Advanced in the Codex Step Procedure

11. Below are examples of provisions contained in draft CCFICS texts for which "traceability/product tracing" may assist in implementation. Only draft CCFICS texts, which are at an advanced stage in the Codex step procedure have been analysed:

A. Proposed Draft Guidelines for Food Import Control Systems (Advanced to Step 8, ALINORM 03-30 Appendix II): The objective of this draft text 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 including the date and point of entry; mode of transport; comprehensive descriptions 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, and destination. Paragraph 38 states that a clear rationale should exist if a product registration system is required.

B. Proposed Draft Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems (At Step 5, ALINORM 03-30 Appendix III): The objective of this draft 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 7 provides guidance on the information required by authorities to assess equivalence of sanitary measures including broad categorisation of sanitary measures associated with a food inspection and certification system: infrastructure (e.g. the legislative basis and administrative systems); programme design, implementation and monitoring (e.g. documentation of systems, provisions for certification and audit); and/or specific requirements (e.g. processes, such as HACCP plans, procedures, tests and methods of sampling and inspection).

Traceability/Product Tracing in Draft CCFICS Texts which are at an early stage in the Codex Step Procedure

12. The following draft texts under elaboration by CCFICS may contain provisions relating to "traceability/product tracing". Due to their early stage in the Codex step procedure these texts have not been examined in detail.

- A. Proposed Draft Guidelines on the Judgement of Equivalence of Technical Regulations Associated with Food Inspection and Certification Systems (CX-FICS 02/5);
- **B.** Proposed Draft Guidelines for the Utilisation and Promotion of Quality Assurance Systems to Meet Requirements in Relation to Food (CX-FICS 02/6); and
- C. Proposed Draft Revision to the Guidelines for the Exchange of Information in Food Control Emergency Situations (CX-FICS 02/7).

Analysis and Conclusions

13. The majority of references in CCFICS texts address the issues of information exchange, product identification for recall purposes, or process control for the purpose of both food safety and non-food safety issues. Within each of these broad areas, information needs are identified, which in some circumstances will contribute to the ability to trace a product according to the information provided. There is a further specified requirement that the systems developed for these purposes are audited to verify that the information provided is consistent with requirements and is not fraudulent.

14. The current CCFICS texts neither require a specific "traceability/product tracing" system nor set out guidelines for the establishment of "traceability/product tracing" systems. The collection and collation of information outlined in each of the existing and pending texts related to a specific product varies. This reflects the fact that "traceability/product tracing" requirements were developed on a case-by-case basis, as necessary, to address specific objectives for which the CCFICS texts were written.

15. With a view to fulfilling the objectives outlined in the individual texts and pending the development of a definition of "traceability/product tracing", the existing provisions of adopted Codex Texts, elaborated by CCFICS, and draft CCFICS texts, as indicated in Paragraphs 10 and 11, were analysed. The Working Group also took into account the various elements of "traceability/product tracing" as referenced in Paragraph 7.

Framework

16. The Working Group agreed on the following framework for the review of the CCFICS texts referenced in Paragraphs 10 and 11 above, with a view to examining the adequacy and applicability of "traceability/product tracing" within CCFICS:

- i. Does the text address "traceability/product tracing" (elements of Paragraph 7 above)?
- 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 any gaps in the text with regard to "traceability/product tracing"?
- vi. What are the options, if gaps are identified?

Working Group Recommendation

17. The working document was extensively discussed by the Working Group. However, due to time constraints, the Working Group could not fulfil its mandate as given in Paragraph 67, ALINORM 03/30. The Working Group was unable to undertake a full review of the CCFICS texts based on the framework referenced in Paragraph 16 above, with a view to considering the adequacy and applicability of "traceability/product tracing" within CCFICS. The Working Group also felt that other CCFICS members

may wish to comment on the work it had undertaken so far. Nonetheless, considerable progress was made and the Working Group put forward this discussion paper to be examined by the CCFICS at its 11th Session, scheduled to be held in Australia in December 2002.

18. While acknowledging the fact that the final decision on how to proceed lies with the CCFICS, the Working Group recommends that CCFICS adopt the framework (Paragraph 16) as a basis for further analysis of CCFICS texts by the Working Group with a view to fulfilling its mandate, and suggests that the CCFICS considers the merit of circulating the agreed framework to other Codex Committees.