

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD  
HEALTH  
ORGANIZATION



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**Agenda Item 2**

**CX/FICS 02/11/2  
November 2002**

## **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**

### **MATTERS REFERRED FROM THE EXECUTIVE COMMITTEE OF THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES**

#### ***PREPARATION OF THE MEDIUM TERM PLAN FOR 2003-2007***

#### **OBJECTIVE 1: PROMOTING SOUND REGULATORY FRAMEWORKS**

##### ***Activity 22 – Traceability***

1. The 50<sup>th</sup> Session of the Executive Committee (June 2002) agreed<sup>1</sup> to add the term "product tracing" in the title as it was consistent with the terms under consideration in other Codex Committees. Some Members supported the written comments of the United States and proposed to consider traceability as a priority for public health reasons and secondarily as a legitimate objective in a technical measure. The Member from Europe expressed the view that both aspects should be addressed and that no distinction should be established as to their importance.
2. After an exchange of views, the Executive Committee agreed to retain both aspects without mentioning priorities and to indicate that first consideration should be given to the use of traceability as a food safety risk management option, as already agreed at its 49<sup>th</sup> Session.
3. The 23<sup>rd</sup> Session of the Coordinating Committee for Europe (September 2002) agreed<sup>2</sup> that the reference to "tracing of food products" should be replaced with the terms traceability/product tracing in order to ensure consistency throughout Codex. Several delegations pointed out that although first consideration would be given to traceability/product tracing as a food safety risk management option, as agreed by the Executive Committee, this was a time issue and did not imply an order of priority. The Committee agreed that all applications of traceability/product tracing were equally important and that Codex work should not be limited to risk management aspects. The Committee therefore agreed that the last sentence should be deleted as it might create confusion concerning priorities. The Committee also proposed to amend the date of completion for this activity, as some committees had only recently started work on traceability/product tracing and it was unlikely to be completed by 2005.

<sup>1</sup> ALINORM 03/3A, paras. 32-61.

<sup>2</sup> ALINORM 03/19, paras. 17-18.

4. At the 13<sup>th</sup> Session of the Coordinating Committee for Asia (September 2002), it was stated<sup>3</sup> that the wording be amended in order to “establish international principles and guidelines for the tracing of food products/ food ingredients through various links in the food chain for having either a food safety objective or a legitimate objective as a TBT measure”.

5. The 7<sup>th</sup> Session of the Coordinating Committee for North America and the South West Pacific (October 2002) was of the opinion<sup>4</sup> that this activity as worded was premature in light of consideration being given to the issue in other Codex Committees. The Coordinating Committee recommended that this activity be reworded so as to read:

“Review the need for, and as appropriate, establish international principles and guidelines for tracing of food products/ingredients through various links in the food chain for public health reasons as a risk management option or having a legitimate objective as a technical measure: First consideration should be given to product tracing as a risk management option.”

6. The Coordinating Committee also recommended that the performance indicator for this activity should be reworded so as to read:

“As appropriate, principles/guidelines drafted by CCGP and CCFICS in association with other Committees.”

#### ***Activity 27 – Judgement of Equivalence***

7. The 50<sup>th</sup> Session of the Executive Committee agreed to describe the activity as the "development of guidelines" rather than their "application". Some Members questioned the need to develop specific guidelines for the judgement of equivalence of measures. The Executive Committee also discussed the proposal for specific Committees to develop such guidelines, although it was noted that the Committee on Food Hygiene was considering some aspects of equivalence of food hygiene measures. The Executive Committee did not come to a conclusion and agreed that further consideration should be given to this complex question.

8. At the 13<sup>th</sup> Session of the Coordinating Committee for Asia it was stated<sup>5</sup> that efforts should instead be concentrated on generic guidelines and therefore proposed that this activity should be deleted from the Medium-Term Plan.

9. The 7<sup>th</sup> Session of the Coordinating Committee for North America and the South West Pacific (October 2002) recommended<sup>6</sup> that the scope of the activity should be extended to cover food safety requirements as well as essential quality requirements. However, in pursuing this Activity it was also recommended that careful attention be paid to the on-going work of the Committee on Food Import and Export Inspection and Certification Systems and the development of generic rather than specific guidelines in this area.

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<sup>3</sup> ALINORM 03/15, para. 40.

<sup>4</sup> ALINORM 03/32, paras. 32-33.

<sup>5</sup> ALINORM 03/15, para. 42.

<sup>6</sup> ALINORM 03/32, para. 35.

## **OBJECTIVE 2 – PROMOTING WIDEST AND CONSISTENT APPLICATION OF SCIENTIFIC PRINCIPLES AND RISK ANALYSIS**

### ***Activity 2 – Review Codex Standards to Provide Risk Management Options to Achieve National ALOPs***

10. Some Members of the 50<sup>th</sup> Session of the Executive Committee proposed to delete this activity because the determination of the Appropriate Level of protection was the responsibility of member states and it was not clear how this task could be carried out in the framework of Codex Committees. The Executive Committee deleted this Activity and also noted a comment that this could be addressed through capacity building at the national level.

## ***DISCUSSIONS CONCERNING TRACEABILITY/PRODUCT TRACING IN OTHER CODEX COMMITTEES***

### **BACKGROUND**

11. The 49<sup>th</sup> (Extraordinary) Session of the Executive Committee (October 2001) discussed how to address the general issue of traceability in the framework of Codex on the basis of a document prepared by the Codex Secretariat. The Executive Committee recommended that the Committee on General Principles consider the following aspects of traceability: as a food safety objective (i.e., as an SPS measure); and as a legitimate objective as a TBT measure. However, the Executive Committee was of the opinion that the first consideration should be given to the use of traceability as a risk management option in the Working Principles for Risk Analysis and also noted that the role of Committee on Food Import and Export Inspection and Certification Systems. The Executive Committee agreed that the Committees concerned (including the Committees on General Principles, Food Import and Export Inspection and Certification Systems, Food Hygiene and Labelling) should undertake work as they deemed appropriate, within their respective mandates (ALINORM 03/3, paras. 29-33).

### **CODEx COMMITTEE ON FOOD HYGIENE**

12. The 34<sup>th</sup> Session of the Committee on Food Hygiene (October 2001) recalled its previous decision that traceability would be considered in the context of its work on the proposed draft *Principles and Guidelines for the Conduct of Microbiological Risk Management*. However, the Committee was of the opinion that specific work on traceability as related to food hygiene was premature. The Committee therefore reiterated its request to the drafting group that the concept of traceability should be taken into account in the further elaboration of the above Principles and Guidelines (ALINORM 03/13, paras. 170-171).

### **CODEx AD HOC INTERGOVERNMENTAL TASK FORCE ON FOODS DERIVED FROM BIOTECHNOLOGY**

13. The 3<sup>rd</sup> Session of the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology (March 2002) considered the issue of traceability in the framework of the *Draft Principles for the Risk Analysis of Foods Derived from Modern Biotechnology* (Section III - Principles - Risk Management).

14. The Task Force was of the opinion that the resolution of this issue was important in order to reach a final conclusion on the text of the Draft Principles. It noted that the addition of a new paragraph after paragraph 20 concerning tools for the implementation and enforcement of risk management measures made it possible to place the question of traceability into context as a one of these tools, leaving aside its use for other purposes. On this basis a compromise text was drafted and accepted by the Task Force. In drafting this compromise text, the Task Force recognized that there were applications of product tracing (traceability) other than the risk management of foods derived from biotechnology, and that these applications be consistent with the provisions of the SPS and TBT Agreements. The Task Force noted that further consideration of these broader issues would continue within Codex (ALINORM 03/34, paras. 22-29, and Appendix II).

15. The following paragraphs and footnote were therefore included in the Draft Principles for the Risk Analysis of Foods Derived from Modern Biotechnology:

20. Post-market monitoring may be an appropriate risk management measure in specific circumstances. Its need and utility should be considered, on a case-by-case basis, during risk assessment and its practicability should be considered during risk management. Post-market monitoring may be undertaken for the purpose of:

- *verifying conclusions about the absence or the possible occurrence, impact and significance of potential consumer health effects; and*
- *monitoring changes in nutrient intake levels, associated with the introduction of foods likely to significantly alter nutritional status, to determine their human health impact.*

21. Specific tools may be needed to facilitate the implementation and enforcement of risk management measures. These may include appropriate analytical methods; reference materials; and, the tracing of products<sup>7</sup> for the purpose of facilitating withdrawal from the market when a risk to human health has been identified or to support post-market monitoring in circumstances as indicated in paragraph 20.

16. The Task Force finalized the Draft Principles for the Risk Analysis of Foods Derived from Modern Biotechnology and the Draft Guideline for the Conduct of Food Safety Risk Assessment of Foods Derived from Recombinant-DNA Plants and advanced them to Step 8 for adoption by the 25<sup>th</sup> Session of the Codex Alimentarius Commission.

#### **CODEX COMMITTEE ON GENERAL PRINCIPLES**

17. The 17<sup>th</sup> Session of the Codex Committee on General Principles (April 2002) discussed the need to undertake work on traceability/product tracing in the light of the recommendations of the Executive Committee. The Committee discussed in particular whether it should be considered in the framework of risk management as a matter of priority or whether it should be used for other purposes, such as the authenticity of consumer information. The Committee agreed that the Secretariat should prepare a discussion paper for further consideration of this issue at its next session. During the discussion, it was agreed that the results of the discussion in Regional Coordinating Committees would be integrated in the document prepared for consideration by the Committee (ALINORM 03/33, paras. 5-13).

#### **CODEX COMMITTEE ON FOOD LABELLING**

18. The 30<sup>th</sup> Session of the Codex Committee on Food Labelling (May 2002) considered a background paper prepared by Canada presenting the status of current discussions in Codex Committees. Some delegations proposed to undertake new work on traceability as it was especially relevant for the purposes of labelling, while other delegations expressed the view that it was premature since work was already underway in other committees. Some delegations pointed out that product tracing should be considered primarily as a risk management measure and that further clarification was needed on its application for other purposes before undertaking new work. The Committee could not come to a consensus and agreed to circulate the background document prepared by Canada for comments and to discuss the matter further at its next session (ALINORM 03/22, paras. 4-9).

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<sup>7</sup> It is recognised that there are other applications of product tracing. These applications should be consistent with the provisions of the SPS and TBT Agreements. The application of product tracing to the areas covered by both Agreements is under consideration within Codex on the basis of the decisions of 49th Session of the Executive Committee.

## **CODEx COMMITTEE ON FISH AND FISHERY PRODUCTS**

19. The 25<sup>th</sup> Session of the Codex Committee on Fish and Fishery Products (June 2002) considered the Draft Code of Practice for Fish and Fishery Products, which includes general requirements and incorporates all current codes of practice for fish and fishery products, surimi and aquaculture. Section 3 of the Code describes the Pre-Requisite Programme based on good hygienic practice that should be established prior to the application of the HACCP system. The Committee agreed to include provisions for product tracing under Section 3.7 *Product Tracing and Recall*. The Section initially referred to "traceability" but the Committee agreed that the reference to product tracing was adequate for the purposes of the Code, taking into account the approach taken in the Intergovernmental Ad hoc Task Force on Foods Derived from Modern Biotechnology. The section refers to product tracing, lot identification and recall in order to allow an effective recall procedure and to address health hazards when applicable. The Draft Code (general sections and three specific sections) was advanced to Step 8 for adoption by the 25<sup>th</sup> Session of the Commission (ALINORM 03/18, para. 58 and Appendix II).

## **CODEx AD HOC INTERGOVERNMENTAL TASK FORCE ON ANIMAL FEEDING**

20. The 3rd Session of the Codex Ad Hoc Intergovernmental Task Force on Animal Feeding (June 2002) considered the Proposed Draft Code of Practice on Animal Feeding, currently at Step 3 of the Procedure, which contains an extensive section on "Traceability (product tracing) and Record Keeping of Feed and Feed Ingredients" (Section 4.3). The objective of the provision is to facilitate the prompt trace-back or trace-forward of materials and products if any actual or potential health risks are identified, and prompt and complete withdrawal or recall of products where necessary (ALINORM 03/38, paras 50-51 and Appendix II).

## **COORDINATING COMMITTEE FOR EUROPE**

21. The 23<sup>rd</sup> Session of the Coordinating Committee for Europe (September 2002) agreed that traceability/product tracing could be used for the purposes of food safety or as another legitimate objective, for example to ensure the authenticity of the product. Both aspects were equally important and should be addressed in the framework of Codex, while ensuring coordination with other international organizations in this area, especially ISO. In the framework of Codex, the Codex Committee on General Principles should provide overall guidance to Codex Committees on the definition and application of traceability/product tracing and the CCFICS should proceed with its work to develop further the main elements identified in the their discussion paper (ALINORM 03/19, paras. 30-32).

## **COORDINATING COMMITTEE FOR ASIA**

22. The 13<sup>th</sup> Session of the Coordinating Committee for Asia (September 2002) expressed the view that comprehensive application of traceability would not serve the desired purposes and so it shall be applied strictly on a case-to-case basis after taking account all the following five criteria (ALINORM 03/15, paras. 75-85):

- The nature and extent of risk has to be determined on the basis of specific risk assessment and only after this assessment should a product be considered for traceability.
- It should be demonstrated that traceability was an effective management option for the identified risk and that there was no other more cost effective alternative to manage that risk.
- The extent of application of traceability in the food chain should be clearly listed out on the basis of the risk assessment, practical applicability and the cost effectiveness.
- The cost/benefit analysis should be worked out in advance before traceability is considered for a particular product.
- There should be a clear demonstration of the fact that traceability tracing will not be used as a technical barrier to trade.

## **COORDINATING COMMITTEE FOR NORTH AMERICA AND THE SOUTH WEST PACIFIC**

23. The 7<sup>th</sup> Session of the Coordinating Committee for North America and the South West Pacific (October 2002), as a result of its discussions, agreed<sup>8</sup> that the following should be brought forward with respect to product tracing to inform CCFICS, CCGP and other Codex committees, as appropriate, as they discuss the issue of product tracing relative to their particular responsibilities and mandates.

- a) That the term “product tracing” is the appropriate terminology to employ for the concept of the tracing of food products and/or their ingredients. The Codex Ad-Hoc Intergovernmental Task Force on Foods Derived from Biotechnology reached consensus on the use of this term and, subsequently, the term is gaining acceptance within Codex.
- b) In considering product tracing, Codex should give priority to considering its use as a tool with respect to risk management.
- c) That product tracing<sup>9</sup> can be considered to include the following possible elements:
  - The ability to identify a food (product identification);
  - How the food product was changed, if appropriate; and, where the food product came from and to where it was sent - one step forward and one step backward (product information); and,
  - Linkages between product identification and product information.
- d) That the use of product tracing within a food control system be consistent with the provisions of the WTO SPS and TBT Agreements. In this regard, provisions relating to product tracing should, as appropriate to the application:
  - Be science based.
  - Be consistent with fair trade practices criteria.
  - Be subject to equivalence determinations.
  - Be no more trade restrictive than necessary.
- e) That product tracing is not a stand-alone activity, i.e., it is a tool that may be applied within a broader food control system.
- f) That product tracing requirements must have clear justification with respect to food safety and/or ensuring fair practices in food trade.
- g) That the need for and scope of application and specifications regarding each element of product tracing should be considered on a case-by-case basis according to the objective(s) of the food control system within which product tracing is implemented. For example, whether product tracing should be applied within a specific portion of the food chain or whether such tracing may be required across two or more links in the food chain would be dependent on the objectives to be achieved by the food control system.
- h) That decisions on whether a mandatory product tracing system should be implemented should be based on whether such an approach is necessary to achieve the objectives of the food control system.
- i) That certain other considerations may apply to product tracing, including, for example, that product tracing be:
  - Outcomes based;
  - Cost effective;
  - Practical; and,
  - Enforceable.

#### ***CONSIDERATION OF TRACEABILITY/PRODUCT TRACING IN***

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<sup>8</sup> ALINORM 03/32, paras. 51-52

<sup>9</sup> CX/FICS 02/11/7, *Discussion Paper on Traceability/Product Tracing in the Context of Food Inspection and Certification Systems*, paragraph 7.

## ***OTHER INTERNATIONAL ORGANIZATIONS***

### **INTERNATIONAL ORGANIZATION FOR STANDARDIZATION (ISO)**

24. The standard definition of "Traceability" used by the Secretariat in its paper to the Executive Committee has since been modified by the ISO with the publication of the new ISO 9000:2000 series of Quality Management Standards. The new Definition is as follows:

**Traceability:** 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.

NOTE 2 In the field of metrology the definition in VIM:1993,6.10, is the accepted definition."

25. ISO Technical Committee 34 on Food Products is also developing a standard on "Traceability system in the agriculture food chain -- General principles for design and development (ISO/AWI 22519)".