

# codex alimentarius commission



FOOD AND AGRICULTURE  
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JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 6

CX/GP 04/20/6

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON GENERAL PRINCIPLES

Twentieth Session  
Paris, France, 3 - 7 May 2004

### DEFINITION OF TRACEABILITY/PRODUCT TRACING OF FOODSTUFFS (Prepared by France)

Governments and international organizations wishing to provide comments should do so in writing, preferably by email, to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla 00100 Rome, Italy, Fax: +39 (06) 5705 4593, E-mail: [codex@fao.org](mailto:codex@fao.org) with a copy to the Codex Contact Point for France, SGCI/CODEX, Carré Austerlitz, 2 Boulevard Diderot 75703 Paris Cedex 12, Fax. 33 (0)1 4487 16 04, Email: [sgci-codex-fr@sgci.gouv.fr](mailto:sgci-codex-fr@sgci.gouv.fr), **no later than 29 February 2004**

### BACKGROUND

1. The 49<sup>th</sup> (Extraordinary) Session of the Executive Committee (October 2001) discussed how to address the general issue of traceability/product tracing in the framework of Codex. 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/product tracing as a risk management option in the Working Principles for Risk Analysis and also noted 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<sup>1,2</sup>
2. The 50<sup>th</sup> Session of the Executive Committee (June 2002) agreed to add the term "product tracing after the word "traceability" as it was consistent with the terms under consideration in other Codex Committees. 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/product tracing as a food safety risk management option, as already agreed at its 49<sup>th</sup> Session<sup>3</sup>.

<sup>1</sup> ALINORM 03/3, para. 29-33

<sup>2</sup> CX/GP 03/7, para. 1 & 2

<sup>3</sup> ALINORM 03/3A, para. 41 & 42

3. At its sixteenth session (April 2001), the Codex Committee on General Principles discussed traceability. All Delegations that spoke on this occasion, highlighted the importance of the issue and the importance of a uniform approach to the concept and application of traceability. Individual issues that Delegations and observers believed to be important in the development of the topic included: the place of traceability/product tracing in risk management; the use of traceability/product tracing for product integrity, authenticity and identification; the use of equivalent measures; practicability of traceability, and in particular the feasibility of its application in developing countries; consumer confidence and information concerning the nature and origin of products; the possibility of using traceability/product tracing for liability and redress.

4. The 17<sup>th</sup> Session of the Committee on General Principles (April 2001) 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 discussions in Regional Coordinating Committees would be integrated in the document prepared for consideration by the Committee<sup>5,6</sup>

5. The 18<sup>th</sup> Session of the Committee on General Principles (April 2003) resumed its discussion on "traceability/product tracing", on the basis of a paper prepared by the secretariat to report the views expressed during the sessions of the Regional coordinating Committees<sup>7</sup>. The Committee concluded that there was sufficient support only to proceed with the development of a definition of "traceability/product tracing" for Codex purposes and agreed to establish an open-ended electronic working group under the direction of the Delegation of France to develop a draft for the consideration of the next regular session of the Committee.

6. During its third session (March 2002), the Task Force on Foods Derived from Biotechnology noted that the Executive Committee discussed traceability/product tracing as a general issue confronting Codex. The Task force recalled that the Secretariat paper<sup>9</sup> prepared for the Commission (July 2001) had pointed out that traceability/product tracing was not new to Codex but that it had not been treated in a systematic manner and that any measures requiring traceability/product tracing must be justified as having a food safety objective (i.e., as an SPS measure), or having a legitimate objective as a TBT measure. The Task force noted that the Executive Committee had generally supported the analysis and approach outlined in the Secretariat paper. In the context of its discussion on the Draft Principles for the Risk Analysis of foods derived from modern biotechnology at step 7, the Task Force agreed that the resolution of this issue was important in order to reach a final conclusion on the text of the Draft Principles. It amended the Draft principles to place the question of traceability/product tracing into context as one of the tools for implementation and enforcement of risk management measures, without prejudice to its use for other purposes.

7. During its fourth session (March 2003), the Task force had an open discussion on traceability. In his summary, the Chairperson outlined the main elements of the discussion : consideration of traceability/product tracing had started in this Task Force and there was consensus to continue further discussion in the framework of Codex; traceability/product tracing was an important element to ensure food safety throughout the food chain; it could address the request of consumers for transparency and

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<sup>4</sup> ALINORM 01/33A., para. 13 & 14

<sup>5</sup> ALINORM 03/33, paras. 5-13

<sup>6</sup> CX/GP 03/7, para. 1 & 2

<sup>7</sup> CX/GP 03/7

<sup>8</sup> ALINORM 03/33A para.97

<sup>9</sup> ALINORM 01/21, Part IV- Add.1

<sup>10</sup> ALINORM 03/34, para. 8

<sup>11</sup> ALINORM 03/34, para. 27

improved information; and its implications for developing countries should be further considered, especially to ensure fair trade.

8. At its tenth session (February 2002), the Codex Committee on Food Import and export Inspection and Certification Systems (CCFICS) addressed the issue of traceability/product tracing in the context of food inspection and certification systems. The Committee noted that the concept of “traceability” was already included in many Codex texts and was linked in most cases to product identification and recall procedures, that Codex texts generally did not apply traceability/product tracing to the origin of foods and ingredients although Country of Origin provisions included traceability/product tracing requirements in at least two Codex texts<sup>13</sup>, that traceability/product tracing might also be used to ensure fair practices as it correlated to the prevention of deceptive practices (e.g., organically produced food) as a legitimate objective described by the WTO Agreement on Technical Barriers to Trade. The Australian Secretariat’s paper<sup>14</sup>, tabled at this meeting, described traceability/product tracing as a means to preserve the identity of the food product and according to several definitions adopted by the Commission, the concept of traceability/product tracing might be considered to be included as a requirement. The Committee considered different scenarios to address traceability/product tracing in the context of its mandate such as to acknowledge the fact that inspection and certification may be in some situations be the most efficacious means of implementing a requirement for food to be traceable; to attempt to codify the circumstances in which traceability/product tracing should be applied as a requirement. The Committee decided that a working group led by Switzerland, should draft a discussion paper for circulation, comment and further consideration at its next meeting.

9. At its eleventh session (December 2002), the CCFICS considered the elements, identified by the Working Group, convened by Switzerland (Fribourg, August 2002), related 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 would depend on the objectives being pursued by the individual texts<sup>18</sup>. The Committee agreed that responsibility for the development of a definition for traceability/product tracing rested with the CCGP; that CCFICS was responsible for traceability/product tracing related to food inspection and certification systems, and that existing Codex texts related to food inspection and certification as well as discussions in CCFICS and other Codex Committees and written comments submitted should be taken into account in the determination of the current adequacy and applicability of CCFICS texts related to traceability/product tracing and the need for further work in this area. The Committee reconvened the Working Group on Traceability under the Chairmanship of Switzerland in order to carry out the above review and to complete its mandate. The Working Group should take into account discussions on traceability/product tracing in other relevant Codex committees.

10. At its forty-fourth session (October 2001), the Codex Committee on Food Hygiene recalled the recommendation of the 49<sup>th</sup> Session of the Executive Committee which agreed that it should be for the Committees concerned (including the Codex Committees on General Principles, Food Import and Export Inspection and Certification Systems, Food Hygiene and Food Labelling) to undertake work on traceability/product tracing as they deemed appropriate, within their respective mandates. In this regard, the CCFH noted its previous decision that traceability/product tracing would be considered in

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<sup>12</sup> ALINORM 03/34a, para. 80

<sup>13</sup> ALINORM 03/30, para. 57

<sup>14</sup> CX/FICS 02/INF.2

<sup>15</sup> ALINORM 03/30, para. 58

<sup>16</sup> ALINORM 03/30, para. 60

<sup>17</sup> ALINORM 03/30, para. 67

<sup>18</sup> ALINORM 03/30A, para. 49

<sup>19</sup> ALINORM 03/30A, para. 52

<sup>20</sup> ALINORM 03/30, para. 53

the context of its work on the Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management and was of the opinion that specific work on traceability/product tracing as related to food hygiene was premature. At its forty-fifth session (January 2003), the Committee noted, in the same context, that ongoing discussions within other Codex committees, including the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) and the Codex Committee on General Principles (CCGP), should be taken into account before proceeding further on the proposed definition for product tracing/traceability<sup>22</sup>.

11. At this thirtieth session (May 2002), the Codex Committee on Food Labelling recalled the recommendations of the 49<sup>th</sup> Session of the Executive Committee concerning the consideration of traceability/product tracing in Codex and noted the work undertaken by other committees in this area and that several Codex labelling texts and commodity standards included provisions concerning product tracing, including country of origin. Some delegations and observers pointed out that traceability/product tracing was especially relevant to the work of the Committee in order to ensure the authenticity of labelling ; a more systematic approach was necessary and principles should be defined to ensure consistency in the approach to labelling issues. The work of the Committee on Food Import and Export Inspection and Certification Systems would not address specific labelling issues. They also stressed the importance of the input from the Committee on Food Labelling to facilitate the general debate in the Committee of General Principles. Other delegations and observers expressed the view that it was premature to undertake specific work on traceability/product tracing since the CCGP was expected to provide general guidance for Codex committees and the CCFICS was already working in this area. It was also noted that no definition of traceability/product tracing had been developed for the purposes of Codex work, and that this question should be addressed first by the CCGP<sup>23</sup>. There was no consensus on the need to undertake specific work on traceability/product tracing and food labelling but the Committee agreed that this question should be discussed further at the next session, taking into account the work undertaken by other Committees. The Thirty-first session (May 2003) essentially repeated the same point.

## **GENERAL ISSUES ON TERMINOLOGY AND DEFINITIONS**

12. In its 2003 paper<sup>25</sup>, the Codex secretariat identified two components in the concept of traceability/product tracing : the ability to trace products and the act itself, the success of which relies on the existence of an information system.

13. At its first meeting in Fribourg (August 2002), the working group on traceability/product tracing, in order to fulfill its mandate, had to agree on an interim definition of traceability/product tracing (a "working definition"). The relevance of this achievement was recognized by several Regional Coordinating Committees. In this regard, the Working Group considered the following possible elements: 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.

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<sup>21</sup> ALINORM 03/13, para. 170 & 171

<sup>22</sup> ALINORM 03/13A, para. 91

<sup>23</sup> ALINORM 03/22, para. 4-6

<sup>24</sup> ALINORM 03/22, para. 9

<sup>25</sup> CX/GP 03/7

<sup>26</sup> CX/FICS 02/11/7, para. 7

14. In its 2003 paper<sup>27</sup>, the Codex secretariat noted that the appropriateness of the ISO 9000:2000 definition of "Traceability"<sup>28</sup> for Codex purposes has been questioned. The ISO definition, being very broad, encompasses the concepts in the Secretariat's paper on "traceability/product tracing" discussed by the 49<sup>th</sup> Session of the Executive Committee ; it is possible, however,<sup>29</sup> that the definition is too broad for Codex purposes. The Codex Secretariat suggested the development of an operational definition that would be consistent with the ISO definition, but would be narrower and confined to Codex purposes. This idea received a general support from the Committee at its 18<sup>th</sup> session : Many delegations noted that the general ISO definition was not appropriate for Codex purposes and that the same terminology was used to describe very different systems.

15. Guidelines or principles relating to "traceability/product tracing" would more than likely relate to both aspects (food safety and matters other than food safety) regardless of efforts to theoretically separate the two concepts. Once there is the ability to trace a product, that product can be traced for whatever purpose. The question arises as to the degree of detail required in the record keeping at each step in the production, processing and marketing chain. "Traceability/product tracing" has the benefit, however, of being applicable to the management of previously unforeseen or unidentified risks<sup>33</sup>.

16. The 50<sup>th</sup> Session of the Executive Committee (June 2002) agreed to add the term "product tracing" after the word "traceability", as it was consistent with the terms under consideration in other Codex Committees. During its session held prior to the 18<sup>th</sup> session of the Codex Committee on General Principles, one Regional Coordinating Committee welcomed this addition, since, in its view, this new term would be the appropriate terminology to employ for the concept of the tracing of food products and/or their ingredients. However, other comments emphasised that the terminology surrounding traceability/product tracing was unclear, that this would be a substantial obstacle to achieving consensus and that, moreover, there were substantial problems in understanding the meaning of the term traceability/product tracing in different languages<sup>36</sup>. There was some suggestion that one should not open a semantic discussion, at this stage, and that it would be preferable to reach an agreement on a definition of the system, whatever terminology is used, and on how it should be implemented.

## **PARTICIPATION IN THE ELECTRONIC WORKING GROUP**

17. The 18<sup>th</sup> Session of the Committee on General Principles (April 2003) established an electronic working group, open to all members of Codex and observers, under the direction of the Delegation of France to develop a draft for the consideration of the next regular session of the Committee. The French secretariat issued an invitation to submit initial suggestions, on April 24<sup>th</sup> 2003, to all the

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<sup>27</sup> CX/GP 03/7

<sup>28</sup> *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 (i.e In metrology and laboratory accreditation systems, the term traceability means a process whereby the indication of a measuring instrument (or a material measure) can be compared with a national standard for the measurand in question in one or more stages (International Laboratory Accreditation Conference: ILAC-G2: 1994 Traceability). The ISO definition also refers to this aspect of traceability. This aspect of traceability falls within the terms of reference of the Codex Committee on Methods of Analysis and Sampling, but for the purposes of this paper it will not be discussed further (see ALINORM 01/21 Part IV - Add. 1 footnote 2).

<sup>29</sup> ALINORM 01/21 Part IV - add. 1

<sup>30</sup> CX/GP 03/7 --, para. 7 & 8

<sup>31</sup> ALINORM 03/33A, para. 87

<sup>32</sup> ALINORM 03/33A, para. 89

<sup>33</sup> CX/GP 03/7, para. 9

<sup>34</sup> ALINORM 03/3A, para. 41

<sup>35</sup> CX/GP 03/7, para. 52a

<sup>36</sup> CX/GP 03/7, para. 54

members of Codex, observers, and participants at the last regular session of the CCGP, whose e-mail addresses were available in the listings compiled by the Codex secretariat. A first draft of this paper was sent, on July 16<sup>th</sup> 2003 using the same mailing list. Comments were requested before October, 1<sup>st</sup> 2003.

18. At various stages in the development of this paper, suggestions and comments have been received from Argentina, Australia, Canada, Cuba, Finland, Mexico, Morocco, New Zealand, Spain, United Kingdom, United States, the observer from the European Commission, ALA (Asociación Latinoamericana de Avicultura), EAN International, 49<sup>th</sup> Parallel Biotechnology Consortium.

## **ANALYSIS OF THE WRITTEN COMMENTS RECEIVED FROM PARTICIPANTS**

19. The French secretariat developed a first draft presenting, in outline, the current status of the discussion about traceability/product tracing within the Codex system, and sifting through the available material for clues suitable to help draft a general definition of traceability/product tracing. The resulting content of this working document was but a patchwork of quotations and paraphrases of past Codex meeting reports and working documents, organized accordingly : a Background section summarized the past decisions by the Commission and/or the Executive Committee to manage the discussion on this issue within the Codex system and recalled the responses from the various subsidiary bodies concerned (para. 1-11 above). A shorter section on general issues of terminology and definition analysed the (somewhat meagre) material directly relevant to the task at hand. The definition itself (in English, French, and Spanish) was placed in Appendix 1.

20. During the development of this paper, it became obvious that a coherent narrative of past exchanges of view on traceability/product tracing within Codex could not be presented (and the usefulness of this working document as an user-friendly reference document for members of Codex and observers on this issue would be seriously compromised), if opinions and comments on the subject of traceability/product tracing, expressed repeatedly by many members or observers of Codex on various occasions, but clearly irrelevant to the fulfilment of the work at hand, were not recalled in the document.

21. The decision was taken, by the French secretariat, to review this (abundant) material in a separate Appendix (Appendix 2). The difference of status of this Appendix 2 was duly noted by some members, in their comments submitted in response to the first draft : They concurred with the assessment of the French secretariat that, although its content raised some interesting points that would benefit from further discussion, this part of the paper add nothing to the debate on the proposed definition. They questioned the need to retain the Appendix 2 in the final version of the document. On the other hand, several members felt free to submit, on the same occasion, written comments the content of which was entirely unrelated to the issue of definition, and could only be reported, as they should be, separately.

22. In the final version, the Appendix 2 was retained. To meet the concerns expressed by the abovementioned members, editorial changes have been introduced to emphasize the difference of status of this part of the document : a preamble to this effect has been inserted ; the content of the Appendix 2 has been cross-referenced exhaustively to document the source of each statement in previous Codex documents.

23. Regarding the method used to draft the definition itself, an observer criticized the approach taken by the French secretariat, as limited, illogical, slow and inefficient, and urged the CCGP to start again its work on the definition of traceability/product tracing from scratch. Some members reiterated their preference for defining only one of the two individual components of the phrase "traceability/product tracing". However, all other participants accepted to position their comments within the framework agreed by the Commission so far and work with the terminology agreed upon by the Executive Committee at its 50<sup>th</sup> session (June 2002 -- para. 2 above).

24. One member, contradicting previously expressed views on the need for a general definition of traceability/product tracing, before proceeding any further with the discussion of this topic in more specialized areas, stressed the difficulty of fulfilling the working group's mandate, at such a high level of abstraction, where no specific information was available about the nature of the product, the risk to be avoided, the geographical origin of the product and the sanitary status thereof.

25. Regarding the wording of the definition itself, the French secretariat has amended the draft definition, it has circulated in the first version of this document, by taking into account the following points made by working group's participants : it is now specified that product identification is implemented by the use of a unique identifier of the product (or a batch thereof) and that the time of the arrival or dispatching of the product should be recorded along its origin and/or destination ; two new items has been added on the listing of the information; that need be recorded, if appropriate ; and, last, the timeframe for conservation of the records is now mentioned, and all those having access to the information have been identified.

26. The title of the working document has been amended to emphasize that the intended scope of the definition of traceability/product tracing, in Appendix 1, is limited to foodstuffs.

27. In this new wording, the definition of traceability/product tracing in Appendix 1 takes fully into account the view expressed by various participants, on the following aspects :

- This definition does not entail in any way implementing "generalized and compulsory" traceability/product tracing.
- This definition fully complies with a concept of traceability/product tracing as a tool comprising only the elements necessary to establish the path of the product and capable of providing ready access to any relevant information about a product required by a broader food control system, as recorded at specified steps of the food chain, rather than a flow of information accompanying the product.

#### **RECOMMENDATIONS TO THE CODEX COMMITTEE ON GENERAL PRINCIPLES :**

28. The Committee is invited :

- To discuss the proposed draft definition in Appendix 1 and advance the text in the step procedure.
- To decide on the best way to address the others concerns expressed in the written comments and during the discussion (cf. Appendix 2).

**PROPOSED DRAFT DEFINITION OF  
"TRACEABILITY/PRODUCT TRACING" OF FOODSTUFFS**

"The implementation of measures to ensure, at any stage of the food chain, that the path of a food and the relevant informations about it are known, including :

- product identification, a unique means to identify a food or batch thereof
- product information :
- the raw materials used,
- how it was changed (if appropriate),
- where and when it came from and where and when it was sent (one step backward and one step forward)
- the controls, which the product has been subject to, and
- the linkages between product identification and product information.

These informations are generated for the purpose of food safety and/or of fair practices in food trade, and may be used, as appropriate, by industry, government and other third-party. They are recorded by each business involved and are stored, during an appropriate timeframe, in a way making fast and easy retrieval possible."

## OTHER RELEVANT TOPICS

## ABOUT THE "TRACEABILITY/PRODUCT TRACING" OF FOODSTUFFS

1. In order to provide a basis for the development of a definition of traceability/product tracing, the French secretariat conducted a thorough analysis of Codex working documents and reports of meeting where this topic has been discussed in the past. It is obvious that this copious and repetitive material does contribute almost nothing to the specific need of this working group devoted exclusively to drafting a definition of traceability/product tracing. However, several members in their written comments, specifically endorsed several items presented in the first draft of this Appendix (they have been retained in the final version) and even added new material, unrelated to the working group's concerns, which had to be inserted in this Appendix, if these views were to be fairly represented.
2. In its final form, this Appendix is a short compendium of the many opinions, expressed since the Codex System started working on traceability/product tracing. It comprises comments, the past discussion has not been able to address thoroughly, as required by the Codex procedure<sup>37</sup> and may be used, in the future, a resource for further discussion of traceability/product tracing within the Codex system.

## TRACEABILITY IN THE FRAMEWORK OF CODEX

3. In its paper (ALINORM 01/21 Part IV Add.1), the Codex secretariat clarified the place of traceability/product tracing in the framework of Codex, in relation to the Codex mandate and the issues to be addressed, in Codex standards and related texts, to accommodate provisions on traceability/product tracing. This paper also gave some thought on how to traceability/product tracing could be implemented.
4. According to ISO, traceability/product tracing can entail high costs. A decision to apply traceability/product tracing should therefore be justified and the justification documented. Consideration must be given to the reasons for applying traceability/product tracing for food products and the extent to which traceability/product tracing is to be required as part of a food standard, code of practice, food labelling text or similar document. Such reasons must lie within the overall mandate of the Commission, namely: *To protect the health of consumers and ensure fair practices in the food trade.*
5. The ISO definition of "Traceability" states in a note that "*All aspects of traceability requirements, if any, should be clearly specified, for example, in terms of period of time, point of origin or identification*". The ISO definition implies that traceability/product tracing may or may not be required, or may begin at a certain point within the production chain, or may end at a point before the end of the chain.
6. The extent to which traceability/product tracing may be applied "*to protect the health of consumers*" may be considered as part of a food safety risk management decision. Such a decision would also need to take into account other measures that would achieve the same ALOP that may be less costly or may be more appropriate in a given situation. Such decisions may need to be specified on a case-by-case basis taking into account: i) the nature of the risk; and ii) the ability to manage the risk by the use of traceability/product tracing or by other means.
7. The use of traceability/product tracing "*to ensure fair practices in the food trade*" correlates to the "*prevention of deceptive practices*" as a legitimate objective described by the WTO Agreement on Technical Barriers to Trade. A decision to apply traceability/product tracing would need therefore to specify

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<sup>37</sup> see para 21. of Codex guidelines for Committees... (Procedural manual 12<sup>th</sup> edition -- p. 51)

<sup>38</sup> ALINORM 01/21 Part IV Add.1, para. 11

<sup>39</sup> ALINORM 01/21 Part IV Add.1, para. 12

<sup>40</sup> ALINORM 01/21 Part IV Add.1, para. 13

whether it is to be applied throughout the production and distribution chain or only to some part of the chain, on a case-by-case basis taking into account: i) the legitimate objective being fulfilled; ii) the risks that non-fulfilment would create; and iii) whether or not the legitimate objective can be addressed in a less trade-restrictive manner<sup>41</sup>.

8. Traceability/product tracing may also serve to meet the needs of contracting parties in fulfilling the requirements of Article 18 of the Cartagena Protocol on Biosafety in regard to living modified organisms that are intended for direct use as food or feed, or for processing and are not intended for intentional introduction into the environment.

9. There is the question of how traceability/product tracing is to be applied: what are the modalities to be applied, especially in regard to international food trade; what information needs to be transmitted from one regulatory authority to another, and when; how are the traceability/product tracing requirements of voluntary or mandatory food quality and safety management systems to be integrated into an international regulatory framework. Consideration should also be given to its practicability and in particular the feasibility of its application in developing countries.

## **OTHER CONCERNS**

10. At several points, during past discussions, and again in the written comments submitted in response to the circulation of the proposed draft definition (in Appendix 1), various concerns were expressed, the nature of which prevented them to be addressed in the proposed draft definition. These concerns can be grouped under the following headings :

### ***PURPOSE***

11. The importance in establishing a comprehensive traceability/product tracing system in order to trace-back and withdraw products from the market, which were susceptible in provoking harmful effects to the health of consumers, was stressed.

12. There is willingness to consider traceability/product tracing as a food safety risk management measure but The system should not be extended to non-food safety related areas such the verification of authenticity or for labelling purposes<sup>45</sup>.

13. The mandatory or regulatory use of traceability/product tracing for purposes other than food safety risk management to protect consumers' health<sup>46</sup>, meets opposition.

14. Such a system should not be extended to the regulation of commercial "Identity Preservation". The use of traceability/product tracing for these purposes was a commercial response to consumer demand and could therefore be left to market forces to determine when and how the system should be applied.

15. Traceability/product tracing was used as a voluntary measure to provide added value and premium prices in situations where particular claims were being made as to the nature of the food, such as "organic" foods to make such tracing systems mandatory would eliminate the comparative advantage enjoyed by the producers of such foods and they would be unable to recoup the additional costs involved in the maintenance of a traceability/product tracing system.

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<sup>41</sup> ALINORM 01/21 Part IV Add.1, para. 15

<sup>42</sup> ALINORM 01/21 Part IV Add.1, para. 16

<sup>43</sup> ALINORM 01/21 Part IV Add.1, para. 17

<sup>44</sup> ALINORM 01/30, para. 64

<sup>45</sup> ALINORM 03/33A, para. 87

<sup>46</sup> CX/GP 03/7, para. 58

<sup>47</sup> ALINORM 03/33A, para. 95 & 96

<sup>48</sup> CX/GP 03/7, para. 61

## ***CONSISTENCY WITH WTO SPS AND TBT AGREEMENTS***

16. The use of a system of traceability/product tracing should be consistent with the provisions of the WTO SPS and TBT Agreements and be not more trade-restrictive than necessary<sup>49</sup>.

### ***ISSUES OF COST***

17. The importance of addressing cost implications, and the possible denial of market access related to the implementation of traceability/product tracing, including the subsequent economic impact on production systems for developing countries, and especially the least-developed ones, was noted.

18. Traceability/product tracing could lead to economic benefits in certain circumstances and that the costs of the absence of traceability/product tracing should also be taken into account. In particular, the absence of traceability/product tracing systems in the production chain and food businesses might actually lead to a lack of control in food-borne disease outbreaks and/or the withdrawal of unsafe foods from the market in emergency situations.

19. The costs of such systems should be borne by all concerned, but that certification and auditing bodies could also underwrite these systems<sup>51</sup>.

20. In their comments, some members recalled the fact that certain consumer groups wish additional guarantees or information on certain production processes, although they aren't detectable in the final product. These valid concerns could be met voluntary certification systems, in relation to the conditions agreed by trade operators. It is logical since, while governments are responsible for responding to consumers' concerns, when they are raised by reduced and well-identified groups, it is neither proportional nor logical to force all trade operators to abide by said additional requirements. If the traceability/product tracing requirements are generalized, consumers in general would have to pay an unavoidable over price that not all of them could afford because of matters they didn't demand or didn't care about. That is, all would bear the cost due to the demand of a few.

21. This system should only be used as a risk management option on a voluntary basis and that there should be a cost/benefit analysis before proceeding with the use of traceability/product tracing. If a cost/benefit analysis was to be carried out then the costs of not implementing the traceability/product tracing system should also be analyzed<sup>52</sup>.

### ***SITUATION OF DEVELOPING COUNTRIES***

22. A system of traceability/product tracing that would serve multiple purposes would most likely be costly, especially for producers and small-scale enterprises in developing countries

23. Traceability/product tracing would be more difficult for developing countries to implement. Even "trace-back" was not practical for developing countries where most agricultural production was on small farms. Economic considerations should be taken into account and traceability/product tracing could only be considered as an optional tool for those industries that could afford to use it.

24. In their written comments, some members recalled that in order to implement traceability/product tracing programs an appropriate product identifier must exist (alphanumeric, bars or electronic codes); as well as record keeping of relevant information, which in most of the cases is fragmented amongst several responsible areas of the production and supply chain. Finally a mechanism for retrieving and consulting data which makes possible the linking between the product, its origin, process and destiny, is needed. When implementing the above mentioned, one must take into account that the technologies

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<sup>49</sup> ALINORM 03/33A, para. 88

<sup>50</sup> ALINORM 03/30, para. 64-66

<sup>51</sup> ALINORM 03/33A, para. 91

<sup>52</sup> ALINORM 03/33A, para. 93

<sup>53</sup> ALINORM 03/33A, para. 87

<sup>54</sup> ALINORM 03/33A, para. 91

applied may be different among countries and that less developed countries frequently face technical and economic difficulties, mainly in the first phases of the production chain.

25. Traceability/product tracing should be applicable only to processed foods and exclude primary foods and processes

26. State-regulated systems of traceability/product tracing for the determination of product authenticity would benefit developing countries wishing to market and export “organic” foods. Such regulations were in force in some developed countries<sup>56</sup>.

### ***ALTERNATIVE SYSTEMS***

27. The HACCP System required similar record-keeping and provided the tools necessary for food safety risk management. The Codex General Principles of Food Hygiene already contained the elements of record-keeping that were necessary to establish a traceability/product tracing system that would be applicable to all food products throughout the food chain.

### ***GUIDELINES TO IDENTIFY SITUATIONS WHERE TRACEABILITY/PRODUCT TRACING IS THE METHOD OF CHOICE***

28. Traceability/product tracing was not capable in itself of ensuring product safety. Traceability/product tracing is not a stand-alone activity, i.e., it is a tool that may be applied within a broader food control system.

29. The need for and scope of application and specifications regarding each element of traceability/product tracing should be considered on a case-by-case basis according to the objective(s) of the food control system within which traceability/product tracing is implemented.<sup>59</sup>

30. In their written comments, some members recalled that, when it is essential to have recourse to elements that differ from the ones already established under the Codex rules to ensure the product safety, and when it is necessary to use traceability/product tracing procedures, it should be considered: the kind of product; the specific safety objectives that are pursued, assessed on a case-by-case basis; the chain links where risks have been identified; the alternative measures, if any. Then, it should be established the particular traceability conditions for those products.

31. Decisions on whether a mandatory traceability/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.

32. In their written comments, some members recalled that, concerning traceability/product tracing application for purposes different to food safety, the legal jurisdiction of the sanitary authorities must be considered, as in many countries does not covers traceability/product tracing regulation and sanction in order to address conditions other than consumer health protection.

33. Comprehensive application of traceability/product tracing would not serve the desired purposes and so it shall be applied strictly on a case-to-case basis.

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<sup>55</sup> ALINORM 03/33A, para. 93

<sup>56</sup> ALINORM 03/33A, para. 95

<sup>57</sup> ALINORM 03/33A, para. 92

<sup>58</sup> CX/GP 03/7, para. 55

<sup>59</sup> ALINORM 03/32, para. 52, lit. e) - h)

<sup>60</sup> ALINORM 03/32, para. 52, lit. e) - h)

<sup>61</sup> CX/GP 03/7, para. 80