codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Via delle Terme di Caracalla 00100 ROME Tel.: 52251 Telex: 625825-625853 FAO I Cables: Foodagri Rome Facsimile: (6)5225.4593

ALINORM 97/22 A

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION
Twenty-second Session
Geneva, 23-28 June 1997

REPORT OF THE TWENTY-FIFTH SESSION OF THE CODEX COMMITTEE ON FOOD LABELLING

Ottawa, Canada, 15-18 April 1997

Note: This document incorporates Codex Circular Letter 1997/10-FL

W5097/E

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CX 4/15

CL1997/10-FL
April 1997

TO: - Codex Contact Points
- Interested International Organizations
- Participants at the 25th Session of the Codex Committee on Food Labelling

FROM: - Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, 00100 Rome, Italy

SUBJECT: Distribution of the Report of the 25th Session of the Committee on Food Labelling (ALINORM 97/22 A)

A. MATTERS FOR ADOPTION BY THE 22nd SESSION OF THE CODEX ALIMENTARIUS COMMISION

Draft Standard at Step 5 of the Accelerated Procedure

1. Proposed Draft Amendment to the Standard for Quick Frozen Fish Sticks (Fish Fingers) Fish Portions and Fish Fillets - Breaded or in Batter (CODEX STAN. 166-1989-Rev 1. 1995) (para. 51, Appendix II)

Governments wishing to submit comments on all aspects of the Amendment, including possible implications for their economic interests should do so in writing to the Secretary, Joint FAO/WHO Food Standards Programme, FAO, via delle terme di Caracalla, 00100, Italy before **31 May 1997**.

Draft Standard at Step 5 of the Procedure

2. Proposed Draft Amendment to the General Standard for the Labelling of Prepackaged Foods (Recommendations for the Labelling of Foods and Ingredients that can cause Hypersensitivity) (para. 48 , Appendix IV)

Governments wishing to submit comments on the implications which the Draft Amendment may have for their economic interests should do so in writing in conformity with the Procedure for the Elaboration of Worldwide Standards at Step 5 to the Secretary, Joint FAO/WHO Food Standards Programme, FAO, via delle terme di Caracalla, 00100, Italy before **31 May 1997**.

B. REQUEST FOR COMMENTS AND INFORMATION

Draft Guidelines at Step 6 of the Procedure

3. Draft Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (para. 42, Appendix III)

Governments and international organizations are invited to present comments on the Draft Guidelines, especially on the sections which remain to be developed. Comments should be sent in writing to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO,

via delle Terme di Caracalla, 00100 Rome, Italy, with a copy to the Secretary of the Committee, Mr. Ron B. Burke, Deputy Director, Bureau of Food Regulatory International and Interagency Liaison, Food Directorate - Health Protection Branch, Health Canada, H.P.B. Building, Room 200, Tunney's Pasture, Ottawa, Ontario K1A OL2 Canada (Fax. No. 613.941.3537) **before 1 September 1997**.

Proposed Draft Standard and Guidelines at Step 3 of the Procedure

4. Proposed Draft Recommendations on the Labelling of Foods Obtained through Biotechnology (Proposed Draft Amendment to the General Standard for the Labelling of Prepackaged Foods) (para. 60, Appendix VI)

5. Proposed Draft Recommendations for the Use of Health Claims (para. 71 , Appendix VII)

Governments and international organizations wishing to comment on points 4. and 5. should do so in writing to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, via delle Terme di Caracalla, 00100 Rome, Italy, with a copy to the Secretary of the Committee, Mr. Ron B. Burke, Deputy Director, Bureau of Food Regulatory International and Interagency Liaison, Food Directorate - Health Protection Branch, Health Canada, H.P.B. Building, Room 200, Tunney's Pasture, Ottawa, Ontario K1A OL2 Canada (Fax. No. 613.941.3537) **before 1 October 1997**.

Proposed Draft Standard at Step 3 of the Accelerated Procedure

6. Proposed Draft Amendment to the General Standard for the Labelling of Prepackaged Foods (Class Names) (para.25 , Appendix V)

Subject to confirmation by the 22nd Session of the Commission, the Proposed Draft Amendment is hereby circulated for comments at Step 3 of the Accelerated Procedure, for consideration at Step 4 by the next session of the Committee. Governments wishing to submit comments on all aspects of the Amendment, including possible implications for their economic interests should do so in writing to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, via delle Terme di Caracalla, 00100 Rome, Italy, **before 15 December 1997.**

SUMMARY AND CONCLUSIONS

The summary and conclusions of the 25th Session of the Committee on Food Labelling are as follows:

Matters for adoption by the Commission:

The Committee:

- agreed to advance to Step 5 of the Accelerated Procedure the Proposed Draft Amendment to the Standard for Quick Frozen Fish Sticks (Labelling Section) (para. 51, Appendix II)

- agreed to advance to Step 5 the Proposed Draft Amendment to the General Standard for the Labelling of Prepackaged Foods (Foods than can cause Hypersensitivity) (para. 48, Appendix IV)

- agreed to use the Accelerated Procedure for a Proposed Draft Amendment to the General Standard for the Labelling of Prepackaged Foods (class names) (para. 25, Appendix V)

Other Matters of Interest to the Commission

The Committee:

- returned to Step 6 the Draft Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods for further comments (para. 42, Appendix III)

- agreed to circulate at Step 3 the Proposed Draft Recommendations for the Labelling of Foods Obtained through Biotechnology (para. 60, Appendix VI)

- agreed to circulate at Step 3 the Proposed Draft Recommendations for the Use of Health Claims (para. 71, Appendix VII)

- agreed to undertake a partial revision of the Guidelines on Nutrition Labelling (para. 65)

- agreed to initiate work on the definition of the term "vegetarian" and to ask the advice of the Commission on the need for new work on "sports drinks" and "energy drinks" (paras. 73 and 78)

- agreed to recommend to the Commission to ask FAO and WHO to consider how to address the need for the evaluation of scientific data on hypersensitivity (paras. 45-47)

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INTRODUCTION

1 The Codex Committee on Food Labelling held its Twenty-Fifth Session in Ottawa, from 15 to 18 April 1997, at the kind invitation of the Government of Canada. The meeting was attended by 213 delegates and observers representing 42 Members and 24 international organizations. The meeting was chaired by Dr. Anne MacKenzie, Director-General, Food Inspection Directorate, Canadian Food Inspection Agency. The complete list of participants is attached as Appendix I to this report.

OPENING OF THE SESSION (Agenda Item 1)

2 The Session was opened by Dr. Art Olson, President, Canadian Food Inspection Agency, who welcomed the participants and recalled the important role played by the Committee on Food Labelling in international harmonization of food standards. Referring to the recently created Agency as the single federal agency responsible for inspection and quarantine services in Canada, he stressed the need to meet the new challenges regarding food control, including the incorporation of a risk-based approach.

3 The Chairperson informed the Committee of the major conclusions of the Joint FAO/WHO Consultation on Risk Management and Food Safety, 27 to 31 January 1997.

ADOPTION OF THE AGENDA (Agenda Item 2)

4 The Committee adopted the Provisional Agenda as proposed in document CX/FL 97/1. Following the request received in writing from South Africa (CRD 1), it was agreed that the proposal to elaborate new Codex texts would be discussed under Agenda Item 11, Other Business.

MATTERS REFERRED TO THE COMMITTEE BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES[1] (Agenda Item 3)

Table of Conditions for Claims

5 The Committee noted that the Committee on Nutrition and Foods for Special Dietary Uses had finalized the conditions for claims for certain nutrients, and that the Table of Conditions (part A) would be forwarded as part of the Draft Guidelines for adoption by the Commission at Step 8.

6 The Delegation of the United States, supported by the Delegation of Australia, stressed that the conditions for claims should also be expressed per serving, whereas the present text referred only to nutrient contents per 100g or 100 ml. The Committee noted that the CCNFSDU had agreed in principle to establish conditions for claims on the basis of servings, to be added to the Table, and had requested specific government comments on this issue for consideration by the next session. The Delegation of the United States expressed the view that the value for "saturated fat free" was too low and did not take into account the difficulties relating to available methods of analysis, especially reproducibility.

7 In reply to a question on the expression of claims for sodium for solids only, the Secretariat recalled that the CCNFSDU had not discussed the expression of these claims for liquids when considering the Table and the initial draft had been based on the Standard for low sodium foods, which refers only to the amount of sodium per mass; this question should, therefore, be raised in the CCNFSDU with a view to defining conditions applicable to liquids.

8 In reply to a question by the Delegation of France, the Committee recalled that reference was made to sugars in the plural in the Table (in the English version) to include sugars other than sucrose. The Delegation of Sweden expressed the view that in the case of claims for "free", the nutrient should not be detected in the food.

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[1] CX/FL 97/2

9 The Delegation of Brazil indicated that the Draft Guidelines would be adopted in MERCOSUR and questioned the use of "energy free" only for liquids. The Committee noted that the CCNFSDU had discussed this claim and agreed that it was not applicable to solids.

10 The Delegation of Germany expressed the view that the footnote concerning trans-fatty acids in connection with the claims for cholesterol was not precise and should be clarified or deleted by the CCNFSDU.

11 The Committee agreed that the concerns expressed at the present session would be forwarded to the CCNFSDU for further consideration.

12 Some delegations and the Observer from IDF expressed the view that the Guidelines should allow for an exception for the "low fat" claim in the case of products with a traditionally high fat content. It was, however, noted that the last session of the Committee had already taken a decision on the general applicability of the Guidelines and that any comments at Step 8 should be directed to the Commission.

Code of Principles for Milk and Milk Products

13 With reference to the recommendation of the Committee on General Principles to redraft the Code of Principles as a standard, the Delegation of the United Kingdom expressed the view that the Committee should have the opportunity to review the new standard extensively in view of the important labelling aspects to be covered. The Chairperson noted that this would be the case and there were no objections.

CONSIDERATION OF LABELLING PROVISIONS IN CODEX STANDARDS[2] (Agenda Item 4)

Draft Standards for Milk and Milk Products

14 Some Delegations and the Observer from Consumers International stressed that it was premature to endorse the labelling provisions in these standards in view of the recommendation to redraft the Code of Principles for Milk and Milk Products as a standard and in view of the close link between the Code and the standards. They also highlighted a number of inconsistencies across all standards, especially differences in the expression of fat content and deviations from the General Standard for the Labelling of Prepackaged Foods in the declaration of ingredients; as a number of issues remained to be resolved, the standards needed further consideration as a whole and their adoption might be delayed.

15 Other delegations noted that there had been consensus in the CCMMP on the technical content of the standards, and on the need to finalize them in view of their importance for international trade; while additional clarification could be sought from the CCMMP on the rationale for specific deviations from the General Standard, consideration of labelling provisions should not delay the adoption of the standards.

16 The Committee agreed to the proposal of the Delegation of New Zealand to harmonize the wording of the Sections on Labelling of Non-Retail Containers in all standards as follows:

" Information specified in sections 4.1 to 4.8 of the General Standard for the Labelling of Prepackaged Foods, and, if necessary, storage instructions, shall be given either on the container or in accompanying documents, except that the name of the product, lot identification, and the name and address of the manufacturer or packer shall appear on the container [A-6 and A-7; and in the absence of such a container, on the cheese/whey cheese itself]. However, lot identification, and the name and address of the manufacturer or packer may be replaced by an identification mark, provided that such a mark is clearly identifiable with the accompanying documents."

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2 CX/FL 97/3, CRD 3 (Consumers International), CRD 4 (Comments of New Zealand), CRD 5 (comments of Canada) CRD 7 (comments of India)

17 The Delegation of Slovakia expressed the view that the Declaration of Milkfat Content should generally refer to "mass fraction in percentage" instead of "percentage by weight" in all relevant standards.

Draft Revised Standard for Cheese - Draft Revised Standard for Whey Cheese
Draft Standard for Cheeses in Brine

18 The following issues were identified as requiring further consideration:

- designation of cheese: potential conflict between the first and second sentences in section 7.1;
- inconsistency in the wording of Section 7.1.2 as compared with similar sections of other standards (reference to "all animals");
- declaration of the country of origin (7.2) in relation with the General Standard for Labelling;
- discrepancy between the expression of milkfat content (7.3) for cheese and for other dairy products, including butter;
- exception in date-marking requirements for ripening cheese (7.5) (indication of date after ripening).

19 The Delegation of Norway expressed its opposition to the use of three alternatives for the declaration of milkfat content and suggested that only the declaration as a percentage by mass should be allowed; this should apply to all cheese standards.

20 Several delegations pointed out that the definition of "low fat" for cheese (Section 7.3) differed from the conditions set out in the Draft Guidelines for Use of Nutrition Claims, although the Committee had reasserted the general applicability of the Guidelines.The Committee noted that the general comments made for the cheese standards also applied to the other standards under consideration.

Draft Revised Standard for Butter - Draft Revised Standard for Milkfat Products

21 The Committee had no specific comments on the Draft Standards for Butter and for Milkfat Products.

Draft Revised Standard for Evaporated Milks
Draft Revised Standard for Sweetened Condensed Milks
Draft Revised Standard for Milk and Cream Powders

22 The Delegation of the United Kingdom expressed the view that no exemption from ingredient declaration should be allowed for protein adjustment (7.3) as this was a major deviation from general labelling principles and did not allow for adequate consumer information. The Delegation of France and the Observer from IDF pointed out that the CCMMP had provided specific technical justification for this exception and that detailed labelling would not necessarily provide accurate information to the consumer in the case of protein adjustment.

Status of the Labelling Provisions in the Draft Standards for Milk and Milk Products

23 The Committee agreed that as important issues remained to be addressed, the labelling provisions in the draft standards for milk and milk products referred to in paras. 15 to 22 could not be endorsed at this stage. The CCMMP should provide further clarification on the issues identified above and review the standards accordingly.

Other Labelling Provisions: Milk Protein Products

24 The Committee agreed that the class names for "milk protein products" and "milk protein" as defined by the CCMMP, should be included in the list of class names in the General Labelling Standard (Section 4.2 List of Ingredients - sub-section 4.2.2.1).

Status of the Proposed Draft Amendment to the General Standard on the Labelling of Prepackaged Foods

25 As it was noted that the Accelerated Procedure was applicable in the case of revisions of standards, and in view of the non-controversial nature of the amendment, the Committee agreed to circulate the Proposed Draft Amendment, as included in Appendix V, at Step 3 of the Accelerated Procedure, subject to confirmation by the Commission.

Proposed Draft Code of Principles for Milk and Milk Products (Article 4 - Milk Products)

26 The Delegation of Canada, supported by the Delegation of the United States, proposed to delete the last sentence in order to allow the use of standardized cheese names when their composition had been modified. Many delegations, however, strongly supported the view that for cheese subject to individual standards, the product name should apply only to products conforming with the standard. The Committee could not come to a consensus on this question at this stage.

Draft Standard for Canned Bamboo Shoots

27 The Committee endorsed the labelling section as drafted by the CCASIA, while noting that this draft standard would be further developed by the Committee on Processed Fruits and Vegetables.

Draft Standard for Salted Dried Anchovies
Draft Standard for Crackers from Marine and Freshwater Fish, Crustacean and Molluscan Shellfish

28 The Delegation of Thailand, supported by the Delegation of the Philippines, proposed that no reference should be made to scientific names in the labelling and that only common names should be used for both standards. The Delegation of Japan, however, expressed the view that common names differed considerably from one country to another and that it was preferable to use scientific names for clarification purposes.

29 The Committee agreed that this question should be addressed by the Committee on Fish and Fishery Products in view of its responsibility for further development of both draft standards, initially prepared by the CCASIA.

Draft Revised Standard for Natural Mineral Waters

30 Some delegations recalled that the Committee had not been able to come to a consensus on the definition of the claim for "natural" and proposed that the use of this term should not be made mandatory in the name of the product. They pointed out that mineral waters labelled as "natural" might appear to be of a higher quality and could therefore mislead the consumer. Other delegations expressed the view that "natural" was not used as a claim or qualifier in the case of natural mineral waters, but was part of the product name itself and did not require to be defined. This was also reflected in the terms of reference of the Committee on Natural Mineral Waters. The Committee noted that general issues relating to the draft standard and the mandate of the CCNMW would be addressed by the Commission at its forthcoming session.

31 Under 6.3 Additional Labelling Requirements the Delegation of Canada noted that a minimum mineral content was not defined in the draft standard; accordingly it proposed that a declaration of mineral contents should be required, especially in view of consumers' concerns on sodium contents. Some delegations stressed the need for consistency in the approach to health claims and proposed to delete section 6.4.1 as no exception should be made for mineral waters; in accordance with the General Guidelines on Claims, such matters should be left for national authorities to regulate. The Committee could not come to a consensus on these points. It was brought to the attention of the Committee by the Delegation of Switzerland that, in the report of the CCNMW (ALINORM 97/20), agreement was recorded on all points of the labelling section, excepting section 6.4.1.

32 The Committee recognized that a number of issues in the labelling section of the Draft Standard for Natural Mineral Waters remained to be addressed and agreed to inform the Commission of the concerns raised at the present session. The Committee could not reach a consensus on the labelling provisions of the Draft Standard.

Proposed Draft Standard for Fat Spreads and Blended Spreads

33 The Delegation of the United Kingdom pointed out that the use of comparative nutrition claims such as "reduced fat" should be allowed in conformity with the Draft Guidelines for Use of Nutrition Claims, and not exclusively as an alternative to the terms "three quarter" or "half". While noting that this point should be brought to the attention of the Committee on Fats and Oils, the Committee agreed to endorse the labelling section as drafted.

DRAFT GUIDELINES FOR THE PRODUCTION, PROCESSING, LABELLING AND MARKETING OF ORGANICALLY PRODUCED FOODS (Agenda Item 5)[3]

34 The Committee recalled that its 24th Session had considered the Draft Guidelines at Step 7 and made a number of amendments, and returned the draft guidelines to Step 6 for further government comments. On the basis of the comments received to Circular Letter 1996/23-FL, a revised draft was prepared by Ms. Ruth Lovisolo (Australia), consultant to the Codex Secretariat, and was circulated as a working paper[4].

35 Ms. Lovisolo, Chairperson of the *ad hoc* Working Group which had met prior to and during the session, indicated that it had thoroughly reviewed Sections 5-8 and the Annexes with the exception of Annex 3.B. However, due to lack of time, it was not able to review the Foreword and Sections 1-4, which had previously been reviewed at the last meeting.

36 The Committee noted that consideration of the provisions regarding livestock production had been deferred and would be integrated into ongoing work. It also noted that criteria had been established for determining substances complying with the principles of organic production.

37 The Committee expressed its appreciation of the achievement and progress made by the Working Group and examined its proposals for amendment of the draft guidelines section by section.

38 While the Committee agreed to endorse the proposals of the Working Group for amendments, it did not reach consensus to advance the document to Step 8, in view of the reservations expressed by many delegations on a number of issues throughout the text.

39 Such issues included, among others, the extent to which the guidelines should be detailed, particularly in respect of the list of ingredients allowed for the processing of organic products, as well as the comments of the EC, in particular on Sections 5.1 (a) and 5.1 (b) (criteria for the inclusion of substances used for fertilization, plant disease and pest control).

40 Some delegations suggested to narrow the scope of the guidelines to labelling issues with a view to finalizing them rapidly, or to provide for supplementary resources; other delegations stressed the need for further consultations in the Working Group.

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3 CX/FL 97/4, CX/FL 97/4-Add.1 Part I (comments from Poland, Morocco, Uruguay, New Zealand, Canada, Israel, Japan, USA, Switzerland Norway and South Africa), CX/FL 97/4-Add.1 Part II (Marinalg International, International Dairy Federation and European Community), CX/FL 97/4-Add.1 Part III (International Federation of Organic Agriculture Movements),CX/FL 97/4-Add.2 (Consumers International, European Dairy Federation and International Federation of Organic Agriculture Movements), CX/FL 97/4-Add.3 (Canada), CRD 7 (India)

4 CX/FL 97/4

41 The Committee noted the need for ongoing resources to complete the development of the guidelines and to ensure their regular review.

Status of the Draft Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods

42 The Committee agreed that the Draft Guidelines, as amended at the present session, should be returned to Step 6 for government comments (see Appendix III). The Committee agreed that the Working Group should pursue its work at its next Session.

Proposed Draft Recommendations for the Labelling of Foods that can cause Hypersensitivity (Agenda Item 6)[5]

43 The Committee, at its 24th Session, had considered the proposed draft recommendations at Step 4 and, after making amendments in the light of the conclusions of the FAO Technical Consultation on Food Allergies, returned them to Step 3 for government comments.

44 Concerning the proposal to amend the so-called "25% rule" under which the individual ingredients of compound ingredients present at less than 25% in any food did not need to be labelled, several delegations were of the view that the reduction from 25% to 5% would offer a better protection of consumers' health; other delegations noted that this change would not protect all affected consumers.

45 With regard to the list of foods and ingredients which should always be declared regardless of their content, several delegations stressed the need to include sesame seed and celery in the list, in view of the adverse reactions reported in some countries. Other delegations stated that scientific evidence should be provided for inclusion of any foods or food ingredients in the list and that regional variation in the pattern of major sources of hypersensitivity should also be taken into consideration.

46 The Committee was of the view that a mechanism should be developed to include new foods and ingredients in the list as well as to delete current entries if necessary. The Committee recognised that this function should be assumed by a scientific body in order to evaluate scientific data on hypersensitivity on the basis of the criteria developed by the Technical Consultation and advise the Committee accordingly. The Committee also noted an opinion that the criteria needed further development.

47 The Committee agreed to recommend to the Commission to ask FAO and WHO to urgently explore possible options to address this issue, including the opportunity of creating a new expert committee or extending the mandate of an existing scientific body to evaluate the scientific date relating to food hypersensitivity.

Status of the Proposed Draft Recommendations for the Labelling of Foods that can cause Hypersensitivity
(Proposed Draft Amendment to the General Standard for the Labelling of Prepackaged Foods)

48 The Committee agreed to advance the current Proposed Draft Recommendations to Step 5 (see Appendix IV), with the understanding that guidance was required on how to proceed with updating the list of substances capable of causing hypersensitivity and subject to mandatory labelling.

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[5] CL 1996/18-FL and ALINORM 97/22, paras 32-38 and Appendix IV; CX/FL 97/5 (comments from Denmark, New Zealand, Spain, United Kingdom, Uruguay and AOECS); CX/FL 97/5-Add.1 (Norway); CX/FL 97/5-Add.2 (France, United States, Consumers International and European Dairy Association);CX/FL 97/5-Add.3 (Canada); CRD No.6 (ILSI); CRD No.7 (India).

PROPOSED DRAFT AMENDMENT TO THE LABELLING SECTION OF THE STANDARD FOR QUICK FROZEN FISH STICKS, FISH PORTIONS AND FISH FILLETS - BREADED OR IN BATTER (Agenda Item 7)[6]

49 The Committee, at its 24th Session, had agreed that the labelling provisions in the Standard for Quick Frozen Fish Sticks, Fish Portions and Fish Fillets - Breaded or in Batter should include the declaration of the proportion of fish core. The Proposed Draft Amendment was subsequently circulated for government comments at Step 3 of the Accelerated Procedure.[7]

50 Many delegations and the Observer from Consumers International expressed the view that mandatory labelling of the proportion of the fish core would allow consumers to make an informed choice and facilitate fair competition between manufacturers, whereas the Delegations of the United States and Canada stated that the labelling could be left voluntary, as the composition of the product was already defined in the standard. The Delegation of Japan reserved its position on this question.

Status of the proposed Draft Amendment to the Labelling section of the Standard for Quick Frozen Fish Sticks, Fish Portions and Fish Fillets - Breaded or in Batter

51 The Committee agreed to advance the proposed draft amendment to Step 5 of the Accelerated Procedure (see Appendix II).

RECOMMENDATIONS FOR THE LABELLING OF FOODS OBTAINED THROUGH BIOTECHNOLOGY (Agenda Item 8) [8]

52 The Committee recalled that its last session had agreed that, subject to the advice of the Executive Committee, the Secretariat should initiate the preparation of guidelines to address the labelling issues associated with foods obtained through biotechnology. The Executive Committee had recommended that the Statements of Principle concerning the Role of Science[9] should be closely adhered to and that the recommendations of the Joint FAO/WHO Expert Consultation on Food Safety and Biotechnology[10] should be taken into account.

53 The Secretariat indicated that the recommendations had been presented in the form of an amendment to the General Labelling Standard, following the approach taken for similar issues, and presented the conclusions of the Expert Consultation of particular relevance where labelling was concerned. The Committee noted that the elaboration of the recommendations had already been approved by the CCEXEC and that comments at Step 3 had not yet been requested in view of time constraints.

54 Several delegations indicated that their national policy supported comprehensive labelling of genetically modified foods and expressed the view that the food safety approach reflected in the paper did not address concerns of consumers in such areas as ethics and environmental protection. It was pointed out that the Expert Consultation was essentially focused on food safety rather that food labelling and that the document under

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6 ALINORM 97/22, paragraphs 4-5 and Appendix V; CX/FL 97/6 (comments from New Zealand); CX/FL 97/6-Add.1 (United States and Consumers International); CX/FL 97/6-Add.2 (Canada).

7 CL 1996/18-FL

8 CX/FL 97/7, CX/FL 97/7-Add.1 (Consumers International), Add.2 (European Community), Add. 3 (Canada), CRD 6 (ILSI), CRD 8 (Argentina), CRD 9 (IFOAM), CRD 10 (Norway), CRD 11 (ASSINSEL)

9 ALINORM 95/37, Appendix 2

10 FAO Food and Nutrition Paper No.61 (1996)

consideration should be redrafted in order to encompass all relevant issues. Other delegations expressed their appreciation of the document which was consistent with traditional food labelling approaches and provided a basis for further development of the recommendations.

55 The Delegation of Norway expressed the view that the issues associated with modern biotechnology went beyond information about products characteristics, that the right of consumers to make their choice should be respected even if this meant broadening the basis for labelling requirements, and that reliable labelling was the only means to ensure consumer confidence in this area.

56 Some delegations suggested that a distinction be established according to the presence of genetically modified organisms in the food, and that the definitions, including that for "organism", should be clarified in this respect. Other delegations suggested that the term "modern biotechnology" or "genetically modified" be used to differentiate the technology in question from other traditional techniques.

57 The Observer from the EC informed the Committee that the recently adopted EC Regulation No.258/97 concerning novel foods and novel foods ingredients, included provisions for foods containing or consisting of genetically modified organisms as well as foods derived from them.

58 The Observer from Consumers International stressed the need for comprehensive labelling in order to allow consumers to make an informed choice and the necessity to proceed rapidly in this area in view of the importance of the subject for consumers. The Observer from IFOAM pointed out that this issue was also very important for the organically produced food industry and supported comprehensive labelling of all genetically modified foods.

59 In view of the considerable implications of this question both for consumers and industry, many delegations indicated that they needed more time to review the document in detail, in order to establish their national position accordingly. The Committee agreed that as a first step, comprehensive governments comments would be required in order to identify the issues to be addressed and provide specific orientations for the work of the Committee.

Status of the Proposed Draft Recommendations for the Labelling of Foods Obtained through Biotechnology (Proposed Draft Amendment to the General Standard for the Labelling of Prepackaged Foods)

60 The Committee agreed that the Proposed Draft Recommendations, as included in Appendix VI, should be circulated for government comments at Step 3, redrafted by the Secretariat, taking into acount all comments received, for further consideration and thorough discussion in the plenary meeting at the next session.

REVIEW OF GOVERNMENT COMMENTS ON NUTRITION LABELLING (Agenda Item 9)[11]

61 The Committee considered a comparison of government comments on nutrition labelling with the relevant provisions in the Guidelines for Nutrition Labelling, with a view to determining if further action was needed in this area.

62 The Delegation of Japan informed the Committee that its recently approved regulations on nutrition labelling took into account Codex provisions on nutrition labelling and claims. The Delegation of Norway pointed out that significant differences still existed between national regulations on nutrition labelling but that it might be premature to undertake a comprehensive revision of the Guidelines.

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[11] CX/FL 97/8, CX/FL 97/8- Add. 1 (comments of Canada)

63 The Delegation of the United States emphasized the positive response of consumers to mandatory nutrition labelling in that country, which had contributed significantly to improved consumer education while encouraging product innovation in the industry. Some delegations and the Observer from Consumers International expressed the view that mandatory nutrition labelling would be a desirable option in order to improve consumer information.

64 The Delegation of the United Kingdom also stressed the importance of updating the Nutrient Reference Values (NRVs) in the framework of the CCNFSDU, and recalled that the Scientific Committee for Foods of the EC had agreed on a list of revised NRVs.

65 The Delegation of the United States, while noting that comprehensive revision of the Guidelines would be premature at this stage, proposed to amend Section 3.2, Listing of Nutrients, in order to require the declaration of saturated fat, sugars, fibre and sodium in cases where nutrition labelling was used. The Committee concurred with this suggestion and agreed to submit a proposal for new work on a partial revision of the Guidelines on Nutrition Labelling to the Commission.

REVIEW OF GOVERNMENT COMMENTS ON HEALTH CLAIMS (Agenda Item 10)[12]

66 The Committee recalled that, following its decision to continue its review of health claims, information on national policies had been requested from governments in CL 1997/3-FL. Many delegations informed the Committee of the current status of their national legislation on health claims. The Committee agreed that although national regulations in this area differed considerably from one country to another, this issue deserved careful and continuous attention, in view of increasing interest concerning health claims by many parties including consumers.

67 It was noted that there were several sub-categories of health claims, ranging from health promotion and disease prevention effects to therapeutic ones, and that this situation could often lead to confusion when the subject was discussed.

68 Recalling that all provisions on health claims had been removed from the Draft Guidelines for Use of Nutrition Claims when they were advanced to Step 8 by the last session, as no agreement was reached with regard to certain subcategories of Health Claims[13], the Committee agreed that there was a clear need to develop an internationally agreed definition for Health Claims on the basis of the work already done by the Committee.

69 The Delegation of France suggested that the definition of Health Claims might need to be revised in such a way as to differentiate subcategories of Health Claims and the Delegation of Canada noted that new types of claims, such as structure/function claims, would require consideration.

70 Several delegations indicated that those health claims relating to the prevention, cure and treatment of disease were not accepted in their countries but there was a need to consider further other specific health claims made in the context of a balanced diet, and they expressed their interest in the experience presented by the Delegation of the United States in this respect.

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12 CX/FL 97/9 (comments from Denmark, New Zealand, South Africa, United Kingdom); CX/FL 97/9-Add.1 (France, Sweden, United States, Consumers International and European Dairy Association); CX/FL 97/9-Add.2 (Canada); CRD No.7 (India).

13 ALINORM 97/22, paragraph 15.

Status of the Proposed Draft Recommendations for the Use of Health Claims

71 The Committee agreed to circulate the sections on Health Claims as previously contained in the Draft Guidelines for Use of Health and Nutrition Claims as Proposed Draft Recommendations for government comments at Step 3 (see Appendix VII) with a view to developing a draft amendment to the Guidelines for Use of Nutrition Claims, subject to their adoption by the Commission.

OTHER BUSINESS, FUTURE WORK AND DATE AND PLACE OF THE NEXT SESSION (Agenda Item 11)

Future Work

72 The Delegation of South Africa introduced the proposals presented in CRD1 and stressed the need for definitions of the different vegetarian categories, namely "Vegan", "Ovo-lacto Vegetarian" and "Lacto Vegetarian", for possible inclusion in either the General Standard for the Labelling of Prepackaged Foods or, as conditional claims, in the General Guidelines on Claims. The Delegation also proposed new work to develop Codex guidelines on the so-called "Sport drinks" and "Energy drinks".

73 The Committee agreed to request the approval of the Commission regarding the elaboration of definitions for the claim "vegetarian".

74 With regard to the guidelines on "Sport drinks" and "Energy drinks", many delegations expressed their view that, since such guidelines largely consisted of compositional requirements, it would be more appropriate for the Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) than the Committee on Food Labelling to consider their elaboration. The Delegation of Denmark expressed a general reservation against the development of specific products standards as the horizontal approach should be generally followed.

75 The Observer from the European Community informed the Committee that the EC Scientific Committee on Foods was reviewing various issues relative to so-called "Sport drinks" and "Energy drinks", and its report would be made available shortly. The Observer from the International Dairy Federation indicated that the definition of "Beverage" mentioned in the document prepared by South Africa would need to be expanded to include milk and milk products.

76 The Observer from Consumers International supported the development of Codex guidance in this area as the wide range of product descriptors and claims for such products created some confusion for consumers.

77 The Observer from the International Soft Drink Council stressed the need to address the issue on a horizontal basis, by recalling that the Committee on Food Additives and Contaminants (CCFAC) had recognised soft drinks as a food category within the General Standard for Food Additives, with sport drinks as a sub-category. It was noted that concerns relating to claims should also be addressed in the framework of the General Guidelines on Claims.

78 The Committee agreed to request guidance from the Commission on the need for the CCNFSDU to undertake new work in this area.

79 The Delegation of Australia informed the Committee that the World Customs Organization was in the process of elaborating the Rules of Origin, which might not be consistent with Codex labelling provisions. The Committee requested the Codex Secretariat to provide relevant information on this matter at its next session.

Date and Place of the Next Session

80 The Committee noted that its next session was tentatively scheduled to be held in Ottawa in the Spring of 1998, the exact date to be determined between the host country and Codex Secretariats.

SUMMARY STATUS OF WORK

Subject Matter	Step	Action by	Document Reference in ALINORM 97/22A
Proposed Draft Amendment to the Standard for Quick Frozen Fish Sticks	5[1]	Governments 22nd CAC	para. 51 Appendix II
Draft Guidelines for Organically Produced Foods	6	Governments 26th CCFL	para. 42 Appendix III
Proposed Draft Amendment to the General Labelling Standard (Hypersensitivity)	5	Governments 22nd CAC	para. 48 Appendix IV
Proposed Draft Amendment to the General Labelling Standard (Class Names)	3[1]	Governments 22nd CAC 26th CCFL	para. 25 Appendix V
Proposed Draft Amendment to the General Labelling Standard (Biotechnology)	3	Governments Secretariat 26th CCFL	para. 60 Appendix VI
Proposed Draft Recommendations for the Use of Health Claims	3	Governments 26th CCFL	para. 71 Appendix VII
Proposals for new work: - Revision of the Guidelines on Nutrition Labelling		22nd CAC Secretariat	para. 65
- "Vegetarian" claim		22nd CAC South Africa	para. 73
- Sports and Energy Drinks		22nd CAC	para. 78

[1] Accelerated Procedure

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PROPOSED DRAFT AMENDMENT TO THE STANDARD FOR QUICK FROZEN FISH STICKS (FISH FINGERS) FISH PORTIONS AND FISH FILLETS-BREADED OR IN BATTER

(At Step 5 of the Accelerated Procedure)

6. LABELLING

In addition to Sections 2, 3, 7 and 8 of the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985) the following specific provisions apply:

6.1 The Name of the Food

6.1.1 The name of the food to be declared on the label shall be "breaded" and/or "battered", "fish sticks" (fish fingers), "fish portions", or "fillets" as appropriate or other specific names used in accordance with the law and custom of the country in which the food is sold and in a manner so as not to confuse or mislead the consumer.

6.1.2 The label shall include reference to the species or mixture of species.

6.1.3 The proportion of fish core shall be declared on the label.

6.1.4 In addition there shall appear on the label either the term "quick frozen" or the term "frozen" whichever is customarily used in the country in which the food is sold, to describe a product subjected to the freezing processes as defined in subsection 2.2.

6.1.5 The label shall show whether the products are prepared form minced fish flesh, fish fillets or a mixture of both in accordance with the law and custom of the country in which the food is sold and in a manner so as not to confuse or mislead the consumer.

6.1.6 The label shall state that the product should be maintained under conditions that will maintain the quality during transportation, storage and distribution.

DRAFT GUIDELINES FOR THE PRODUCTION, PROCESSING, LABELLING AND MARKETING OF ORGANICALLY PRODUCED FOODS

(At Step 6 the Procedure)

Contents

DRAFT GUIDELINES FOR THE PRODUCTION, PROCESSING, LABELLING AND MARKETING OF ORGANICALLY PRODUCED FOODS

FOREWORD

Background

1. Sustainable agriculture represents a broad spectrum of agricultural methodologies which are supportive of the environment. These range from conventional, more intensive methods to alternative methods such as bio-dynamics. Organic agriculture is one method within this range which calls for specific and precise standards of production.

2. Organic agriculture is a holistic production management system which promotes and enhances biodiversity, biological cycles and soil biological activity. It is based on the low use of external inputs and non-use of artificial fertilizers and pesticides. This takes into account that regional conditions require locally adapted systems. Organic agricultural practices can only guarantee that no chemicals have been used during production. It cannot guarantee total absence of chemical residues due to general environmental pollution, even on land where no chemicals have been used. However, in such cases, any residue levels would be well below established maximum residue levels for agricultural products and foodstuffs.

3. Requirements for organically produced foods differ from those for other agricultural products in that production procedures are an intrinsic part of the identification and labelling of, and claims for, such products.

4. The term "organic" has generally become well understood by those associated with this form of agriculture. Other terms have also been introduced such as "biological" and "ecological" in an effort to describe the organic system more clearly.

5. For the practical application of organic production methods, more detailed standards are needed to assist the operator in achieving optimal systems which are socially, ecologically and economically sustainable. With the increased interest in organic production, a system of farm evaluation has developed to ensure that products labelled and sold as "organic" actually originate from farms that follow organic production methods. In this way, the consumer is assured of the authenticity of the product and the integrity of the operator is protected. Processor and handler evaluations have also been added to help ensure that the integrity of organically produced products is not lost through the processing and distribution system.

6. Adoption of organic practices requires a period of conversion. This period gives the operator time to adapt to and refine the production practices necessary to the environment in which the product is being produced. The system which supports production, ie soil, existing livestock, etc, may also need time for the depletion of possible residues of agricultural chemicals which may exist in the soil, manure heaps, etc and time for livestock to respond to the changed environment.

7. The concept of close contact between the consumer and the producer is common. Greater market demand, the increasing economic interests in production, and the increasing distance between producer and consumer has stimulated the introduction of external control and certification procedures.

8. An integral component of certification is the inspection of the organic management system which provides formal product verification. Procedures for operator certification are based primarily on a yearly description of the agricultural enterprise as prepared by the operator in cooperation with the inspection body. Likewise, at the processing level, standards are also developed against which the processing operations and plant conditions can be inspected and verified. Inspection bodies which certify the procedures of the operator should be independent of economic interests with regard to the certification of operators in order to maintain their integrity.

9. Apart from a small portion of agricultural commodities marketed directly from the farm to consumers, most products find their way to consumers via established trade channels. To minimise deceptive practices in the market place, specific measures are necessary to ensure that trade and processing enterprises can be audited effectively. Therefore, the regulation of a process, rather than a final product, demands responsible action by all involved parties.

10. These guidelines have been prepared for the purpose of providing an agreed approach to the requirements which underpin production of, and the labelling and claims for, organically produced foods.

11. The aims of these guidelines are:

- to protect consumers against deception and fraud in the market place and unsubstantiated product claims;

- to protect producers of organic produce against misrepresentation of other agricultural produce as being organic;

- to ensure that all stages of production, preparation, storage, transport and marketing are subject to inspection and comply with these guidelines;

- to harmonise provisions for the production, certification, identification and labelling of organically grown produce;

- to provide international guidelines for organic food control systems in order to facilitate recognition of national systems as equivalent for the purposes of imports; and

- to maintain and enhance organic agricultural systems in each country so as to contribute to the local and global preservation.

12. These guidelines set out the principles of organic production at farm, preparation, storage, transport, labelling and marketing stages, and provides an indication of accepted permitted inputs for soil fertilising and conditioning, plant and animal pest and disease control and, food additives and processing aids. For labelling purposes, the use of certain terms inferring that organic production methods have been used are restricted to products derived from operators under the supervision of an inspection body.

13. Import requirements should be based on the principles of equivalency and transparency as set out in the Principles for Food Import and Export Inspection and Certification[1]. In accepting imports of organic products, countries would usually assess the inspection and certification procedures and the standards applied in the exporting country.

14. Recognizing that organic production systems continue to evolve and that organic principles and standards will continue to be developed under these guidelines, the Codex Committee on Food Labelling (CCFL) shall review these guidelines on a regular basis. The CCFL shall initiate this review process by inviting member governments and international organizations to make proposals to the CCFL regarding amendments to these guidelines prior to each CCFL meeting.

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[1] CAC/GL 20-1995.

SECTION 1. SCOPE

1.1 These guidelines apply to the following products which carry, or are intended to carry, descriptive labelling referring to organic production methods:

(a) unprocessed plants and plant products, animals and unprocessed animal products, and

(b) processed product for human consumption derived mainly from (a) above.

1.2 A product will be regarded as bearing indications referring to organic production methods where, in the labelling or claims, advertising material or commercial documents, the product, or its ingredients, is described by:

- the terms "organic", "biodynamic", "biological", "ecological", or words of similar intent which, in the country where the product is placed on the market, suggests to the purchaser that the product or its ingredients were obtained according to organic production methods;

1.3 Paragraph 1.2 does not apply where these terms clearly have no connection with the method of production.

1.4 These guidelines apply without prejudice to other Codex Alimentarius Commission (CAC) provisions governing the production, preparation, marketing, labelling and inspection of the products specified in paragraph 1.1.

1.5 All materials and/or the products produced from genetically modified organisms (GMO) are not compatible with the principles of organic production (either the growing, manufacturing, or processing) and therefore are not accepted under these guidelines.

SECTION 2. DESCRIPTION AND DEFINITIONS

2.1 Description

Foods described using the term organic or words of similar intent, are the product of an organic farming system employing management practices that seeks to nurture ecosystems which achieve sustainable productivity, and provide weed, pest and disease control through a diverse mix of mutually dependent life forms, recycling plant and animal residues, crop selection and rotation, water management, tillage and cultivation. Soil fertility is maintained and enhanced by a system which optimises soil biological activity and the physical and mineral nature of the soil as the means to provide a balanced nutrient supply for plant and animal life as well as to conserve soil resources. Pest and disease management is attained by means of the encouragement of a balanced host/predator relationship, augmentation of beneficial insect populations, biological and cultural control and mechanical removal of pests and affected plant parts.

2.2 Definitions

For the purpose of these guidelines:

(a) "accreditation" means the recognition by the competent authority or its delegated agent, that an inspection and/or certification body is complying with the requirements as set down in paragraphs 6.5 and 6.6 of these guidelines.

(b) "agricultural product/product of agricultural origin" means any product or commodity, raw or processed, that is marketed for human consumption (excluding water and salt) or animal feed.

(c) "animal" means any cattle, sheep, goats, swine, poultry, equine animals raised for food or in the production of food; fish used for food; domesticated game, or other non-plant life.

(d) "audit" is a systematic and functionally independent examination to determine whether activities and related results comply with planned objectives[2].

(e) "certification" is the procedure by which official certification bodies, or officially recognised certification 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.

(f) "competent authority" means the official government agency having jurisdiction.

(g) genetically modified organisms are all materials produced through the modern methods of biotechnology; specifically gene technology "recombinant DNA (r DNA)" and all other techniques using molecular and/or cell-biology for altering the genetic make-up of living organisms in ways or with results which do not occur in nature or through traditional breeding.

(h) "ingredient" means any substance, including a food additive, used in the manufacture or preparation of a food and present in the final product although possibly in a modified form [3].

(i) "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[4].

(j) "inspection body" means a body which is responsible for verifying that a product sold or labelled as "organic" is produced, processed, prepared handled, and imported according to these guidelines. This procedure may also carried out by a certification body.

(k) "labelling" means any written, printed or graphic matter that is present on the label, accompanies the food, or is displayed near the food, including that for the purpose of promoting its sale or disposal[5].

(l) "marketing" means holding for sale or displaying for sale, offering for sale, selling, delivering or placing on the market in any other form.

(m) "officially recognized inspection systems"/" officially recognized certification systems" are systems which have been formally approved or recognized by a government agency having jurisdiction.

(n) "operator" means any person who produces, prepares or imports, with a view to the subsequent marketing thereof, products as referred to in Section 1.1, or who markets such products.

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[2] CAC/GL 20-1995

[3] Codex Alimentarius Volume 1A - General Requirements, Section 4 - Labelling of Prepackaged Foods (Stan 1-1985 Rev 1-1991)

[4] CAC/GL 20-1995

[5] Codex Stan 1-1985 (rev 1-1991)

(o) "plant protection product" means any substance intended for preventing, destroying, attracting, repelling, or controlling any pest including unwanted species of plants or animals during the production, storage, transport, distribution and processing of food, agricultural commodities, or animal feeds.

(p) "preparation" means the operations of slaughtering, processing, preserving and packaging of agricultural products.[, and also alterations made to the labelling concerning the presentation of the organic production method.]

(q) "production" means the operations undertaken to supply agricultural products in the state in which they occur on the farm, including initial packaging and labelling of the product.

(r) "veterinary drug" means any substance applied or administered to any food-producing animal, such as meat or milk-producing animals, poultry, fish or bees, whether used for therapeutic, prophylactic or diagnostic purposes or for modification of physiological functions or behaviour[6].

SECTION 3. LABELLING AND CLAIMS

3.1 Organic products should be labelled in accordance with the Codex General Standard for the Labelling of Prepackaged Foods[7].

3.2 The labelling and claims of a product specified in Section 1.1(a) may refer to organic production methods only where:

(a) such indications show clearly that they relate to a method of agricultural production;

(b) the product was produced in accordance with the requirements of Section 4 or imported under the requirements laid down in Section 7;

(c) the product was produced or imported by an operator who is subject to the inspection measures laid down in Section 6, and

(d) the labelling refers to the name and/or code number of the officially approved recognised inspection or certification body to which the operator is subject.

3.3 The labelling and claims of a product specified in paragraph 1.1(b) may refer to organic production methods only where:

(a) such indications show clearly that they relate to a method of agricultural production and are linked with the name of the agricultural product in question, as obtained on the farm;

(b) all the ingredients of agricultural origin of the product are, or are derived from, products obtained in accordance with the requirements of Section 4, or imported under the arrangements laid down in Section 7;

(c) the product should not contain any ingredient of non-agricultural origin not listed in Annex 2, Table 5A;

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6 Codex Alimentarius Commission Procedural Manual, Definitions

7 Codex Stan 1-1985 (Rev 1-1995)

(e) the product or its ingredients have not been subjected during preparation to treatments involving the use of ionizing radiation or substances not listed in Annex 2, Table 4B;

(f) the product was prepared or imported by an operator subject to the regular inspection system as set out in Section 6 of these guidelines; and

(g) the labelling refers to the name and/or the code number of the official or officially recognised inspection/certification body to which the operator who has carried out the most recent preparation operation is subject.

3.4 By way of derogation from paragraph 3.3(b), certain ingredients of agricultural origin not satisfying the requirement in that paragraph may be used, within the limit of a maximum level of 5% m/m of the ingredients of agricultural origin in the final product, in the preparation of products as referred to in paragraph 1.1(b);

- where such ingredients of agricultural origin are not available, or in sufficient quantity, in accordance with the requirements of Section 4 of these guidelines;

3.5 The labelling and claims of a product as referred to in paragraph 1.1(b) which has been prepared partly from ingredients not satisfying the production requirements of paragraph 3.3(b) may refer to organic production methods provided that:

(a) at least 70% of the ingredients of agricultural origin satisfy the production requirements of paragraph 3.3(b),

- where such ingredients are less than 70% of the total ingredients of agricultural origin, reference to the organic production method may appear only in the list of ingredients;

(b) the product satisfies the requirements of paragraphs 3.3(c), (d) (e), (f) and (g);

(c) the indications referring to organic production methods appear in the list of ingredients and only in relation to those ingredients obtained in accordance with the organic production method

- the statement shall be in the following form: "x% of the agricultural ingredients were produced in accordance with the rules of organic production;

(d) the ingredients, appear in descending order (mass/mass) in the list of ingredients;

(e) indications in the list of ingredients appear in the same colour and with an identical style and size of lettering as other indications in the list of ingredients, and

(f) the labelling refers to the name and/or the code number of the official or officially approved inspection/certification body to which the operator who has carried out the most recent preparation is subject.

Labelling of product in Transition/Conversion to Organic

3.6 Products of farms in transition to organic production methods may only be labelled as "transition to organic" after 12 months of production using organic methods providing that:

(a) the requirements referred to in paragraphs 3.2 and 3.3 are fully satisfied;

(b) the indications referring to transition/conversion do not mislead the purchaser of the product regarding its difference from products obtained from farms and/or farm units which have fully completed the conversion period;

(c) such indications take the form of words, such as "product under conversion to organic farming", or similar words or phrase, and must appear in a colour, size and style of lettering which is not more prominent than the sales description of the product";

(d) foods composed of a single ingredient may be labelled as "transition to organic" on the principal display panel;

(e) product prepared of more than one ingredient of agricultural origin may only refer to transition to organic in the list of ingredients providing it satisfies the requirements of paragraphs 3.2 and 3.3;

(f) the labelling refers to the name and/or the code number of the official or officially approved inspection/certification body to which the operator who has carried out the most recent preparation is subject.

Labelling of non-retail containers

3.7 Information on non-retail containers of a product specified in paragraph 1.1 should be given either on the container or in accompanying documents, except that the name of the product, lot identification, and the name and address of the manufacturer or packer [and the name and/or the code number of the official or officially recognised inspection/certification body] should appear on the container.

- Lot identification, and the name and address of the manufacturer or packer may be replaced by an identification mark provided that such a mark is clearly identifiable with the accompanying documents.

SECTION 4. RULES OF PRODUCTION AND PREPARATION

4.1 Organic production methods require that for the production of products referred to in paragraph 1.1(a):

(a) at least the production requirements of Annex 1 should be satisfied;

(b) in the case where (a) (above) is not effective, substances listed in Annex 2, Tables 1, 2 and 3 may be used as plant protection products, fertilizers, soil conditioners, animal feedstuffs, or animal protection products insofar as the corresponding use is not prohibited in general agriculture in the country concerned in accordance with the relevant national provisions

4.2 Organic processing methods require that for the preparation of products referred to in paragraph 1.1(b):

(a) at least the processing requirements of Annex 1 should be satisfied;

(b) substances listed in Annex 2, Tables 4A and 4B [or substances approved by individual countries that meet the criteria established in Section 5.1] may be used as ingredients of non-agricultural origin or processing aids insofar as the corresponding use is not prohibited in the relevant national requirements concerning the preparation of food products and according to good manufacturing practice.

4.3 Organic products should be stored and transported according to the requirements of Annex 1.

SECTION 5. REQUIREMENTS FOR INCLUSION OF SUBSTANCES IN ANNEX 2 AND CRITERIA FOR THE DEVELOPMENT OF LISTS OF SUBSTANCES BY COUNTRIES[8]

5.1 At least the following criteria should be used for the purposes of amending the permitted substance lists referred to in Section 4. These lists include products whose use is established in organic agriculture as well as new products that have to meet this criteria. Each input is necessary/essential and should be considered in the context in which the product will be used. Their use satisfies the principles of organic production as outlined in these guidelines. Available alternatives, including inputs which are already in use in organic production, should be evaluated:

(a) if they are used for fertilization, soil conditioning purposes--

- they are essential for obtaining or maintaining the fertility of the soil or to fulfil specific nutrition requirements of crops, or specific soil-conditioning and rotation purposes which cannot be satisfied by the practices included in Annex 1 or other products included in Table 2 of Annex 2; and,

- the ingredients will be of plant, animal, microbial, or mineral origin and may undergo the following processes:
  - physical (eg. mechanical, thermal)
  - enzymatic
  - microbial; and

- their use does not result in, or contribute to, unacceptable effects on, or contamination of, the environment, including soil organisms; and

- their use has no unacceptable effect on the quality and safety of the final product.

(b) if these substances are used for the purpose of plant disease or pest and weed control-

- they should be essential for the control of a harmful organism or a particular disease for which other biological, physical, or plant breeding alternatives and/or effective management practices are not available, and

- substances should be plant, animal, microbial, or mineral origin and may undergo the following processes:
  -physical (eg. mechanical, thermal)
  -enzymatic
  -microbial (eg. composting, digestion);

- their use does not result in, or contribute to, unacceptable effects on, or contamination of, the environment.

- however, if they are nature identical products such as pheromones, which are chemically synthesized they will be considered for addition to lists if the products are not available in sufficient quantities in their natural form, provided that the conditions for their use do not directly or indirectly result in the presence of residues of the product in the edible parts.

(c) if they are used for the purpose of animal health - (criteria to be developed).

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[8] These criteria are recommended to governments on a trial basis for a period of two years in order to achieve experience in line with organic production principles at the national level.

(d) if they are used as additives or processing aids in the preparation or preservation of the food–

- they are indispensable for ensuring the safety of the food, or
- they are essential to prepare or preserve such foods, and
- such substances are as found in nature and may have undergone mechanical/physical processes (eg extraction, precipitation), biological/enzymatic processes (eg fermentation) and microbial processes;
- however, if they are nature identical products which are chemically synthesized and it is not possible to prepare or preserve such food products without having recourse to such ingredients they will be considered for addition to the lists if the ingredients are not available in sufficient quantities in their natural form.

5.2 Countries should develop a list of substances which satisfy the requirements of these guidelines. Substances included in the list developed by a country but not yet included in Annex 2 of these guidelines may be a part of the equivalence judgement and decision referred to in section 7.4 of these guidelines. In doing so, countries may reduce the list of substances indicated in the lists included in Annex 2. Countries may include in their own lists substances other than those listed in Annex 2 only if:

- the criteria in 5.1 are used as a basis for these additions;

5.3 When a country proposes inclusion of a substance in Annex 2 it should submit the following information:

(a) a detailed description of the product and the conditions of its envisaged use;

(b) any information to demonstrate that the requirements under Section 5.1 are satisfied.

The open nature of the lists

5.4 Because of the primary purpose of providing a core list of substances, the lists in Annex 2 are open and subject to the inclusion of additional substances or the removal of existing ones on an ongoing basis. The procedure for requesting amendments to the lists is set out under Section 8 of these Guidelines.

SECTION 6. INSPECTION AND CERTIFICATION SYSTEMS[9]

6.1 Inspection and certification systems are used to verify the labelling of, and claims for, organically-produced foods. Development of these systems should take into account the Principles for Food Import and Export Inspection and Certification and the (draft) Guideline for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems.[10]

6.2 Competent authorities should establish an inspection system operated by one or more designated authorities and/or officially recognized inspection/certification[11] bodies to which the operators producing,

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[9] The systems conducted by certification bodies may in some countries be equivalent to those systems conducted by inspection bodies. Therefore, the term "inspection and certification" has been used wherever these systems may be synonymous.

[10] CAC/GL 20-1995, ALINORM 97/30A, Appendix II, respectively

[11] In organic approval processes reference is frequently made to certification performed by either a 'certification body' or an 'inspection body'. Where these functions are conducted by the same body there must be clear separation of the inspection and certification roles.

preparing or importing products as referred to in paragraph 1.1 should be subject.

6.3 The officially recognized inspection and certification systems should comprise at least the application of the measures and other precautions set out in Annex 3.

6.4 For the application of the inspection system operated by the official or officially recognized inspection/certification body, countries should identify a competent authority responsible for the approval and supervision of such bodies;

- The identified competent authority may delegate the assessment of private inspection and certification bodies to a private or public third party. If delegated, the private or public third party should not be engaged in inspection and/or certification;

- for this purpose an importing country may recognise a third party accrediting body when the exporting country lacks an identified competent authority and a national program.

6.5 In order to attain approval as an officially recognized inspection or certification body, the competent authority, or its designate should take into account the following:

(a) the standard inspection/certification procedures to be followed, including detailed description of the inspection measures and precautions which the body undertakes to impose on operators subject to inspection;

(b) the penalties which the body intends to apply where irregularities and/or infringements are found;

(c) the availability of appropriate resources in the form of qualified staff, administrative and technical facilities, inspection experience and reliability;

(d) the objectivity of the body vis-a-vis the operators subject to inspection.

6.6 After an inspection or certification body has been approved, the competent authority or its designate should:

(a) ensure that the inspections carried out on behalf of the inspection or certification body are objective;

(b) verify the effectiveness of inspections;

(c) take cognizance of any irregularities and/or infringements found and penalties applied;

(d) withdraw approval of the inspection or certification body where it fails to satisfy the requirements referred to in (a) and (b) or, no longer fulfils the criteria indicated in paragraph 6.5 or, fails to satisfy the requirements laid down in paragraphs 6.7 to 6.9.

6.7 Official and/or officially recognized inspection and certification bodies referred to in paragraph 6.2 should:

(a) ensure that at least the inspection measures and precautions specified in Annex 3 are applied to undertakings subject to inspection; and

(b) not disclose confidential information and data obtained in their inspection or certification activities to persons other than the person responsible for the undertaking concerned and the competent authorities.

6.8 Official or officially recognized inspection and/or certification bodies should:

(a) give the competent authority or its designate, for audit purposes, access to their offices and facilities and, for random audit of its operators, access to the facilities of the operators, together with any information and assistance deemed necessary by the competent authority or its designate for the fulfilment of its obligations pursuant to these guidelines;

(b) send to the competent authority or its designate each year a list of operators subject to inspection for the previous year and present to the said authority a concise annual report.

6.9 The designated authority and the official or officially recognized inspection/certification bodies referred to in paragraph 6.2 should:

(a) ensure that, where an irregularity is found in the implementation of Sections 3 and 4, or of the measures referred to in Annex 3, the indications provided for in paragraph 1.2 referring to the organic production method are removed from the entire lot or production run affected by the irregularity concerned;

(b) where a manifest infringement, or an infringement with prolonged effects is found, prohibit the operator concerned from marketing products with indications referring to the organic production method for a period to be agreed with the competent authority or its designate.

6.10 The requirements of the Guidelines for the Exchange of Information between Countries on Rejections of Imported Food [12] should apply where the competent authority finds irregularities and/or infringements in the application of these guidelines.

SECTION 7. IMPORTS

7.1 Products as specified in paragraph 1.1 which are imported may be marketed only where the competent authority or designated body in the exporting country has issued a certificate of inspection stating that the lot designated in the certificate was obtained within a system of production, preparation and inspection applying at least the rules provided for in all sections and annexes of these guidelines and satisfy the decision on equivalency referred to under 7.4.

7.2 The certificate referred to in paragraph 7.1 above should accompany the goods, in the original copy, to the premises of the first consignee; thereafter the importer should keep the transactional certificate for not less than two years for inspection/audit purposes.

7.3 The authenticity of the product should be maintained after import through to the consumer. If imports of organic products are not in conformity with the requirements of these guidelines due to treatment required by national regulations for quarantine purposes that is not in conformity with these guidelines they loose their organic status.

7.4 An importing country may:

(a) require detailed information, including reports established by experts mutually agreed between competent authorities of the exporting and importing countries, on the measures applied in the exporting country to enable it to make judgements and decisions on equivalency with its own rules provided that these rules of the importing country are in conformity with these guidelines, and/or

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[12] Alinorm 97/30, Appendix 2

(b) arrange for site visits to examine the rules of production and preparation, and the inspection/certification measures including production and preparation itself as applied in the exporting country.

(c) require, in order to avoid any confusion to the consumer, that the product is labelled in accordance with the labelling requirements applied, in accordance with the provisions of section 3, in the importing country for the products concerned.

SECTION 8. ONGOING REVIEW OF THE GUIDELINES

8.1 In line with the purpose of the guidelines to provide advice to governments, member governments and international organizations are invited to make proposals to CCFL on an ongoing basis. Once a final document is agreed, the CCFL shall conduct a review each 4 years of these guidelines and review each two years (or as required) the lists included in Annex 2 in order to take into account the latest developments in this area.

8.2 Proposals should be directed in the first instance to the Chief, Joint FAO/WHO Food Standards Programme, FAO, 00100, Rome ITALY.

ANNEX 1

PRINCIPLES OF ORGANIC PRODUCTION

A. Plants and plant products

1. The principles set out in this Annex should have been applied on the parcels, farm or farm units during a conversion period of at least two years before sowing, or in the case of perennial crops other than grassland, at least three (3) years before the first harvest of products as referred to in paragraph 1.1(a) of these guidelines. The official or officially recognized inspection/certification body may decide in certain cases (such as idle use for two years or more) to extend or reduce that period in the light of previous parcel use but the period must equal or exceed 12 months, unless in individual cases the inspection body has adequate justification to reduce further this period.

2. Whatever the length of the conversion period it may only begin once a production unit has been placed under an inspection system as required by 6.2 and once the unit has started the implementation of the production rules referred to in Section 4 of these Guidelines.

3. In cases where a whole farm is not converted at one time, it may be done progressively whereby these guidelines are applied from the start of conversion on the relevant fields. Conversion from conventional to organic production should be effected using permitted techniques as defined in these guidelines.

4. Areas in conversion as well as areas converted to organic production must not be alternated (switched back and forth) between organic and conventional production methods.

5. In cases where a whole farm is not converted at the one time, the holding must be split into units as referred to in Annex 3, part A, paragraphs 3 and 11.

6. The fertility and biological activity of the soil should be maintained or increased, where appropriate, by:

(a) cultivation of legumes, green manures or deep-rooting plants in an appropriate multi-annual rotation programme;

(b) incorporation in the soil of organic material, composted or not, from holdings producing in accordance with these guidelines. By-products from livestock farming, such as farmyard manure, may be used if they come from livestock holdings producing in accordance with these guidelines;

Substances, as specified in Annex 2, Table 1 may be applied only to the extent that adequate nutrition of the crop or soil conditioning are not possible by the methods set out in 6(a) and (b) above.

(c) for compost activation, appropriate micro-organisms or plant-based preparations may be used;

(d) biodynamic preparations from stone meal, farmyard manure or plants may also be used for the purpose covered by paragraph 6.

7. Pests, diseases and weeds should be controlled by any one, or a combination, of the following measures:

- choice of appropriate species and varieties;

- appropriate rotation programs;

- mechanical cultivation;

- protection of natural enemies of pests through provision of favourable habitat, such as hedges and nesting sites;

- diversified ecosystems. These will vary between geographical locations. For example, ecological buffer zones which maintain the original vegetation to house pest predators, counteract erosion, etc;

- flame weeding;

- release of predators and parasites;

- biodynamic preparations from stone meal, farmyard manure or plants;

- mulching and mowing;

- grazing of livestock;

- mechanical controls such as traps, barriers, light and sound;

- steam sterilization when proper rotation of soil renewal cannot take place.

8. Only in cases of imminent or serious threat to the crop and where the measures identified in 6. (above) are, or would not be effective, recourse may be had to products referred to in Annex 2.

9. Seeds and vegetative reproductive material should be from plants grown in accordance with the provisions of Section 4.1 of these guidelines for at least one generation or, in the case of perennial crops, two growing seasons. Where an operator can demonstrate to the official or officially recognized inspection/certification body that material satisfying the above requirements is not available, the inspection/certification body may support:

(a) in the first instance, use of untreated seeds or vegetative reproductive material, or

(b) If (a) is not available, use of seeds and vegetative reproductive material treated with substances other than those included in Annex 2.

10. The collection of edible plants and parts thereof, growing naturally in natural areas, forests and agricultural areas, is considered an organic production method provided that:

- the products are from a clearly defined collection area that is subject to the inspection/certification measures set out in Section 6 of these guidelines;

- those areas have received no treatments with products other than those referred to in Annex 2 for a period of three years before the collection;

- the collection does not disturb the stability of the natural habitat or the maintenance of the species in the collection area.

B. Animal Production in an Organic System

At Step 6- see CX/FL 97/4.

C. Processing (To be Developed)

D. Packaging, Storage and Transport

1. Where only part of the unit is certified, other product not covered by these guidelines should be stored and handled separately and both types of products should be clearly identified.

2. Bulk stores for organic product should be separate from conventional product stores and clearly labelled to that effect.

3. Storage areas and transport containers for organic product should be cleaned using methods and materials permitted in organic production. Measures should be taken to prevent possible contamination from any pesticide or other treatment not listed in Annex 2 before using a storage area or container that is not dedicated solely to organic products.

4. Permitted specific storage conditions may include substances listed in Annex 2, Table 4.

5. Pests should be avoided by good manufacturing practice. Pest control measures within storage areas or transport containers may include physical barriers or other treatments listed in Annex 2, Table 4.

6. Use of pesticides not listed in Annex 2 for post harvest or quarantine purposes should not be permitted on products prepared in accordance with these guidelines and would cause organically produced foods to lose their organic status. Irradiation is not permitted as a pest control measure under the organic system.

7. All materials used for packaging must conform to food grade packaging materials as established by national regulations and should minimise the migration of substances not permitted under these guidelines.

8. Any contamination of packaging material from substances that could comprise the organic product should be excluded.

ANNEX 2

PERMITTED SUBSTANCES FOR THE PRODUCTION OF ORGANIC FOODS

Precautions

1. Any substances used in an organic system for soil fertilisation and conditioning, pest and disease control, for the health of livestock and quality of the animal products, or for preparation, preservation and storage of the food product should comply with the relevant national regulations.

2. Conditions for use of certain substances contained in the following lists may be specified by the inspection/certification body, eg volume, frequency of application, specific purpose, etc.

3. Where substances are required for primary production they should be used with care and with the knowledge that even permitted substances may be subject to misuse and may alter the ecosystem of the soil or farm.

4. The following lists do not attempt to be all inclusive or exclusive, or a finite regulatory tool but rather provide advice to governments on internationally agreed inputs. A system of review criteria as detailed in Section 5 of these Guidelines for products to be considered by national governments should be the primary determinant for acceptability or rejection of substances.

5. The lists of ingredients and processing aids of non-agricultural origin included in Tables 5 and 6 take into account the expectations of consumers that processed products from organic production systems should be composed essentially of ingredients as they occur in nature.

TABLE 1: SUBSTANCES FOR USE IN SOIL FERTILIZING AND CONDITIONING

Substance	Description; compositional requirements; conditions of use
Farmyard and poultry manure	need recognised by inspection body if not sourced from organic production systems. 'Factory' farming sources not permitted.
Slurry or urine	If not from organic sources, need recognised by inspection body. Use preferably after controlled fermentation and/or appropriate dilution. 'Factory' farming sources not permitted.
Composted animal excrements, including poultry manure and composted farmyard manure	need recognised by the inspection authority. 'Factory' farming sources not permitted.
Dried farmyard manure and dehydrafted poultry manure	need recognised by inspection body. 'Factory' farming sources not permitted.
Guano	need recognised by inspection body
Straw	need recognised by inspection body
Composts from spent mushroom & vermiculture substrates	need recognised by inspection body The initial composition of the substrate must be limited to the products on this list.
Composts from organic household refuse	need recognised by inspection body
Composts from plant residues	----
Processed animal products from slaughterhouses & fish industries	need recognised by inspection body
By-products of food & textile industries	need recognised by inspection body and not treated with synthetic additives.
Seaweeds and seaweed products	need recognised by inspection body
Sawdust, bark and wood waste	need recognised by inspection body
Wood ash	----
Natural phosphate rock	need recognised by inspection body Cadmium should not exceed 90mg/kg P_2O5.
Basic slag	need recognised by inspection body
Rock potash, Mined potassium salts (eg kainit, sylvinite)	less than 60% chlorine
Sulphate of potash (eg patentali)	need recognised by inspection body
Calcium carbonate of natural origin (eg chalk, marl, maerl, limestone, phosphate chalk)	
Magnesium rock	----
Calcareous magnesium rock	----
Epsom salt (magnesium-sulphate)	----
Gypsum (calcium sulphate)	----
Stillage and stillage extract	ammonium stillage excluded
Sodium chloride	only mined salt
Aluminium calcium phosphate (pH >7.5)	maximum 90 mg/kg P205. Use limited to basic soils
Trace elements (eg. boron, copper, iron, manganese, molybdenum, zinc)	need recognised by inspection body
Sulphur	need recognised by inspection body
Stone meal	----
Clay (eg. bentonite, perlite, zeolite)	----
Naturally occurring biological organisms (eg worms)	providing not genetically modified
Vermiculite	----
Peat	excluding synthetic additives; permitted for seed, potting module composts. Other use as recognised by inspection body.
Humus from earthworms and insects	----
Zeolites	----

Wood charcoal	----
Chloride of lime/soda	need recognised by inspection body (calcium chloride only for foliar treatment against bitter pit on apples)
Human excrements	need recognised by inspection body, if possible aerated or composted
By-products of the sugar industry (eg Vinasse)	need recognised by inspection body
By-products of industries processing ingredients from organic agriculture	need recognised by inspection body

TABLE 2: SUBSTANCES FOR PLANT PEST AND DISEASE CONTROL

Substance	Description; compositional requirements; conditions for use
Preparations on basis of pyrethrins extracted from Chrysanthemum cinerariaefolium, containing possibly a synergist	need recognised by inspection body
Preparations from Derris elliptica	need recognised by inspection body
Preparations from Quassia amara	need recognised by inspection body
Preparations from Ryania speciosa	need recognised by inspection body
Preparations on basis of metaldehyde containing a repellent to higher animal species and as far as applied in traps	need recognised by inspection body
Inorganic compounds (Bordeaux mixture, copper hydroxide copper oxychloride)	need recognised by inspection body
Burgundy mixture	need recognised by inspection body
Copper salts	need recognised by inspection body
Sulphur	need recognised by inspection body
Pheromone preparations	in traps, not sprayed on crops
Bacillus thuringiensis preparations	need recognised by inspection body
Granulose virus preparations	need recognised by inspection body
Propolis	need recognised by inspection body
Mineral powders (stone meal, silicates, Betonit)	----
Diatomaceous earth	need recognised by inspection body
Silicates, clay (e.g. Bentonite)	----
Sodium silicate	----
Sodium bicarbonate	----
Potassium permanganate	need recognised by inspection body
Carbon dioxide and nitrogen gas	need recognised by inspection body
Potassium soap (soft soap)	----
Plant and animal oils	----
Paraffin oil	need recognised by inspection body
Seaweed, seaweed meal, seaweed extracts, sea salts and salty water	not chemically treated
Gelatine	----
Lecithin	need recognised by inspection body
Casein	
Ethyl alcohol	need recognised by inspection body
Natural acids (eg vinegar)	need recognised by inspection body
Neem oil and extracts	need recognised by inspection body
Homoeopathic preparations	----
Fermented product from Aspergillas	
Extract from mushroom (shiitake fungus)	
Extract from Chlorella	
Natural plant extracts, excluding tobacco	need recognised by inspection body
Tobacco tea (except pure nicotine)	need recognised by inspection body
Herbal and biodynamic preparations	----
Release of predators of insect pests	need recognised by inspection body
Sterilised insect males (if not genetically modified)	need recognised by inspection body

TABLE 3: SUBSTANCES FOR ANIMAL PEST AND DISEASE CONTROL

(To be Developed)

TABLE 4: SUBSTANCES AND METHODS PERMITTED FOR PEST CONTROL IN STORAGE AND TRANSPORT UNITS.

Substance/physical method	**Conditions of use**
Physical barriers	
Sound	
Ultra-sound	
Light	
Ultra-violet light	
Traps (pheromone traps and static bait traps)	Not in sealed containers
Controlled temperature	
Controlled atmosphere (carbon dioxide, oxygen, nitrogen)	
Diatomaceous earth	

TABLE 5: INGREDIENTS OF NON AGRICULTURAL ORIGIN REFERRED TO IN SECTION 3 OF THESE GUIDELINES

A1. Food additives, including carriers

INS	Name	Specific conditions
170	Calcium carbonates	
220	Sulphur dioxide	wine products
270	Lactic acid	concentrated fruit and vegetable juice and fermented vegetable products
290	Carbon dioxide	
296	Malic acid	
300	Ascorbic acid	if not available in natural form
306	Tocopherols, mixed natural concentrates	----
322	Lecithin	obtained without the use of bleaches and organic solvents
330	Citric acid	concentrated fruit and vegetable juice, jam and fermented vegetable products
331	Sodium citrates	meat products
332	Potassium citrates	meat products
333	Calcium citrates	meat products
335	Sodium tartrate	cakes/confectionary
336	Potassium tartrate	cereals/cakes/confectionary
341i	Mono calcium phosphate	only for raising flour
400	Alginic acid	
401	Sodium alginate	
402	Potassium alginate	
406	Agar	
407	Carageenan	
410	Locust bean gum	
412	Guar gum	
413	Tragacanth gum	
414	Arabic gum	Milk, fat and confectionary products
415	Xanthan gum	fat products, fruit and vegetables, cakes & biscuits, salads
416	Karaya gum	
440	Pectins (unmodified)	
500	Sodium carbonates	cakes & biscuits/confectionary
501	Potassium carbonates	cereals/cakes & biscuits/confectionary
503	Ammonium carbonates	
504	Magnesium carbonates	
508	Potassium chloride	frozen fruit and vegetables/canned fruit and vegetables, vegetable sauces/ketchup and mustard
509	Calcium chloride	milk products/fat products/fruit & vegetables/soy bean products
511	Magnesium chloride	soy bean products
516	Calcium sulphate	cakes & biscuits/soy bean products/bakers yeast Carrier
524	Sodium hydroxide	cereal products
938	Argon	
941	Nitrogen	
948	Oxygen	

A2. Flavourings

Substances and products labelled as natural flavouring substances or natural flavouring preparations as defined in Codex Alimentarius 1A- 1995, Section 5.7

A3. Water and salts

Drinking water
Salts (with sodium chloride or potassium chloride as basic components generally used in food processing).

A4. Preparations of Microorganisms and Enzymes

(a) Any preparations of microorganisms and enzymes normally used in food processing, with the exception of microorganisms genetically modified or enzymes derived from genetic engineering;

A5. Minerals (including trace elements), vitamins, essential fatty and amino acids, and other nitrogen compounds. Only approved in so far as their use is legally required in the food products in which they are incorporated.

TABLE 6: PROCESSING AIDS WHICH MAY BE USED FOR THE PREPARATION OF PRODUCTS OF AGRICULTURAL ORIGIN REFERRED TO IN SECTION 3 OF THESE GUIDELINES

Name	Specific conditions
Water	
Calcium chloride	coagulation agent
Calcium carbonate	
Calcium hydroxide	
Calcium sulphate	coagulation agent
Magnesium chloride (or nigari)	coagulation agent
Potassium carbonate	drying of grape raisins
Carbon dioxide	
Nitrogen	
Ethanol	solvent
Tannic acid	filtration aid
Egg white albumin	
Casein	
Gelatin	
Isinglass	
Vegetable oils	greasing or releasing agent
Silicon dioxide	as gel or colloidal solution
Activated carbon	
Talc	
Bentonite	
Kaolin	
Diatomaceous earth	
Perlite	
Hazelnut shells	
Beeswax	releasing agent
Carnauba wax	releasing agent
Sulphuric acid	pH adjustment of extraction water in sugar production
Sodium hydroxide	pH adjustment in sugar production
Tartaric acid and salts	
Sodium carbonate	sugar production
Diatomaceous earth	
Preparations of bark components	
Potassium hydroxide	pH adjustment for sugar processing
Citric Acid	pH adjustment

Preparations of microorganisms and enzymes:
Any preparations of microorganisms and enzymes normally used as processing aids in food processing, with the exception of genetically modified organisms and enzymes derived from genetically modified organisms.

ANNEX 3

MINIMUM INSPECTION REQUIREMENTS AND PRECAUTIONARY MEASURES UNDER THE INSPECTION OR CERTIFICATION SYSTEM

1. Inspection measures are necessary across the whole of the food chain to verify product labelled according to Section 3 of these guidelines conforms to internationally agreed practices. The official or officially recognised inspection/certification body and the competent authority should establish policies and procedures in accordance with these guidelines.

2. Access by the inspection body to all written and/or documentary records and to the establishment under the inspection scheme is essential. The operator under an inspection program should also give access to the competent or designated authority and provide any necessary information for third party audit purposes.

A. Production units

3. Production should take place in a unit where the land parcels, production areas and storage facilities are clearly separate from those of any other unit which does not produce according to these guidelines; preparation and/or packaging workshops may form part of the unit, where its activity is limited to preparation and packaging of its own agricultural produce.

4. When the inspection arrangements are first implemented, the operator and the official or officially recognised inspection/certification body should draw up and sign a document which includes:

- a full description of the unit and/or collection areas, showing the storage and production premises and land parcels and, where applicable, premises where certain preparation and/or packaging operations take place;

- and, in the case of collection of wild plants, the guarantees given by third parties, if appropriate, which the producer can provide to ensure that the provisions of Annex 1, para 10 are satisfied;

- all the practical measures to be taken at the level of the unit to ensure compliance with these guidelines;

- the date of the last application on the land parcels and/or collection areas concerned of products the use of which is not compatible with Section 4 of these guidelines;

- an undertaking by the operator to carry out operations in accordance with Sections 3 and 4 and to accept, in event of infringements, implementation of the measures as referred to in Section 6, paragraph 9 of these guidelines.

5. Each year, before the date indicated by the inspection body, the operator should notify the official or officially recognised inspection/certification body of its schedule of production of crop products and livestock, giving a breakdown by land parcel/herd.

6. Written and/or documentary accounts should be kept which enable the official or officially recognised inspection/certification body to trace the origin, nature and quantities of all raw materials bought, and the use of such materials; in addition, written and/or documentary accounts should be kept of the nature, quantities and consignees of all agricultural products sold. Quantities sold directly to the final consumer should preferably be accounted for on a daily basis.

7. Storage, on the unit, of input substances, other than those whose use is compatible with paragraph 4.1(b) of these guidelines is prohibited.

8. Apart from unannounced inspection visits, the official or officially recognised inspection/certification body should make a full physical inspection, at least once a year, of the unit. Samples for testing of products not listed in these guidelines may be taken where their use is suspected. An inspection report should be drawn up after each visit.

9. The operator should give the inspection/certification body, for inspection purposes, access to the storage and production premises and to the parcels of land, as well as to the accounts and relevant supporting documents. The operator should also provide the inspection body with any information deemed necessary for the purposes of the inspection.

10. Products referred to in Section 1 of these guidelines which are not in their packaging for the end consumer should be transported in a manner which would prevent contamination or substitution of the content with substances or product not compatible with these guidelines and provide the following information, without prejudice to any other indications required by law:

- the name and address of the person responsible for the production or preparation of the product;
- the name of the product; and
- that the product is of organic status

11. Where an operator runs several production units in the same area, units in the area producing crop, crop products or livestock not covered by Section 1 should also be subject to the inspection arrangements as regards the dash points of paragraph 4 and paragraphs 6 and 7 above. Plants and animals or their products of the same variety as those produced at the unit referred to in paragraph 3 above should not be produced at these units.

[The official or officially recognised inspection/certification body may grant a derogation for a period determined by the inspection/certification body or the competent authority, subject to supplementary inspection requirements imposed by the inspection/certification body.

OR

The official or officially recognised inspection/certification body may grant a derogation for a period in particular cases such as perennial crop production, subject to the supplementary inspection requirements imposed by the inspection/certification body.]

B. Preparation and packaging units

1. When the inspection arrangements are first implemented, the producer and/or operatorand [inspection body] should draw up:

- a full description of the unit, showing the facilities used for the , preparation, packaging and storage of agricultural products before and after the operations concerning them;

- all the practical measures to be taken at the level of the unit to ensure compliance with these guidelines.

This description and the measures concerned should be contained in an inspection report, countersigned by the responsible person of the unit.

In addition, the report should include an undertaking by the operator to perform the operations in such a way as to comply with Section 4 of these guidelines and to accept, in the event of infringements, the implementation of measures as referred to in paragraph 6.9 of these guidelines.

2. Written accounts should be kept enabling the inspection/certification body to trace:
- the origin, nature and quantities of agricultural products as referred to in Section 1 of these guidelines which have been delivered to the unit;

- the nature, quantities and consignees of products as referred to in Section 1 of these guidelines which have left the unit;

- any other information such as the origin, nature and quantities of ingredients, additives and manufacturing aids delivered to the unit and the composition of processed products, that is required by the inspection/certification body for the purposes of proper inspection of the operations.

3. Where products not referred to in Section 1 of these guidelines are also processed, packaged or stored in the unit concerned:

- the unit should have separate areas within the premises for the storage of products as referred to in Section 1 of these guidelines, before and after the operations;

- operations should be carried out continuously until the complete run has been dealt with, separated by place or time from similar operations performed on products not covered by Section 1 of these guidelines;

- if such operations are not carried out frequently, they should be announced in advance, with a deadline agreed on with the inspection/certification body;

- every measure should be taken to ensure identification of lots and to avoid mixtures with products not obtained in accordance with the requirements of these guidelines.

4. Apart from unannounced inspection visits, the official or officially recognised inspection/certification body should make a full physical inspection, at least once a year, of the unit. Samples for testing of products not listed in these guidelines may be taken where their use is suspected. An inspection report must be drawn up after each visit countersigned by the person responsible for the unit inspected.

5. The operator should give the official or officially recognised inspection /certification body, for inspection purposes, access to the unit and to written accounts and relevant supporting documents. The operator should also provide the inspection body with any information necessary for the purposes of inspection.

6. The requirements in respect to the transport as laid down in paragraph A.11of this Annex are applicable.

PROPOSED DRAFT AMENDMENTS TO CODEX GENERAL STANDARD FOR THE LABELLING OF PRE-PACKAGED FOODS[1]
(at Step 5 of the Procedure)

Section 4.2.1.3

Where an ingredient is itself the product of two or more ingredients, such a compound ingredient may be declared, as such, in the list of ingredients, provided that it is immediately accompanied by a list, in brackets, of its ingredients in descending order of proportion (m/m). Where a compound ingredient (for which a name has been established in a Codex standard or in national legislation) constitutes less than [5%] of the food, the ingredients, other than food additives which serve a technological function in the finished product and ingredients known to cause allergic or intolerance reactions, need not be declared.

The following foods and ingredients are known to cause hypersensitivity and shall always be declared as such:

Cereals containing gluten; i.e., wheat, rye, barley, oats, spelt or their hybridized strains and products of these;

Crustacea and products of these;

Eggs and egg products;

Fish and fish products;

Peanuts, soybeans and products of these;

Milk and milk products (lactose included);

Tree nuts and nut products; and

Sulphite in concentrations of 10 mg/kg or more.

Section 4.2.2.1

Except for those ingredients listed in section 4.2.1.3, and unless a general class name would be more informative, the following class names may be used ..... (remainder of section as is)

Section 4.2.3.2

A food additive carried over into foods at a level less than that required to achieve a technological function, and processing aids, are exempted from declaration in the list of ingredients. The exemption does not apply to food additives and processing aids listed in section 4.2.1.3.

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[1] Proposed additions underlined.

PROPOSED DRAFT AMENDMENT TO THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS

(At Step 3 of the Accelerated Procedure)

Section 4.2 List of Ingredients

4.2.2.1 The following class names may be used for the ingredients falling within these classes:

Milk protein products: products with at least 35% and less than 50% of milk protein(s) (m/m in dry matter) not being a traditional milk product such as skim milk powder or whey protein

Milk Protein: products with at least 50% of milk protein (m/m in dry matter)

PROPOSED DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOOD OBTAINED THROUGH BIOTECHNOLOGY (PROPOSED DRADT AMENDMENT TO THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS)

(At Step 3 of the Procedure)

Background

1. Following earlier consideration of issues related to biotechnology, the 21st Session of the Commission agreed that work on the safety, labelling and nutrition aspects of biotechnology, being undertaken by relevant Committees, should be coordinated by the Executive Committee of the Codex Alimentarius Commission in the framework of a project plan. Support was also expressed for holding a second Joint FAO/WHO Consultation on safety of food produced by biotechnology (ALINORM 95/37, para.10).

2. The 23rd Session of the Codex Committee on Food Labelling (CCFL) considered a discussion paper prepared by the United States on labelling aspects of biotechnology and identified a number of issues: the relation of genetic engineering to conventional breeding techniques; scientific safety evaluation of substances produced through recombinant DNA techniques; the use of marker genes; allergenicity and ethical considerations (ALINORM 95/22, paras. 113-119). Further comments were requested on issues associated with biotechnology and considered by the Committee's 24th Session. It was agreed that, based on the advice of the Executive Committee, the Secretariat should initiate the preparation of such guidelines, taking into account the findings of the Expert Consultation (ALINORM 97/22, para. 45).

3. The 42nd session of the Executive Committee stressed that the four Statements of Principle concerning the Role of Science adopted by the Commission should be closely adhered to. It noted the opinion that, while consumers may claim the right to know whether foods had been produced by biotechnology, this right was ill-defined and variable and in this respect could not be used by Codex as the primary basis of decision-making on appropriate labelling. It highlighted the elements to be taken into account when considering the labelling of foods in relation to production processes. Foremost among these was the protection of consumers' health from any risks introduced by the production process, followed by nutritional implications resulting from changes to the composition of the food, any significant technological changes in the properties of the food itself, and the prevention of deceptive trade practices. To a considerable extent such matters would have to be decided on a case-by-case basis. The Executive Committee noted that the possibility of voluntary labelling always existed.

4. The Executive Committee agreed that a paper containing proposed draft guidelines or other appropriate advice should be prepared on this basis for consideration by the CCFL and recommended that the conclusions of the Joint FAO/WHO Expert Consultation on Food Safety and Biotechnology should be taken into account in the preparation of the paper (ALINORM 97/3, para. 29-30).

Scope of the recommendations

5. Although the CCFL is responsible only for labelling aspects of biotechnology, these should not be considered separately but in the wider context of ensuring food safety and preventing deceptive practices. It is also necessary to determine the issues related to biotechnology which can be addressed in the framework of Codex, as part of the Project Plan, and those which are outside its mandate.

6. A number of issues raised by the use of biotechnology cannot be addressed in the framework of Codex as they are not related to the food itself, but to the process or other factors which have no bearing on the safety and quality of the product as consumed. In particular, environmental aspects of the release of genetically engineered products may be legitimate consumer concerns but they should be addressed by competent organizations dealing with the protection of the environment at the national and international level. Concerns which are not related to the properties of the food are sometimes put forward as justifying systematic labelling of all foods produced through biotechnology, whether or not they differ from conventional foods. Such questions as the production of pharmaceuticals through genetically modified organisms or the use of marker genes were also taken into account by the Expert Consultation, as indicated

below. It is therefore necessary to focus on the questions which are within the mandate of the CCFL, essentially labelling issues related to the characteristics of the food itself.

7. As regards the form in which recommendations should be made, the CCFL's mandate is limited to questions specifically related to labelling. It does not include establishing comprehensive recommendations concerning the production processes related to biotechnology, especially as this essentially involves considerations of food safety for which other Committees or Expert Groups are competent, and the Expert Consultation has already made specific recommendations in this area. Guidelines have been prepared or are under development by CCFL in areas where food safety considerations are not essential, such as organic agriculture or the use of the term "halal". Such matters strengthen the role of labelling as a means to ensure fair practices in food trade. In such cases, the Committee took the responsibility to formulate requirements concerning the production process itself, as no other Codex Committee was competent in such matters, and as it was necessary in order to clarify labelling issues. However, in the case of biotechnology, as the Committee is not responsible for food safety aspects, which are addressed elsewhere, it should focus only on the aspects related to labelling.

8. The recommendations put forward by the CCFL would therefore most adequately take the form of an amendment to the General Standard for the Labelling of Prepackaged Foods. This approach was taken concerning irradiation and is currently followed as regards foods which can cause hypersensitivity. This would also make it clear that labelling requirements related to biotechnology are set in the overall context of the General Standard, and the general objectives of providing clear information to the consumer and preventing misleading description or presentation of pre-packaged food.

9. Section 4.1.2 of the General Standard requires the identification of production processes when it is necessary to identify the nature or type of the food (dried, concentrated, etc.). This relates to the treatment undergone by the food itself, but Codex provisions do not go into the production processes of raw materials at the level of agriculture or the mode of selection of plant or animal species. Only in the case of organic agriculture did the CCFL consider means of production because a specific claim was made concerning the type of agriculture and had to be defined. However, unless such no claim is made, labelling requirements apply only to the nature of the food and not to the agricultural practices or selection processes. An indication relating to the selection and/or production process, as in the case of biotechnology, would go beyond the current area covered by labelling provisions, and this raises an issue of principle concerning the competence of the CCFL and Codex in this area.

10. Such a requirement should be clearly justified in the light of food safety concerns and the prevention of deceptive practices, as all foods put on the market should be clearly identified regarding their characteristics or composition. Any food obtained though biotechnology differing substantively from the corresponding food should be clearly identified as to its specific characteristics, and any new food (with no existing equivalent) should be described. This is a general requirement which should also apply to any new food put on the market, irrespective of the production process. If the character of a food has been modified in any substantive way from the conventional food which is currently used by consumers, they should be informed of the nature of the changes.

11. The rationale for requiring additional information beyond what is usually covered by Codex is not the nature of the process, but the fact that the essential characteristics of the food have been modified. In order to be consistent with general Codex labelling policy, information on the process should apply only in relation to information on the product itself.

Joint FAO/WHO Expert Consultation on Biotechnology and Food Safety[1]

12. As a number of consumer concerns in relation to biotechnology are linked to the safety of what may appear a new type of food, an overview of the conclusions and recommendations of the Consultation would be useful to set the debate on labelling in its general context and facilitate the distinction between food safety issues and specific labelling issues.

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[1] FAO Food and Nutrition Paper No.61 (1996)

General food safety issues

13. The Expert Consultation (30 September - 4 October 1996) addressed the evaluation of the safety, for the purposes of consumption, of all food and food components produced using techniques involving biotechnology, whether plant, animal or microbial in origin. It emphasized the first recommendation of the 1990 Consultation[2], that comprehensive and well-enforced food regulations are important in protecting consumer health, and that all national governments should ensure that such regulations keep pace with developing technology. This general recommendation should be supported by concerned Codex Committees dealing with different aspects of biotechnology.

14. The Consultation recommended that safety assessment based on the concept of substantial equivalence, as described in the report, be applied in establishing the safety of foods and food components derived from genetically modified organisms. It made a number of recommendations on how to determine substantial equivalence and agreed on the following general conclusions:

- When substantial equivalence is established for an organism or food product, it is regarded to be as safe as its conventional counterpart and no further safety consideration is needed.
- When substantial equivalence apart from certain defined differences is established, further safety assessment should focus on those defined differences
- When substantial equivalence cannot be established, it does not necessarily mean that the product is unsafe.

15. The Consultation advised designing any testing program on a case-by-case basis taking into account the reference characteristics of the food or food component. Human nutritional studies may be needed, especially when the new food is intended to replace a significant part of the diet.

Allergenicity

16. The Consultation considered the specific issues related to allergenicity in the case of biotechnology and made recommendations for the assessment of potential allergens, including a number of criteria to be applied in identifying potential allergenicity. It proposed that foods which would pose a health risk should not be released. It recommended that foods that fail to elicit positive results in *in vitro* or *in vivo* tests should be treated like any other foods in regard to allergenicity. The recommendations made by the CCFL concerning the labelling of potential allergens would therefore apply to foods obtained through biotechnology as to conventional foods.

17. As regards the possibility of transfer of allergenic properties to foods which normally are not allergenic, the Consultation made the following recommendations:

- The transfer from commonly allergenic foods should be discouraged unless it can be documented that the gene transferred does not code for an allergen.
- Foods which contain an allergen transferred from the organism which provided the DNA should not be considered for market approval unless they can be clearly identified in the marketplace and this identity would not be lost during distribution or processing. Labelling approaches may not be practical in these situations, and particular problems for consumers who cannot read, or who may not be provided with labels. Foods which are not presented on the market in a pre-packaged form and generally not labelled should be taken into account.

Other aspects

18. The Consultation also considered aspects which are not directly related to food safety but to public health issues. These are mentioned briefly as being of interest to the Committee in view of consumer concerns in those areas and to place labelling issues in a general perspective. It should also be clear that such issues are not within the mandate of Codex and cannot be addressed by the CCFL or any other committee, especially as they were not even within the competence of the Consultation on food safety.

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2 WHO, 1991. Strategies for assessing the safety of foods produced by biotechnology, Report of a Joint FAO/WHO Consultation

19. As regards food organisms expressing pharmaceuticals or chemicals, the Consultation recognised that, generally, genetically-modified organisms (GMOs) would not be used as food without prior removal of the pharmaceutical or industrial chemical. When the GMO or its products were used as food, the concept of substantial equivalence could be applied for safety assessment.

20. In addition to food safety concerns, the Consultation recognised that genetic modification to produce pharmaceuticals may raise ethical and control issues that were outside its remit because the issues were unrelated to food safety and recommended that these be brought to the attention of FAO and WHO.

21. The Consultation considered gene transfer from GMOs and as likelihood of transfer from a genetically modified plant to a micro-organism in the gastro-intestinal tract is remote but cannot be entirely ruled out, the Consultation recommended that FAO/WHO convene an expert consultation to address whether there are conditions or circumstances in which antibiotic-resistance marker gene(s) should not be used in genetically-modified plants intended for commercial use and, if so, to define those conditions/circumstances.

Proposed amendments to the General Standard for the Labelling of Prepackaged Foods

22. Any confusion between safety and labelling issues should be avoided and in particular, it should be clear that labelling is not intended to replace safety evaluation. It is sometimes proposed to label all foods produced through biotechnology as some of them might not be safe. However, the essential principle of any food legislation is to ensure that foods should not be available if they are not safe for consumption, whether conventional or produced through biotechnology. Labelling should provide the consumer with information on precautions for use if necessary, but the inherent safety of the product is a pre-requisite in any case.

23. Under the circumstances, the risk posed by transferred allergens can be addressed as a food safety issue or as a labelling issue. The Committee is invited to consider the opportunity of encouraging national authorities to prevent the approval of such foods in view of the fact that labelling in itself cannot entirely solve the problems for some sections of the population. However, the CCFL is currently considering recommendations for the labelling of foods that can cause hypersensitivity and amendments to the General Standard, and may consider the alternative option of specific requirements in such cases. Section 4.2.2 could therefore be modified to require labelling of foods obtained through biotechnology which contain the gene of a known potential allergen not present in the corresponding food.

24. In view of the above information, it appears that recommendations concerning the labelling of foods produced through biotechnology should focus on the areas which are within the mandate of Codex and of the CCFL, and that is relating to the food itself, its safety, characteristics, nutritional composition or intended use, in order to provide clear information to the consumer for any new product obtained through biotechnology presenting specific characteristics not found in conventional foods. Reference to a particular food manufacturing or production process is not usual in Codex and could be relevant in the perspective of Codex objectives only if it is clearly linked to the food itself. Similarly, the General Standard for the Labelling of Pre-packaged Foods (Section 4.2.2.2) addresses the question of labelling of foods which may pose specific religious or ethical concerns by requiring the declaration of specific food ingredients. It is proposed that the food components derived by biotechnology from these same sources also be declared.

25. Recommendations relating to allergens should be considered in conjunction with the specific discussion on this subject, and the amendment of the General Standard, under Agenda Item 6.

Definition

26. The 1990 Consultation defined biotechnology as "the integration of natural sciences and engineering sciences in order to achieve the application of organisms, cells, parts thereof and molecular analogues for products and services" This was a general definition and reflected the scope of the first consultation. The 1996 Consultation referred to this definition and agreed to focus on the safety assessment of "foods and food components which have been produced by techniques that change the heritable traits of an organism, such as recombinant DNA (rDNA) technology". Following earlier discussions held at the CCFL, it appears that where labelling and consumer information are concerned, the major issues are related to genetically modified organisms, while biotechnology may cover a wide range of processes. It was also suggested that a distinction should be made between genetic engineering and other types of biotechnology. In order to avoid

any confusion, it is therefore proposed to give a more detailed definition for the purposes of labelling recommendations, on the basis of the current EC definition[3].

27. The following amendments to the **General Standard for the Labelling of Prepackaged Foods** are therefore proposed as a basis for discussion and for consideration by the Committee:

Proposed Draft Recommendations for the Labelling of Foods Obtained through Biotechnology (Proposed Draft Amendment to the General Standard for the Labelling of Prepackaged Foods) (At Step 3 of the Procedure)

Section 2. Definition of Terms

Add at the end of the Section:

Products obtained through biotechnology

For the purpose of the General Standard, "products obtained through biotechnology" are foods composed of or containing genetically modified organisms, defined as organisms whose genetic material has been altered in a way which does not occur naturally through multiplication and/or natural recombination.

Genetic modification techniques include:

- recombinant DNA techniques which use vector systems
- techniques involving the direct introduction into the organism of hereditary materials prepared outside the organism including micro-injection, macro-injection and micro-encapsulation
- cell fusion or hybridization techniques in which living cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods which do not occur naturally

Section 5. Additional Mandatory Requirements

Foods obtained through biotechnology

When a food or food ingredient obtained through biotechnology, as defined in Section 2, is no longer substantially equivalent to the corresponding existing food or food ingredient as regards

- composition
- nutritional value
- intended use

the characteristics which make it different from the reference food should be clearly identified in the labelling. In particular, the following requirements apply:

- if the nutrient content is significantly modified, [relevant/comprehensive] nutrient declaration should be provided in conformity with the Guidelines for Nutrition Labelling.
- if the mode of preparation is significantly different from that for the equivalent food, clear instructions for use should be provided.

When a food produced by biotechnology is not substantially equivalent to any existing food in the food supply and no conventional comparator exists, the labelling shall indicate clearly the nature of the product, its nutritional composition, its intended use, [the method by which it was obtained] and any other essential characteristic necessary to provide a clear description of the product.

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3 Council Directive 90/220/EEC of 23 April 1990

Substantial equivalence is established by a demonstration that the characteristics assessed for the genetically modified organism, or the specific food derived therefrom, are equivalent to the same characteristics of the conventional comparator (conventional foods or food components already available in the food supply), within the natural variation for such characteristics, based upon appropriate analysis of data.[4]

In addition, the presence in a food obtained through biotechnology of material from the sources referred to in Section 4.2.2.2 which is not present in an existing equivalent foodstuff shall always be declared.

Recommendations concerning allergens

Two possible approaches are proposed:

[In view of the recommendations of the Consultation, it is not proposed at this stage to establish labelling requirements for material which is not present in an existing equivalent foodstuff and which may have implications for the health of certain sections of the population (especially allergens) as the preferred approach would be to discourage the marketing of such products.]

OR

[Section 4.2.2

The presence in any food or food ingredients obtained through biotechnology of an allergen transferred from any of the products listed in Section 4.2.1.3[5], shall be declared.]

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4 Report of the Expert Consultation, FAO Food and Nutrition Paper 61, p. 23

5 Draft proposal contained in ALINORM 97/22, Appendix IV. See also Agenda Item 6.

PROPOSED DRAFT RECOMMENDATIONS FOR THE USE OF HEALTH CLAIMS [1]
(At Step 3 of the Procedure)

2.2 [Health claim means any representation that states, suggests or implies that a relationship exists between a food or a nutrient or other substance contained in a food and a disease or health-related condition.]

(Examples:

A. Health-related effects on the body attributed to directly to a food or nutrient or substance

"X fish oil lowers serum triglycerides and increases clotting times."

"X bran lowers blood cholesterol levels."

"X vegetable oil is low in saturated fat and will help reduce blood cholesterol levels".

"Contains soluble fibre that lowers blood cholesterol levels."

"Contains sorbitol. Polyols are more slowly absorbed than sugars and decrease the insulin response."

B. Disease prevention attributed to nutrient or substance contained in a food

"X contains soluble fibre which reduces risk of heart disease."

"X is low in saturated fat which reduces risk of heart disease."

C. Disease prevention or health-related effects related to diet

"A low fat diet will reduce risk of cancer. X is a low fat food."

"Saturated fat raises blood cholesterol levels. A diet low in saturated fat will reduce blood cholesterol levels and reduce risk of cardiovascular disease. X is low in saturated fat."

7. HEALTH CLAIMS

7.1 Without prejudice to Section 8, a health claim that a food or nutrient or substance contained in a food has an effect on an adverse health-related condition in the body should not be permitted.

7.2 A claim that the consumption or reduced consumption of a food, nutrient or substance contained in a food, as part of a total dietary pattern, may have an effect on a [disease] or health-related condition [should/should not] be permitted subject to the following conditions:

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[1] The title of this text should be "Proposed Draft Amendment to the Guidelines on Use of Nutrition Claims" if the current Draft Guidelines are adopted by the 22nd Session of the Commission.

7.2.1 There is scientific consensus supported by the competent authority that a relationship exists between the food, nutrient or substance and the disease or adverse health-related condition;

7.2.2 The wording of the claim is within the context of a total dietary pattern;

7.2.3 "The food for which the claim is made should be:

(i) a significant source of the nutrient or substance in the case where increased consumption is recommended; or,

(ii) "low" in or "free" of the nutrient or substance in the case where reduced consumption is recommended."

7.2.4 The claim should not state or imply that the consumption of a particular food would cure, prevent or treat a disease; and

7.2.5 [The claim should not be made it the consumption of the food would result in the intake of a nutrient or substance in an amount that would increase the risk of a disease or health-related condition.]