codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Via delle Terme di Caracalla 00100 ROME Tel.: 396.57051 Telex: 625825-625853 FAO Email: codex@fao.org Facsimile: 396.5705.4593

ALINORM 99/22

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION
Twenty-third Session
Rome, 28 June - 3 July 1999

REPORT OF THE TWENTY-SIXTH SESSION OF THE CODEX COMMITTEE ON FOOD LABELLING
Ottawa, Canada, 26-29 May 1998

Note: This document incorporates Circular Letter CL 1998/18-FL

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CX 5/15 **CL 1998/18-FL**
June 1998

TO: - Codex Contact Points
- Interested International Organizations
- Participants at the 26th 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 26th Session of the Codex Committee on Food Labelling (ALINORM 99/22)**

MATTERS FOR ADOPTION BY THE 23rd SESSION OF THE CODEX ALIMENTARIUS COMMISSION

Draft Standards and Guidelines at Step 8 of the Procedure

1. Draft Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (para. 21, Appendix II)

2. Draft Recommendations for the Labelling of Foods that can Cause Hypersensitivity (Draft Amendment to the General Standard for the Labelling of Prepackaged Foods) (para. 32, Appendix III)

3. Draft Amendment to the Standard for Fish Frozen Fish Sticks (Fish Fingers) Fish Portions and Fish Fillets - Breaded or in Batter (labelling section) (para. 36, Appendix IV)

Governments wishing to propose amendments or comments on the above documents should do so in writing in conformity with the Guide to the Consideration of Standards at Step 8 (see Procedural Manual of the Codex Alimentarius Commission) to the Secretary, Joint FAO/WHO Food Standards Programme, FAO, via delle Terme di Caracalla, 00100 Rome, Italy **before 30 March 1999**.

Proposed Draft Standard at Step 5 of the Procedure

4. Proposed Draft Recommendations for the Labelling of Foods Obtained through Biotechnology (Proposed Draft Amendment to the General Standard for the Labelling of Prepackaged Foods) - Sections 2 and 4.2.2 (para. 49, Appendix VII)

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 Wordwide Standards at Step 5 to the Secretary, Joint FAO/WHO Food Standards Programme, FAO, via delle Terme di Caracalla, 00100 Rome, Italy **before 30 March 1999**.

B. REQUEST FOR COMMENTS AND INFORMATION

Draft Guidelines at Step 6 of the Procedure

5. Draft Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods - Section 5.1 (para. 21, Appendix V)[1]

6. Draft Recommendations for the Labelling of Foods that can Cause Hypersensitivity - Section 4.2.1.3 (para. 32, Appendix VI)

Governments wishing to submit comments on points 5. and 6. should do so in writing to the Secretary, Joint FAO/WHO Food Standards Programme, FAO, via delle Terme di Caracalla, 00100 Rome, Italy, **before 20 September 1998 for point 5. and before 20 January 1999 for point 6**.

Draft Standard and Guidelines at Step 3 of the Procedure

7. Proposed Draft Recommendations for the Labelling of Foods Obtained through Biotechnology (Amendment to the General Standard for the Labelling of Prepackaged Foods) - Section 5 (para. 49, Appendix VIII)

8. Proposed Draft Amendment to the General Standard for the Labelling of Prepackaged Foods (Class Names) (para. 40, Appendix IX)

9. Proposed Draft Amendment to the Guidelines on Nutrition Labelling (para. 53, Appendix XI)

10. Proposed Draft Recommendations for the Use of Health Claims (para. 60, Appendix X)

Governments wishing to submit comments on points 7, 8, 9 and 10. should do so in writing to the Secretary, Joint FAO/WHO Food Standards Programme, FAO, via delle Terme di Caracalla, 00100 Rome, Italy, **before 1 December 1998.**

[1] The sections on animal production will be circulated at Step 6 separately in CL 1998/19-FL

SUMMARY AND CONCLUSIONS

The summary and conclusions of the 26th Session of the Codex Committee on Food Labelling are as follows:

Matters for consideration by the Commission:

The Committee:

- agreed to advance to Step 8 the Draft Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods, with the exception of sections 5.1 and Animal Production, which were returned to Step 6 (para. 21, Appendix II)

- agreed to advance to Step 8 the Draft Recommendations for the Labelling of Foods that can Cause Hypersensitivity (list of ingredients) (para. 32, Appendix III)

- agreed to advance to Step 8 the Draft Amendment to the Standard for Fish Frozen Fish Sticks (declaration of fish core) (para. 36, Appendix IV)

- agreed to advance to Step 5 the sections on Definition and Allergens of the Proposed Draft Recommendations for the Labelling of Foods Obtained through Biotechnology (para. 49, Appendix VII)

Other Matters of Interest to the Commission

- agreed to return to Step 6 the section on the "25% rule" in the Draft Recommendations for the Labelling of Foods that can Cause Hypersensitivity (para. 32, Appendix VI)

- agreed to return to Step 3 for further comments the section on mandatory labelling in the Proposed Draft Recommendations for the Labelling of Foods Obtained through Biotechnology (para. 49, Appendix VIII)

- agreed to return to Step 3 the amendment to the General Labelling Standard proposed by the CCMMP on Class Names (para. 40, Appendix IX)

- agreed to return to Step 3 the Proposed Draft Amendment to the Guidelines on Nutrition Labelling (para. 53, Appendix XI)

- agreed to return to Step 3 the Proposed Draft Recommendations for the Use of Health Claims (para. 60, Appendix X)

TABLE OF CONTENTS

LIST OF APPENDICES

INTRODUCTION

1. The Codex Committee on Food Labelling held its Twenty-Sixth Session in Ottawa, from 26 to 29 May 1998, at the kind invitation of the Government of Canada. The meeting was attended by 239 delegates and observers representing 42 Members and 28 international organizations. The meeting was chaired by Dr. Anne MacKenzie, Associate Vice-President, Science Evaluation, 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. George Paterson, Director General, Food Directorate, Health Protection Branch, Health Canada, who welcomed the delegates to Ottawa. Dr. Paterson reminded delegates that transportation networks and technological advances now allow foodstuffs to move from one continent to another, virtually overnight, creating a truly global marketplace and that consumers welcome this bounty but also expect it to be safe and wholesome. Dr. Paterson outlined the importance of the Committee in providing guidance on the labelling of foods to ensure the safety of consumers in this international context.

ADOPTION OF THE AGENDA (Agenda Item 2)

3. The Committee adopted the Provisional Agenda as proposed in document CX/Fl 98/1. Following discussions held at the 25th CCFL, the Committee agreed with a suggestion made by the delegation of Australia that relevant information on the elaboration of Rules of Origin by the World Customs Organization would be presented by the Codex Secretariat at its 27th Session (ALINORM 97/22A, para, 79).

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

4. The Committee noted that the 22nd Session of the Codex Alimentarius Commission had adopted the draft Guidelines for Use of Nutrition Claims and General Guidelines for the Use of the Term "Halal" at Step 8; the proposed draft Amendment to the Labelling Section of the Standards for Quick Frozen Fish Sticks, Fish Portions and Fish Fillets, Breaded or in Batter at Step 5; and the proposed draft Amendment to the General Standard for the Labelling of Prepackaged Foods (Recommendations for the Labelling of Foods that can Cause Hypersensitivity) at Step 5. The Commission also assigned the consideration of "Sports" and "Energy" Drinks to the CCFL, with the understanding that the Committee would coordinate its work with the Committee on Food Additives and Contaminants and the Committee on Nutrition and Foods for Special Dietary Uses.

5. The Committee was also informed that the recently held Coordinating Committee for Europe had drawn the attention of the CCFL and CCNFSDU to the importance of questions relating to nutrition and health claims and the need to proceed with work in this area in order to provide appropriate guidance and recommendations at the international level (ALINORM 99/19, para. 52).

6. The Committee noted that the labelling provisions in the standards for milk and milk products had been discussed by the Committee on Milk and Milk Products and would be submitted for endorsement to the next session of the CCFL. The Committee noted that the request of Malaysia to consider the description of vegetable fat milks (e.g., coconut milk) in the context of the draft Code of Practice on Milk and Milk Products (now renamed as the draft General Standard for Dairy Terms) should be directed to the Committee on Milk and Milk Products.

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1 CX/FL 98/2

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

Proposed Draft Standard for Pickles (ALINORM 99/15, Appendix III)

7. The Committee could not decide whether the labelling of pickles as "vegetarian" (Section 7.2) should be mandatory or voluntary and therefore did not endorse the labelling provisions. The Committee agreed that they should be further considered by the next Session of the Codex Committee on Processed Fruits and Vegetables when finalizing the standard.

Proposed Draft Standard for Kimchi (ALINORM 99/15, Appendix IV)

8. The Committee endorsed the labelling provisions as proposed.

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

9. The Committee recalled that its 25th Session had returned the draft Guidelines to Step 6 for additional comments. The draft Guidelines and comments submitted in response to CL 1997/10-FL were reviewed by the *ad hoc* Working Group immediately prior to the Committee's current meeting.

10. The Chairperson of the *ad hoc* Working Group, Ms. Ruth Lovisolo (Australia), presented the revised version of the Guidelines to the Committee and noted that with the exception of issues relating to animal production and animal products, the text was considered in its entirety. The Working Group made the following significant amendments to the text:

Foreword

11. The text was restructured in a more logical sequence and additional information was included on the application of the guidelines as a first step towards the international harmonization of requirements for organic products.

Section 1 - Scope

12. The text was revised to allow for the use of "words of similar intent, including diminutives ", in addition to the terms "organic", "biodynamic", "biological" and "ecological", with the understanding that the paragraph did not apply to terms, e.g., "Bio", that had no connection with the method of production and did not mislead consumers as to the true nature of the product.

Section 2 - Definitions

13. The definitions were aligned with definitions already adopted by the Commission, particularly those terms elaborated by the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS). The Working Group agreed that a definition for genetically modified organisms was necessary, but noted that the definition should be considered provisional until such time as the CCFL agreed on a definition in the framework of discussions on biotechnology and therefore would be subject to future review. The Observer of IFOAM expressed its reservation to the sentence in footnote 4: "In the interim member counties may also apply national definitions".

Section 3 - Labelling and Claims

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2 CX/FL 98/3 and comments from Canada (CRD 9) and India (CRD 18).

3 ALINORM 97/22A, Appendix III and comments from France, Japan, Poland, Consumers International, ASSINSEL (CX/FL 98/4), Canada, Thailand, European Commission, European Dairy Association, IFOAM (CRD 1) and India (CRD 19).

14. The Working Group agreed that the text was intended to facilitate the development of the industry while protecting consumers and therefore, the labelling requirements were refined in order to link the ingredients list with the method of production.

15. For claims that a food is "organic", a limit of 5% m/m of the maximum level of total ingredients, including additives but excluding salt and water, was preliminarily established for components derived from non organic sources. In view of divergent opinions for organic claims on products made up of organic and non-organic ingredients, provisions were included for products containing less than 95% of organic ingredients that would enable national governments to determine labelling requirements for these products.

Section 6 - Inspection and Certification

16. In consideration of those texts already finalized by the CCFICS, the Working Group agreed that when accreditation was deferred to a designated authority, the competent authority remained ultimately responsible. It was agreed that this Section of the text should be referred to the CCFICS for advice on the appropriateness of using private bodies for accreditation purposes; a reference to further guidance developed by other international organizations (i.e. ISO 65) was added as a footnote to the text.

Annexes

17. A number of amendments were made to the principles of organic production included in Annex 1, the associated approved inputs used in traditional organic agriculture stipulated in Annex 2 and to the minimum inspection requirements set out in Annex 3.

18. The Committee expressed its appreciation for the achievements and progress made by the Working Group. While discussing the revised text elaborated by the Working Group, the Committee agreed that the term "genetically engineered organisms (GEO)" was a provisional definition intended for the guidance of governments in applying the Guidelines and therefore, supported the explanatory footnote to this effect. The Committee decided, however, to add the term "genetically modified organisms (GMO)" wherever the term GEO appeared throughout the text, as the term GMO was commonly used in some countries.

19. The Committee agreed that "ayurvedic" preparations should be added to the listing of "homeopathic" preparations in the table of Substances for Plant Pest and Disease Control (Table 2) and that other terms indicating traditional practices of this nature could be added in the future.

20. In view of divergent opinions and legislation regarding the Requirements for Inclusion of Substances in Annex 2 and Criteria for the Development of Lists of Substances by Countries (Section 5.1 only), the Committee agreed to append this Section to the report for additional comment and consideration at its next meeting.

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

21. With the exception of Section 5.1, the Committee advanced the draft Guidelines to Step 8 for adoption by the Commission (see Appendix II). The Committee agreed to return Section 5.1 related to criteria for the development of lists of substances to Step 6 for further comments (see Appendix V); the Committee also decided that the texts related to animal production and animal products would be redrafted by Australia at Step 6 for circulation and comments. It was decided that these remaining texts would be considered by the *ad hoc* Working Group immediately prior to the 27th CCFL.

DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOODS THAT CAN CAUSE HYPERSENSITIVITY (Draft Amendment to the General Standard for the Labelling of Prepackaged Foods) (Agenda Item 6)[4]

22. The Committee recalled that the Commission had adopted at Step 5 the Draft Amendment to the General Standard, including a list of foods and ingredients that can cause hypersensitivity, based on the recommendations of the FAO Technical Consultation on Food Allergies. The Commission also considered the request of the Committee concerning the need for further scientific advice on the inclusion on substances in the list and noted that the WHO Secretary of JECFA had agreed in principle that it would be possible to address this issue in the framework of JECFA.

23. Dr. Steve Taylor (University of Nebraska, USA), FAO Consultant, presented a paper which had been prepared in order to facilitate the discussion of the Committee on hypersensitivity and the identification of the issues requiring further work. Dr. Taylor recalled that a clear distinction should be established between allergies, which affected the immune system, and food intolerances, that the establishment of levels of tolerance was a difficult question and still the subject of controversy. He pointed out that as the information available on the prevalence of allergies was still incomplete, it was necessary to collect more information and ensure the participation of specialists and institutions working in this area. He recalled that the Consultation had relied essentially on the criteria of comparative prevalence and evidence of severe reactions to establish the current list of "common" foods that can cause hypersensitivity. The Committee expressed its appreciation to Dr. Taylor for this interesting document, which also included an analysis of each substance included in the list.

24. The Representative of WHO informed the Committee that JECFA was prepared to evaluate the potential hypersensitivity of specific substances at the request of the Committee and that for the development of more generic advice consideration might be given to the possibility of convening a consultation. He also asked for clarification of the request made at the last session of the Committee "to determine the foods to be included in the list and the criteria to do so", especially whether reference should be made to food groups or individual foods, and if consideration should be given only to allergic reactions or also to intolerance.

25. The Committee confirmed that the title of the amendment referred to hypersensitivity in order to include both food allergies and intolerances, in view of their importance from a public health point of view. It was also recalled that the list included both food groups and individual foods, on the basis of the recommendations of the Consultation.

26. The Secretariat indicated that JECFA was prepared to consider the question of hypersensitivity at its 53rd Session (June 1999), provided the Committee clearly identified the issues requiring scientific advice and prioritized them. The Committee was informed that JECFA was in the process of identifying individuals with the required expertise in order to consider scientific evidence on hypersensitivity in the framework of JECFA.

27. The Committee expressed its appreciation for the offer of JECFA to consider further evidence on foods that may cause hypersensitivity and therefore providing a scientific basis and criteria for the inclusion of foods on the list. The Committee noted that this would not delay the finalization of the current amendment under consideration and that the list could be further considered in the framework of JECFA if needed.

28. Several delegations stressed that the current list had been established on the basis of the recommendations of the Consultation, which had also defined criteria. The Committee should therefore finalize the list as currently drafted, as it was necessary to address an important public health issue. The Delegation of Norway pointed out that there was a link between the list and the amendment of the "25% rule" as if many exemptions existed to full ingredient listing, it would be necessary to include more substances in the list.

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[4] CX/FL 98/5 (comments from Australia, Denmark, Singapore,), CX/FL 98/5-Add.1 (Association of European Coeliac Societies-AOECS), CRD 2 (Canada, France, Germany, Norway, Confederation of the Food and Drink industries of the EU-CIAA, European Dairy Association-EDA, International Dairy Federation-IDF), CRD 20 (India), CRD 16 (Discussion paper by Dr. S. Taylor)

29. While there was consensus on the necessity to finalize the list, the Committee noted that it would need to be updated and some of its entries might need to be clarified, as follows. Some delegations pointed out that certain current classes of food, such as "milk and milk products" or "fish and fish products" might be too broad and include products which were not actually causing hypersensitivity. For example, in the case of "soybean, peanuts and their products" the protein fraction was allergenic but there was no evidence that refined or heat treated oil caused such reactions; the definition of foods or food groups would therefore need to be reviewed in this perspective. It was also proposed by some delegations that JECFA consider the limit levels of substances causing hypersensitivity, the question of carry-over in composite ingredients and the question of criteria for the inclusion of substances in the list.

30. The Committee had an exchange of views on the proposal to amend the "25% rule" under which the individual ingredients of compound ingredients present at less than 25% in any food did not need to be labelled, in relation to consumer information on hypersensitivity. Some delegations expressed the view that the reduction to 5% would offer an improvement for affected consumers, although it did not completely solve their problems.

31. Several delegations and the Observer from the EC however stressed that there was no scientific basis for this reduction as reactions might be caused by smaller amounts of allergenic substances. Moreover, the issue of the 25% rule should not be linked to hypersensitivity and required a larger debate in the overall perspective of consumer information through adequate labelling. The Committee, recognizing that there was no consensus at this stage and that further discussion was needed on this important issue, agreed to return this section to Step 6 for further comments and consideration at its next session.

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

32. The Committee agreed to forward the Draft Amendment on the list of ingredients which should always be declared to Step 8 for adoption by the 23rd Session of the Commission (see Appendix III- section 4.2.1.4), and to return Section 4.2.1.3 (on the 25% rule) to Step 6 for additional comments (see Appendix VI).

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)[5]

33. The Committee recalled that the Proposed Draft Amendment to the labelling provisions in the Standard for Quick Frozen Fish Sticks had been adopted at Step 5 of the Procedure at the 22nd Session of the Commission, which had not confirmed the Accelerated Procedure.

34. Several delegations and the Observers from the European Community, Consumers International and Center for Science in the Public Interest (CSPI) expressed the view that mandatory declaration of the proportion of the fish core would allow consumers to make an informed choice. It was also suggested that the term "fish core" included other ingredients such as water and additives and therefore, the designation of the "fish content" was more appropriate. The Delegations of Japan, the United States and Canada stated that the labelling should be voluntary, as the composition of the product was already defined in the Standard, and it was difficult to maintain an exact percentage of fish core, and to ensure enforcement of such a requirement.

35. In reply to a question on the method for the determination of fish core, the Secretariat indicated that this question would be considered by the next session of the Committee on Fish and Fishery Products (June 1998).

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

36. The Committee agreed to retain the mandatory provisions as proposed and advanced the Draft Amendment to Step 8 of the Procedure (see Appendix IV).

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5 ALINORM 97/22A Appendix II; CX/FL 98/6 (comments from Japan, Spain, Denmark, Australia); CRD 6 (France and Canada); CRD 11 (Thailand); CRD 21 (India)

PROPOSED DRAFT AMENDMENT TO THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS (CLASS NAMES) (Agenda Item 8)[6]

37. The Committee recalled that the provisions of the proposed draft amendment on class names for milk protein products and milk protein had been referred by the Committee on Milk and Milk Products and that the last session had agreed to circulate them at Step 3 of the Accelerated Procedure.

38. The Committee agreed with the suggestion of New Zealand for editorial changes in the definition of milk protein products by changing "traditional milk products" to "traditional dry milk products" and changing "whey protein" to "whey powder".

39. However, the Observer from the European Community proposed to replace the two classes with one class name for milk proteins as included in the current EC regulations and the Committee could not come to a conclusion at this stage.

Status of the Proposed Draft Amendment to the General Standard for the Labelling of Prepackaged Foods (Class Names)

40. The Committee agreed to circulate both proposals (see Appendix IX) for additional comments at Step 3 of the Procedure and for consideration at its next session.

PROPOSED DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOODS OBTAINED THROUGH BIOTECHNOLOGY (Agenda Item 9)[7]

41. The Committee recalled that the Proposed Draft Recommendations considered by the last session had been circulated for comments at Step 3 and redrafted in the light of the comments received. In particular, the text included an alternative proposal referring to general labelling of foods containing GMOs and labelling of foods produced from GMOs but not containing them when they were significantly different from conventional foods.

42. The Delegation of Brazil stressed the importance of adhering to the four principles on the role of science in Codex and recalled that the safety of foods was a prerequisite to their marketing in any case; this principle had been followed very strictly in the case of genetically modified products, as the selection process was controlled more effectively than with other techniques. This position was supported by several delegations and observers, who pointed out that the principles for the labelling of such foods should be the following, as proposed in the working paper ALINORM 97/22A, Appendix VI. "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 and any other essential characteristic necessary to provide a clear description of the product". However, there was no justification in terms of food safety for specific labelling of foods that were substantially equivalent to conventional foods, as there was no evidence of any specific health hazards.

43. It was pointed out that the identification of significant modifications in composition were already required for novel foods which were not obtained though biotechnology but were different from conventional foods, and the Committee noted that this was consistent with existing labelling provisions that provide clear information to the consumer.

44. The Observer from the EC informed the Committee that EC legislation required labelling of all foods containing GMOs and of foods produced from GMOs but not containing them when no longer equivalent to existing foods or ingredients. This was intended to ensure transparency and address consumer concerns for clear information on these

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6 ALINORM 97/22A, Appendix V; CX/FL 98/7 (comments from Denmark); CRD 10 (Canada)

7 CX/FL 98/8 (comments from Canada, France, Germany, Japan, New Zealand, Norway, United States, Brazil, ASSINSEL, Consumers International (CI) and revised proposal), CRD 5 (Canada, CI), CRD 14 (Thailand, International Life Sciences Institute-ILSI), CRD 22 (India).

products in order to make informed choices. The Observer also indicated that specific rules provide that foods which do not contain protein or DNA resulting from genetic modification are considered to be equivalent to existing foods or ingredients and shall not be subject to specific labelling requirements. Several delegations supported this position as based on scientific evaluation and expressed the view that the concept of substantial equivalence was not relevant to labelling issues; consequently they supported the alternative proposal on the labelling of foods containing or produced from GMOs in the revised text (see para. 41).

45. The Delegations of Norway and India expressed the view that the issues associated with modern biotechnology went beyond information about product 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.

46. The Observer from Consumers International, supported by several delegations and observers, emphasized the extreme importance of this issue for consumers and the necessity for comprehensive labelling of genetically engineered products in order to allow consumers to make an informed choice. The Observer noted that mandatory comprehensive labelling was needed to allow consumers their fundamental right to information to choose according to their own ethical, cultural, and other personal preferences, and to provide vital health information for consumers sensitive to uncommon or unknown allergens. Substantial equivalence was strongly opposed as a basis for labelling since it involved value judgments that excluded consumer input. Consumers International opposed the terms "biotechnology" and "modern biotechnology" and favored "genetically engineered/modified" instead.

47. The Observer from IFOAM pointed out that organic producers needed to ensure that when they used substances coming from the conventional market, these did not include GMOs and related products; identification of products derived from genetic engineering was essential and consequently IFOAM supported comprehensive mandatory labelling requirements.

48. The Committee, recognizing the need to concentrate its efforts on the areas where consensus could be achieved, as proposed by the Chairperson, had an exchange of views on the definition of foods obtained through biotechnology. The Committee noted the proposals 1) to replace "new" with "modern" biotechnology, and 2) to avoid using the term " biotechnology" as it might create confusion for the consumer. Taking into account the amendments to the definition proposed by Canada and the EC, the Committee agreed on a revised definition which clarified the scope of the text. The Committee also agreed to require the labelling of allergens transferred through genetic modification, as proposed in the current text (section 4.2.2.).

Status of the Proposed Draft Recommendations for the Labelling of Foods Obtained through Biotechnology

49. The Committee agreed to forward the amended Definition in square brackets and Section 4.2.2. (allergens) to Step 5 (see Appendix VII) and to return all other sections of the Proposed Draft to Step 3 for further comments and consideration by the next session (see Appendix VIII).

PROPOSED DRAFT AMENDMENTS TO THE GUIDELINES ON NUTRITION LABELLING (Agenda Item 10)[8]

50. The Committee recalled that, at the suggestion of the United States, the last session had agreed to consider the amendment of Section 3.2 (Listing of Nutrients) of the Guidelines in order to require the declaration of saturated fat, sugars, fibre and sodium in cases where nutrition labelling was used. Following its approval by the Commission as new work, the proposal for the partial revision of the Guidelines had been circulated at Step 3 in CL 1997/19-FL. The Committee recalled that under the current Guidelines, where nutrient declaration was applied, the declaration of energy value, protein, available carbohydrate and fat were mandatory. The suggested amendment proposed that the declaration of sugars, fibre, saturated fat and sodium should also be made mandatory where nutrient declaration was applicable.

51. Several delegations and the Observer of the EC proposed that nutrition labelling should consist of energy value, protein, available carbohydrate and fat when nutrient declarations were made, and that declaration of sugars, fibre, saturated fat and sodium should only be included when a claim was made for one of these nutrients. It was stated that mandatory nutrition labelling for all eight nutrients would lead to consumer confusion, and that nutrition labelling for sugars, fibre, saturated fat and sodium was felt to be expensive, onerous and of little added benefit for consumers. The Observer of the CIAA stressed that labelling should be simple and easy to understand and that when a specific claim was made, mandatory nutrition labelling should only apply to energy, protein, carbohydrate and fat. The Observer of CSPI noted that nutrition labelling had become a widely accepted tool to encourage consumers to choose a healthy diet, and supported the development by the Committee of mandatory labelling programmes requiring nutrition labelling (regardless of whether a nutrient claim was made) and allowing national authorities to determine which nutrients should be listed on foods sold domestically.

52. The Delegation of Malaysia also proposed that, in view of recent additional evidence and developments concerning the link between types of fatty acids and coronary disease, when saturated fat was declared, the declaration of trans-fatty acids should also be included, and proposed that this matter be referred to the CCNFSDU. The Delegation of Argentina indicated that its national legislation required mandatory declaration of fibre expressed as dietary fibre, and that the declaration of monounsaturated fatty acids was required when a claim related to the quantity and type of fatty acids was made. Other delegations noted their various national regulations related to the nutrient declaration of one or more of the nutrients under discussion, and were of the opinion that differences in terminology and public health needs indicated the need for regulations promulgated on a national basis.

Status of the Proposed Draft Amendment to the Guidelines on Nutrition Labelling

53. As the Committee recognized that divergence in opinions existed concerning nutrition labelling on the basis of the current list or its extension to other nutrients, it decided not to amend this section of the Guidelines at this stage and returned the Proposed Draft Amendment to Step 3 for further comments (see Appendix XI). The Committee decided to seek the advice of the Committee on Nutrition and Foods for Special Dietary Uses to determine if public health needs required the mandatory labelling of sugars, fibre, saturated fat and sodium when nutrition labelling was applicable.

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[8] CL 1997/19-FL and comments from Australia, Denmark, Singapore, Spain (CX/FL 98/9); Canada, France, Germany, CIAA, IDF (CRD 7); Thailand, ILSI (CRD 12), and; India (CRD 23).

PROPOSED DRAFT RECOMMENDATIONS FOR THE USE OF HEALTH CLAIMS (Agenda Item 11)[9]

54. The Committee recalled that, following the decision of its last session to reconsider the issue of health claims, the recommendations had been circulated for comments at Step 3, with a view to their ultimate inclusion in the Guidelines for Use of Nutrition Claims.

55. The Committee noted the following proposals for amendments to the text but recognized that there was no consensus to include them at this stage. The Delegation of Thailand proposed 1) to delete section 7.1 since it was considered as covering medicinal claims and not health claims; 2) that health claims should be defined as in section 7.2. The Delegation of Japan proposed to require that function claims for foods should be proven by human studies. The Delegation of Mexico proposed that health claims should be submitted for approval to the competent authorities in accordance with national requirements.

56. The Committee agreed to include the following amendments: a preamble concerning the need for health claims to be consistent with national nutrition policy, as proposed by the Delegation of Norway, in conformity with the Guidelines for Nutrition Claims, and a clarification of section 7.2.5 as proposed by the Delegation of Thailand.

57. Several delegations and the Observer from the EC pointed out that their national legislation did not allow the use of claims related to the prevention, cure and treatment of disease but that a large debate had been initiated on the relation between health and diet. Some delegations and the Observer from Consumers International indicated that they were not in favour of health claims in general; however, as these were found on the market, there was a need to consider this issue further from the point of view of consumer information and education in health and nutrition matters. The Committee noted that the scientific basis of health claims should be considered in more detail and that it would be useful to refer this matter for advice to the Committee on Nutrition and Foods for Special Dietary Uses.

58. The Committee generally agreed that in any case health claims should not refer to one single food but should be placed in the context of the total diet, and that they should be substantiated by scientific evidence. The Delegation of Denmark suggested that examples A and B referring to single foods in the proposal be deleted. The Delegation of the United States pointed out that while the term “prevention” of disease might create some confusion, the claims allowed actually related to a reduction of the risk in a dietary context. The Delegation of South Africa indicated that it followed a similar approach to approve health claims.

59. The Observer from CIAA, supported by the Observers from ICGMA and IDF, expressed the view that health claims based on scientific evidence should be allowed as they would provide useful information for the consumer and facilitate innovation in the industry. The Observer from CSPI expressed the view that allowing health claims would not significantly improve consumer information as regards health and nutrition matters.

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

60. The Committee, recognizing the need for further discussion of this issue, agreed to return the text to Step 3 for further comments and consideration at its next session, and to forward it for advice to the Committee on Nutrition and Foods for Special Dietary Uses regarding the scientific basis for health claims (see Appendix X).

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9 CX./FL 98/10 (comments from Denmark, France, Germany, New Zealand, Consumers International), CRD 3 (Canada, Thailand, CIAA, EDA, ICGMA, IDF), CRD 15 (ILSI), CRD 24 (India)

PROPOSED DRAFT RECOMMENDATIONS FOR SPORT AND ENERGY DRINKS (Agenda Item 12)[10]

61. The Committee recalled that its last session had considered a proposal by South Africa to develop recommendations for "Sports Drinks" and "Energy Drinks" and requested guidance from the Commission on how to proceed in this area. The 22nd Session of the Commission agreed that for "sports" and "energy" drinks the major problem might relate to the claims made for such products and assigned the work to the CCFL, which should also coordinate its work with the Codex Committees on Food Additives and Contaminants and on Nutrition and Foods for Special Dietary Uses (ALINORM 97/37, para. 122).

62. The proposed draft Recommendations for Sports and Energy Drinks were presented to the Committee by the Delegation of South Africa, who stressed that the proposal was limited to the consideration of claims only, and did not refer to other aspects such as product composition. It was noted that such claims could be misleading to consumers and therefore that their terminology needed to be defined on a sound scientific basis.

63. The Committee discussed the need for further development of the Recommendations. Several delegations supported the consideration of guidelines as a claims issues without linkage of the claim to any particular product. The Delegation of Malaysia was of the opinion that Section 1.4 created confusion, and suggested the addition of other provisions under a new Section 2.8 to stipulate that sports drinks were not intended for consumption by infants or as replacement fluids. The Delegation of the United Kingdom expressed the opinion that there was a need to define only a limited number of claims, i.e. isotonic, hypertonic, hypotonic.

64. Other delegations were of the opinion that there was little difference between the energy content of sports and soft drinks and that in any case, nutritional requirements could be met by certain population groups (i.e., athletes) through a normal diet. It was suggested that if any recommendations related to sports drinks were proposed, they should be based on a demonstrated need to meet the requirements of certain population groups. For energy drinks, the appropriate level of energy should be defined by the CCNFSDU. It was also noted that any proposed food additive provisions for the products would be addressed by the Committee on Food Additives and Contaminants in the context of the General Standard for Food Additives. Some delegations expressed the view that it was not appropriate to include caffeine in sports drinks or electrolyte drinks. Some delegations expressed the opinion that the level of 0.05% of alcohol for "alcohol free" was excessively low, and that certain fruit juices could not meet these requirements. The Observer of IDF pointed out that milk ingredients were used in sports and energy drinks and that this would have to be taken into consideration in the further elaboration of the text.

Status of the Proposed Draft Recommendations for Sports and Energy Drinks

65. The Committee thanked South Africa for its efforts, and accepted their offer to redraft the document on the basis of the comments received and the above discussions, for circulation and further consideration at its next session. The Committee noted that the document might be submitted to the CCNFSDU for advice on the use of sports drinks to meet special dietary needs.

PROPOSED DRAFT GUIDELINES FOR USE OF THE TERM "VEGETARIAN" (Agenda Item 13)[11]

66. The Committee recalled that its last session had considered a proposal of South Africa regarding the elaboration of definitions for "vegetarian", as these products were widely sold with a variety of claims which might create consumer

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10 CX/FL 98/11 and comments submitted by Australia, Denmark, Poland, Slovak Republic, Spain, Thailand, AFCASOLE, ETC, ISDC, ISDI (CX/FL 98/11-Add. 1), Canada, Norway, Thailand, Uruguay (CRD 4), India (CRD 25), Thailand (CRD 28) and Austria (CRD 30).

11 CX/FL 98/12 and comments from Australia, Denmark, Slovak Republic, Spain (CX/FL 98/12-Add. 1); Canada, Norway, Uruguay (CRD 8); Thailand (CRD 13); India (CRD 26).

confusion (ALINORM 97/22A, paras. 72-73). Following their approval as new work by the 22nd Session of the Commission, the proposed draft Guidelines had been circulated for comments at Step 3.

67. The proposed draft Recommendations for Use of the Term "Vegetarian" were presented by the Delegation of South Africa, who noted that the use of the term "vegetarian" without qualification created consumer confusion, especially in consideration of the various diets included under this generic classification (e.g., "vegetarian", "lacto-ovo vegetarian", "lacto-vegetarian" and "vegan"). The proposal was presented as an amendment to either the General Standard for the Labelling of Prepackaged Foods or the General Guidelines on Claims.

69. The proposed draft Recommendations for Use of the Term "Vegetarian" were presented by the Delegation of South Africa, who noted that the use of the term "vegetarian" without qualification created consumer confusion, especially in consideration of the various diets included under this generic classification (e.g., "vegetarian", "lacto-ovo vegetarian", "lacto-vegetarian" and "vegan"). The proposal was presented as an amendment to either the General Standard for the Labelling of Prepackaged Foods or the General Guidelines on Claims.

70. The delegation of India pointed out that the majority of the Indian population were strict vegetarians and therefore suggested that the term "vegetarian" or "strict vegetarian" should be restricted to those products which did not contain meat, poultry, fish, dairy products or eggs. India and other delegations noted that any proposed terms would need to be carefully defined in view of varying terminology (e.g., "vegan") and cultural differences in various countries of the world.

71. Other delegations were of the opinion that definitions for specific terms were not required, especially since they felt that the General Labelling Standard and the General Guidelines on Claims adequately covered such claims through the use of ingredient list labelling. The Committee agreed that there was no need to elaborate general guidelines or standards for the use of the term "vegetarian" and that any work in this area should be restricted to the elaboration of definitions for claims used on product labels.

Status of the Proposed Draft Recommendations for the Use of the Term "Vegetarian"

72. The Committee thanked South Africa for its efforts, and accepted their offer to redraft the document, in collaboration with India, on the basis of comments received and the above discussions, for circulation and further consideration at its next session.

OTHER BUSINESS, FUTURE WORK AND DATE AND PLACE OF NEXT SESSION (Agenda Item 14)

73. The Committee had no further business to discuss. The Observer from CSPI expressed the view that the Committee should develop its efforts to ensure that standards were based on the premise of "upward harmonization", as discussed in this organization's report on *Food Labelling for the 21st Century*, which was made available to delegates.

74. The Committee noted that its 27th Session was tentatively scheduled to be held in Ottawa from 19-23 April 1999, the exact arrangements to be determined between the host country and Codex Secretariats.

SUMMARY STATUS OF WORK

Subject Matter	Step	Action by	Document Reference in ALINORM 99/22
Draft Guidelines for Organically Produced Foods (Main text)	8	Governments 23rd CAC	para. 21 Appendix II
Draft Amendment to the General Labelling Standard (Hypersensitivity) (List of ingredients)	8	Governments 23rd CAC	para. 32 Appendix III
Draft Amendment to the Standard for Quick Frozen Fish Sticks	8	Governments 23rd CAC	para. 36 Appendix IV
Draft Guidelines for Organically Produced Foods (Section 5.1 and Animal Production)	6	Governments 27th CCFL	para.21 Appendix V
Draft Amendment to the General Labelling Standard (Hypersensitivity) ("25% rule")	6	Governments 27th CCFL	para. 32 Appendix VI
Proposed Draft Recommendations on Labelling/Biotechnology (Definition & Allergens)	5	Governments 23rd CAC	para. 49 Appendix VII
Proposed Draft Recommendations on Labelling/Biotechnology (Mandatory Labelling)	3	Governments 27th CCFL	Appendix VIII
Proposed Draft Amendment to the General Labelling Standard (Class Names)	3	Governments 27th CCFL	para. 40 Appendix IX
Proposed Draft Recommendations for the Use of Health Claims	3	Governments 27th CCFL 21st CCNFSDU	para. 60 Appendix X
Proposed Draft Amendment to the Guidelines on Nutrition Labelling	3	Governments 27th CCFL 21st CCNFSDU	para. 53 Appendix XI
Proposed Draft Recommendations for Sports and Energy Drinks	3	South Africa Governments 27th CCFL	para. 65
Proposed Draft Guidelines for Use of the Term "Vegetarian"	3	South Africa/ India Governments 27th CCFL	para. 71

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

(At Step 8 of the Procedure)

CONTENTS

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

FOREWORD

1. 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.

2. 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 harmonize provisions for the production, certification, identification and labelling have 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 local and global preservation.

3. These guidelines are at this stage a first step into official international harmonization of the requirements for organic products in terms of production and marketing standards, inspection arrangements and labelling requirements. In this area the experience with the development of such requirements and their implementation is still very limited. Moreover, consumer perception on the organic production method may, in certain detailed but important provisions, differ from region to region in the world. Therefore, the following is recognized at this stage:

- the guidelines are a useful instrument in assisting countries to develop national regimes regulating production, marketing and labelling of organic foods;

- the guidelines need regular improvement and updating in order to take into account technical progress and the experience with their implementation;

- the guidelines do not prejudice the implementation of more restrictive arrangements by member countries in order to maintain consumer credibility and prevent fraudulent practices, and to apply such rules to products from other countries on the basis of equivalency to such more restrictive provisions.

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 fertilizing and conditioning, plant pest and disease control and, food additives and processing aids. For labelling purposes, the use of terms inferring that organic production methods have been used are restricted to products derived from operators under the supervision of an certification body or authority.

5. Organic agriculture is one among the broad spectrum of methodologies which are supportive of the environment. Organic production systems are based on specific and precise standards of production which aim at achieving optimal agroecosystems which are socially, ecologically and economically sustainable. Terms such as “biological” and “ecological" are also used in an effort to describe the organic system more clearly. 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 claim for, such products.

6. “Organic” is a labelling term that denotes products that have been produced in accordance with organic production standards and certified by a duly constituted certification body or authority. Organic agriculture is based on minimizing the use of external inputs, avoiding the use of synthetic fertilizers and pesticides. Organic agriculture practices cannot ensure that products are completely free of residues, due to general environmental pollution. However, methods are used to minimize pollution of air, soil and water. Organic food handlers, processors and retailers adhere to standards to maintain the integrity of organic agriculture products. The primary goal of organic agriculture is to optimize the health and productivity of interdependent communities of soil life, plants, animals and people.

7. Organic agriculture is holistic production management systems which promotes and enhances agroecosystem health, including biodiversity, biological cycles, and soil biological activity. It emphasizes the use of management practices in preference to the use of off-farm inputs, taking into account that regional conditions require locally adapted systems. This is accomplished by using, where possible, cultural, biological and mechanical methods, as opposed to using synthetic materials, to fulfil any specific function within the system. An organic production system is designed to:

a) enhance biological diversity within the whole system;

b) increase soil biological activity;

c) maintain long-term soil fertility;

d) recycle wastes of plant and animal origin in order to return nutrients to the land, thus minimizing the use of non-renewable resources;

e) rely on renewable resources in locally organized agricultural systems;

f) promote the healthy use of soil, water and air as well as minimize all forms of pollution thereto that may result from agricultural practices;

g) handle agricultural products with emphasis on careful processing methods in order to maintain the organic integrity and vital qualities of the product at all stages;

h) become established on any existing farm through a period of conversion, the appropriate length of which is determined by site-specific factors such as the history of the land, and type of crops and livestock to be produced.

8. The concept of close contact between the consumer and the producer is a long established practice. 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.

9. An integral component of certification is the inspection of the organic management system. 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. Where the inspection process is undertaken by the certification body or authority, there must be clear separation of the inspection and certification function. In order to maintain their integrity, certification bodies or authorities

which certify the procedures of the operator should be independent of economic interests with regard to the certification of operators.

10. 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 minimize 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.

11. 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 Certification1. In accepting imports of organic products, countries would usually assess the inspection and certification procedures and the standards applied in the exporting country.

12. 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.

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, 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, including advertising material or commercial documents, the product, or its ingredients, is described by:

> the terms "organic", “biodynamic”, "biological", "ecological", or words of similar intent including diminutives 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 engineered/modified organisms (GEO/GMO) are not compatible with the principles of organic production (either the growing, manufacturing, or processing) and therefore are not accepted under these guidelines.

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1 CAC/GL 20-1995

SECTION 2. DESCRIPTION AND DEFINITIONS

2.1 Description

Foods should only refer to organic production methods if they come from an organic farm system employing management practices which seek 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. Production should be sustainable with the recycling of plant nutrients as an essential part of the fertilizing strategy. 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:

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

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

certification is the procedure by which official certification bodies, or officially recognized 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.[3]

certification 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.

competent authority means the official government agency having jurisdiction.

genetically engineered/modified organisms. The following provisional definition is provided for genetically/modified organisms[4]. Genetically engineered/modified organisms, and products thereof, are produced through techniques in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.

> Techniques of genetic engineering/modification include, but are not limited to: recombinant DNA, cell fusion, micro and macro injection, encapsulation, gene deletion and doubling. Genetically engineered organisms will not include organisms resulting from techniques such as conjugation, transduction and hybridization.

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2 CAC/GL 20-1995

3 CAC/GL 20-1995

4 In the absence of a definition of genetically engineered/modified organisms agreed by the Codex Alimentarius Commission, this definition has been developed in order to provide initial guidance for governments in the application of these guidelines. This definition is therefore to remain under review in the light of other considerations by the Commission and its Committees. In the interim, member countries may also apply national definitions.

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 [5].

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[6]. For organic food, inspection includes the examination of the production and processing system.

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[7].

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

official accreditation is the procedure by which a government agency having jurisdiction formally recognizes the competence of an inspection and/or certification body to provide inspection and certification services. For organic production the competent authority may delegate the accreditation function to a private body.

officially recognized inspection systems/officially recognized certification systems are systems which have been formally approved or recognized by a government agency having jurisdiction.[8]

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.

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

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.

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.

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[9.]

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

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

6 CAC/GL 20-1995

7 Codex Stan 1-1985 (Rev 1-1991)

8 CAC/GL 20-1995

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

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 recognized inspection or certification body to which the operator who has carried out the production or the most recent processing operation 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 indication show clearly that they relate to a method of agricultural production and are linked with the name of the agricultural product in question, unless such indication is clearly given in the list of ingredients;

(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;

(d) the same ingredients shall not be derived from an organic and non-organic origin;

(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 recognized certification body or authority 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 maximum level of 5% m/m of the total ingredients excluding salt and water 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 Pending further review of the guidelines in accordance with Section 8, Member Countries can consider the following with regard to products referred to in paragraph 1.1(b) marketed in their territory:

- the development of specific labelling provisions for products containing less than 95% ingredients of agricultural ingredients;

- the calculation of the percentages in 3.4 (5%) and in 3.5 (95%) on the basis of the ingredients of agricultural origin (instead of all ingredients excluding only salt and water);

- the marketing of product with in transition/conversion labelling containing more than one ingredient of agricultural origin.

3.6 In developing labelling provisions from products containing less than 95% of organic ingredients in accordance with the paragraph above, member countries may consider the following elements in particular for products containing 95% and 70% of organic ingredients:

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

(b) the indications referring to organic production methods should only appear on the front panel as a reference to the approximate percentage of the total ingredients including additives but excluding salt and water;

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

(d) 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 ingredient.

Labelling of product in Transition/Conversion to Organic

3.7 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 indication take the form of words, such as "product under conversion to organic farming", or similar words or phrase accepted by the competent authority of the country where the product is marketed, 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) the labelling refers to the name and/or the code number of the official or officially approved certification body or authority to which the operator who has carried out the most recent preparation is subject.

Labelling of non-retail containers

3.8 The labelling of non-retail containers of product specified in paragraph 1.1 should meet the requirements set out in Annex 3, paragraph 10.

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 1and 2 or substances approved by individual countries that meet the criteria established in Section 5.1, may be used as plant protection products, fertilizers, soil conditioners, 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 satisfied;

(b) substances listed in Annex 2, Tables 3 and 4 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

5.1 Criteria (at Step 6 - see Appendix V)

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 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 developing national lists, 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;

- they are notified in accordance with 5.3 and 5.4 below.

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 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 se out under Section 8 of these Guidelines.

SECTION 6. INSPECTION AND CERTIFICATION SYSTEMS[10]

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[13], the Guideline for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems.[14],[15]

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10 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.

13 CAC/GL 20-1995

14 ALINORM 97/30A, Appendix II

6.2 Competent authorities should establish an inspection system operated by one or more designated authorities and/or officially recognized inspection/certification[16] bodies to which the operators producing, 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 certification body or authority, countries should identify a competent authority responsible for the approval and supervision of such bodies;

- the identified competent authority may delegate, while maintaining the responsibility for the decisions and actions taken, the assessment and supervision of private inspection and certification bodies to a private or public third party hereafter referred to as its "designate". If delegated, the private or public third party should not be engaged in inspection and/or certification;

- for this purpose an importing country may recognize 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 certification body or authority, the competent authority, or its designate, when making its assessment 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 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 certification body or authority 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.

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15 See also other agreed international standards, eg ISO65.

16 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.

6.7 Official and/or officially recognized certification bodies or authority 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 or authority 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 fulfillment 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 certification body or authority 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 [17] 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, marketing 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:

[17] ALINORM 97/30, Appendix 2

(a) require detailed information, including reports established by independent 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 meet the requirements of these guidelines, and/or

(b) arrange together with the exporting country 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 competent authority, or where delegated, the official or officially recognized certification body or authority 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.

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

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. 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 5(a) and (b) above or, in the case of manures, they are not available from organic farming.

(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 5.

6. 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, ecological buffer zones which maintain the original vegetation to house pest predators;
- diversified ecosystems. These will vary between geographical locations. For example, buffer zones to counteract erosion, agro-forestry, rotating crops, etc.
- flame weeding;
- natural enemies including release of predators and parasites;

- biodynamic preparations from stone meal, farmyard manure or plants;
- mulching and mowing;
- grazing of animals;
- mechanical controls such as traps, barriers, light and sound;
- steam sterilization when proper rotation of soil renewal cannot take place.

7. 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.

8. 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 certification body or authority that material satisfying the above requirements is not available, the certification body or authority 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.

The competent authority may establish criteria to limit the application of the derogation in 8 above.

9. 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;

- the products are from an operator managing the harvesting or gathering of the products, who is clearly identified and familiar with the collection area.

B. Handling, Storage, Transportation, Processing and Packaging

1. The integrity of the organic product must be maintained throughout the processing phase. This is achieved by the use of techniques appropriate to the specifics of the ingredients with careful processing methods limiting refining and the use of additives and processing aids. Ionizing radiation should not be used on organic products for the purpose of pest control, food preservation, elimination of pathogens or sanitation.

<u>Pest management</u>

2. For pest management and control the following measures, in order of preference, should be used:

(a) Preventative methods, such as disruption and elimination of habitat and access to facilities by pest organisms, should be the primary methodology of pest management;
(b) If preventative methods are inadequate, the first choice for pest control should be mechanical/physical and biological methods;

(c) If mechanical/physical and biological methods are inadequate for pest control, pesticidal substances appearing in Annex 2 table 2 (or other substances allowed for use by a competent authority in

accordance with Section 5.2) may be used provided that they are accepted for use in handling, storage, transportation or processing facilities by the competent authority and so that contact with organic products is prevented.

3. Pests should be avoided by good manufacturing practice. Pest control measures within storage areas or transport containers may include physical barriers or other treatments such as sound, ultra-sound, light, ultra-violet light, traps (pheromone traps and static bait traps) controlled temperature, controlled atmosphere (carbon dioxide, oxygen, nitrogen), and diatomaceous earth.

4. 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.

Processing and manufacturing

5. Processing methods should be mechanical, physical or biological (such as fermentation and smoking) and minimize the use of non-agricultural ingredients and additives as listed in Annex 2, Tables 3 and 4.

Packaging

6. Packaging materials should preferably be chosen from bio-degradable, recycled or recyclable sources.

Storage and transport

7. Product integrity should be maintained during any storage and transportation and handling by use of the following precautions:

(a) Organic products must be protected at all times from co-mingling with non-organic products; and

(b) Organic products must be protected at all times from contact with materials and substances not permitted for use in organic farming and handling.

8. 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.

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

10. 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.

ANNEX 2

PERMITTED SUBSTANCES FOR THE PRODUCTION OF ORGANIC FOODS

Precautions

1. Any substances used in an organic system for soil fertilization 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 certification body or authority, 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.

TABLE 1: SUBSTANCES FOR USE IN SOIL FERTILIZING AND CONDITIONING

Substance	**Description; compositional requirements; conditions of use**
Farmyard and poultry manure	Need recognized by certification body or authority if not sourced from organic production systems.'Factory' farming[18] sources not permitted.
Slurry or urine	If not from organic sources, need recognized 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 recognized by the certification body or authority. "Factory" farming sources not permitted.
Dried farmyard manure and dehydrated poultry manure	Need recognized by the certification body or authority. Factory" farming sources not permitted.
Guano	Need recognized by the certification body or authority.
Straw	Need recognized by the certification body or authority.
Composts from spent mushroom & Vermiculture substrates	Need recognized by the certification body or authority. The initial composition of products on this list.
Composts from organic household refuse	Need recognized by the certification body or authority..
Composts from plant residues	----
Processed animal products from slaughterhouses & fish industries	Need recognized by the certification body or authority
By-products of food & textile industries	Not treated with synthetic additives. Need recognized by the certification body or authority body.

[18] "Factory" farming refers to industrial management systems that are heavily reliant on veterinary and feed inputs not permitted in organic agriculture.

Seaweeds and seaweed products .	Need recognized by certification body or authority.
Sawdust, bark and wood waste	Need recognized by the certification body or authority.
Wood ash	----
Natural phosphate rock	Need recognized by certification body or authority.. Cadmium should not exceed 90mg/kg $P_2$05.
Basic slag	Need recognized by the certification body or authority.
Rock potash, mined potassium salts (eg kainite, sylvinite)	Less than 60% chlorine.
Sulphate of potash (eg patenkali) chemical processes to increase its solubility	Obtained by physical procedures but not enriched by Need recognized by the certification authority or 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	Maximum 90 mg/kg P205.
Trace elements (eg. boron, copper, iron, manganese, molybdenum, zinc)	Need recognized by certification body or authority.
Sulphur	Need recognized by certification body or authority.
Stone meal	----
Clay (eg. bentonite, perlite, zeolite)	----
Naturally occurring biological organisms (eg worms)	----

Vermiculite	----
Peat	Excluding synthetic additives; permitted for seed, potting module composts. Other use as recognized by certification body or authority.
Humus from earthworms and insects	----
Zeolites	----
Wood charcoal	----
Chloride of lime	Need recognized by the certification body or authority.
Human excrements	Need recognized by certification body or authority. If possible aerated or composted. Not applied to crops intended for human consumption.
By-products of the sugar industry (eg Vinasse)	Need recognized by certification body or
By-products of industries processing ingredients from organic agriculture	Need recognized by certification body or authority

TABLE 2: SUBSTANCES FOR PLANT PEST AND DISEASE CONTROL

Substance	**Description; compositional requirements; conditions for use**
I. Plant and Animal	
Preparations on basis of pyrethrins extracted from *Chrysanthemum cinerariaefolium*, containing possibly a synergist	Need recognized by the certification body or authority.
Preparations of Rotenone from *Derris elliptica, Lonchocarpus, Thephrosia spp.*	Need recognized by the certification body or authority.
Preparations from *Quassia amara*	Need recognized by the certification body or authority.
Preparations from *Ryania speciosa*	Need recognized by the certification body or authority.
Preparations of Neem (Azadirachtin) from *Azadirachta indica*	Need recognized by the certification body or authority.
Propolis	Need recognized by the certification body or authority.
Plant and animal oils	---
Seaweed, seaweed meal, seaweed extracts, sea salts and salty water	Not chemically treated.
Gelatine	---
Lecithin	Need recognized by the certification body or authority.
Casein	---
Natural acids (eg vinegar)	Need recognized by the certification body or authority.
Fermented product from Aspergillus	---
Extract from mushroom (Shiitake fungus)	---
Extract from Chlorella	---
Natural plants preparations, excluding tobacco	Need recognized by certification body or authority..
Tobacco tea (except pure nicotine)	Need recognized by certification body or authority.

II. Mineral	
Inorganic compounds (Bordeaux mixture, copper hydroxide, copper oxychloride)	Need recognized by certification body or authority.
Burgundy mixture	Need recognized by certification body or authority.
Copper salts	Need recognized by certification body or authority.
Sulphur	Need recognized by certification body or authority.
Mineral powders (stone meal, silicates)	---
Diatomaceous earth	Need recognized by certification body or authority.
Silicates, clay (Bentonite)	---
Sodium silicate	---
Sodium bicarbonate	---
Potassium permanganate	Need recognized by certification body or authority.
Paraffin oil	Need recognized by certification body or authority.
III. Micro organisms used for biological pest controls	
Micro-organisms (bacteria, viruses, fungi) e.g.Bacillus thuringiensis, Granulosis virus,etc.	Need recognized by certification body or authority.
IV. Other	
Carbon dioxide and nitrogen gas	Need recognized by certification body or authority.
Potassium soap (soft soap)	---
Ethyl alcohol	Need recognized by certification body or authority.
Homoeopathic and Ayurvedic preparations	---
Herbal and biodynamic preparations	---
Sterilized insect males	Need recognized by certification body or authority.

V. Traps	
Pheromone preparations	---
Preparations on the basis of metaldehyde containing a repellent to higher animal species and as far as applied in traps.	Need recognized by certification body or authority

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

3.1 Food additives, including carriers

INS	Name	Specific conditions
170	Calcium carbonates	----
220	Sulfur dioxide	Wine products
270	Lactic acid	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	Fruit and vegetable 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, confectionery
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/fruits and vegetables/soybean 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	----

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

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

3.4 Preparations of Microorganisms and Enzymes
(a) Any preparations of microorganisms and enzymes normally used in food processing, with the exception of microorganisms genetically engineered/ modified or enzymes derived from genetic engineering.

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

TABLE 4: PROCESSING AIDS WHICH MAY BE USED FOR THE PREPARATION OF PRODUCTS OF AGRICULTURAL ORIGIN REFERRED TO IN SECTION 3 OF THESE GUIDELINES

Substance	**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 collodial solution
Activated carbon	----
Talc	----
Bentonite	----
Kaolin	----
Diatomaceous earth	----
Perlite	----
Hazelnut shells	----
Beeswax	releasing agent
Carnauba wax	releasing agent
Sulfuric acid	pH adjustment of extraction water in sugar production
Sodium hydroxide	pH adjustment in sugar production
Tartaric acid and salts	----
Sodium carbonate	sugar production
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 engineered/modified organisms and enzymes derived from genetically engineered/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 recognized certification body or authority 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 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 recognized certification body or authority 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 certification body or authority, the operator should notify the official or officially recognized certification body or authority of its schedule of production of crop products, giving a breakdown by land parcel.

6. Written and/or documentary accounts should be kept which enable the official or officially recognized certification body or authority 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. When the unit itself processes agricultural products, its accounts must contain the information required in B2, third dash point of this Annex.

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

8. The official or officially recognized certification body or authority should ensure that a full physical inspection is undertaken, 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. Additional occasional unannounced visits should also be undertaken according to need or at random.

9. The operator should give the certification body or authority, 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 should prevent contamination or substitution of the content with substances or product not compatible with these guidelines and 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 (parallel cropping), units in the area producing crop, crop products 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 of indistinguisable varieties as those produced at the unit referred to in paragraph 3 above should not be produced at these units.

If derogations are allowed by the competent authority, the authority must specify the types of production and circumstances for which derogations are granted and the supplementary inspection requirements, such as unannounced site visits; extra inspections during harvest; additional documentary requirements; assessment of an operation’s ability to prevent co-mingling, etc., which are to be implemented.

Pending further review of these guidelines in accordance with Section 8, member countries can accept parallel cropping of the same variety, even if it is not distinguishable, subject to adequate inspection measures being applied.

B. Preparation and packaging units

1. The producer and/or operator and should provide:

- 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 these guidelines.

This description and the measures concerned should be signed by the responsible person of the unit and the certification body.

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 and be countersigned by both parties.

2. Written accounts should be kept enabling the certification body or authority 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 certification body or authority 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 certification body or authority;

- 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. The official or officially recognized certification body or authority should ensure that 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. Additional occasional unannounced visits should also be undertaken according to need or at random.

5. The operator should give the official or officially recognized certification body or authority or authority, 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.10 of this Annex are applicable.

5. On receipt of a product referred to in Section 1 of these Guidelines, the operator shall check:

- the closing of the packaging or contained where it is required;
-
- the presence of the indications referred to in A.10 of this Annex. The result of this verification shall be explicitly mentioned in the accounts referred to in point B.2. When there is any doubt that the product cannot be verified according to the production system provided for in Section 6 of this Guidelines, it must be placed on the market without indication referring to the organic production method.

C. Imports

Importing countries should establish appropriate inspection requirements for the inspection of importers and of imported organic products.

DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOODS THAT CAN CAUSE HYPERSENSITIVITY (DRAFT AMENDMENT TO THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS)[1]

(at Step 8 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 25% of the food, the ingredients, other than food additives which serve a technological function in the finished product, need not be declared.

Section 4.2.1.4

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.

(Current sections 4.2.1.4 and 4.2.1.5 become respectively 4.2.1.5 and 4.2.1.6)

Section 4.2.2.1

Except for those ingredients listed in section 4.2.1.4, 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 4.2.14.

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[1] Proposed additions underlined. Section 4.2.1.3, repeated here for ease of reference, is currently under consideration (see also Appendix VI).

DRAFT AMENDMENT TO THE STANDARD FOR QUICK FROZEN FISH STICKS (FISH FINGERS) FISH PORTIONS AND FISH FILLETS-BREADED OR IN BATTER
(At Step 8 of the 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

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

(At Step 6 of the Procedure)

5.1 At least the following criteria should be used for the purposes of amending the 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 used in traps and dispensers 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.

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[2] 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.

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

- such substances are preferably as found in nature and may have undergone preferably 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;

- it is not possible to produce a similar product without the use of additives or processing aids;

- the consumer will not be deceived, concerning the nature, substance and quality of the food;

- the purpose is to maintain the nutritional value of the product, to enhance the keeping quality or stability of the products, and to provide the products with an acceptable composition, consistency and appearance;

- there is no detrimental effect on the environment.

DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOODS THAT CAN CAUSE HYPERSENSITIVITY (DRAFT AMENDMENT TO THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS)[3]

(at Step 6 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 <u>[5%]</u> of the food, the ingredients, other than food additives which serve a technological function in the finished product, need not be declared.

[3] Proposed amendment underlined.

PROPOSED DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOOD OBTAINED THROUGH BIOTECHNOLOGY
(PROPOSED DRAFT AMENDMENT TO THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS)
(At Step 5 of the Procedure)

[**Section 2 Definition of Terms**]

Products obtained through biotechnology

For the purpose of the General Standard:

"Products obtained through [new/modern] biotechnology" are foods composed of or containing genetically modified organisms, [or foods produced from, but not containing genetically modified organisms.]

["Organism" is any biological entity capable of replication or of transferring genetic material].

["Genetically modified /genetically engineered organism" is an organism in which the genetic material has been changed in a way that does not occur naturally by multiplication and/or natural recombination.]

Examples of these modifications include but are not limited to:

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

Examples of techniques which are not considered to result in genetic modification include but are not limited to:

[on condition that they do not involve the use of recombinant DNA molecules or GMOs]:

- in vitro fertilization
- conjugation, transduction, transformation or any other natural process,
- [polyploidy induction]

[on condition that they do not involve the use of GMOs as recipient or parental organism]:

- mutagenesis
- [cell fusion [including protoplast fusion] of plant cells where the resulting organisms can also be produced by traditional breeding methods]

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 4.2.1.4[1] shall be declared.

When it is not possible to provide adequate information on the presence of an allergen through labelling, the food containing the allergen should not be marketed.

[1] Draft proposal contained in ALINORM 99/22 Appendix III.

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 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, nutrient declaration should be provided in conformity with the Guidelines for Nutrition Labelling.

- if the mode of *storage, preparation, cooking* is significantly different from that for the equivalent food, clear instructions for use should be provided.

[These requirements also apply to novel foods which are not obtained through biotechnology but are significantly different from the corresponding conventional food.]

Alternative proposal

[*All foods that are or contain genetically modified organisms shall be labelled. Foods that are produced from genetically modified organisms but do not contain them shall always be labelled if, natural variations considered, an adequate analysis demonstrates that they differ from equivalent conventional foods.*

The presence of any substance that are absent in existing equivalent foods and may have implications for the health of certain sections of the population and/or are the subject of ethic objections shall be indicated in the label.]

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.

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

PROPOSED DRAFT AMENDMENT TO THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS
(At Step 3 of the 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)

or

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

Milk Proteins: All types of milk protein (caseins, caseinates aand whey proteins) and mixtures thereof

PROPOSED DRAFT RECOMMENDATIONS FOR THE USE OF HEALTH CLAIMS [2]
(At Step 3 of the Procedure)

Health claims should be consistent with national health policy and support that policy. Only health claims that support national health policy should be allowed

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:

[2] This text will ultimtely be incorporated into the Guidelines on Use of Nutrition Claims, in which it was initially included. The numbering of the sections refers to the Guidelines.

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 if 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. The kind and amount of nutrient and substance mentioned should be clearly specified]

PROPOSED DRAFT AMENDMENT TO THE GUIDELINES ON NUTRITION LABELLING
(At Step 3 of the Procedure)

3.2 Listing of Nutrients

3.2.1 Where nutrient declaration is applied, the declaration of the following should be mandatory:

3.2.1.1 Energy value; and

3.2.1.2 The amounts of protein, available carbohydrate (i.e., carbohydrate excluding dietary fibre), **sugars, fibre**, fat, **saturated fat**, **sodium**; and

3.2.1.3 The amount of any other nutrient for which a nutrition claim is made; and

3.2.1.4 The amount of any other nutrient considered to be relevant for maintaining a good nutritional status, as required by national legislation.

3.2.2 Where a claim is made regarding the amount and/or the type of carbohydrate, ~~the amount of total sugars should be listed in addition to the requirements in Section 3.2.1~~ The amounts of starch and/or other carbohydrate constituent(s) may also be listed. ~~Where a claim is made regarding the dietary fibre content, the amount of dietary fibre should be declared~~.

3.2.3 Where a claim is made regarding the amount and/or type of fatty acids, the amounts of saturated fatty acids and of polyunsaturated fatty acids should be declared in accordance with Section 3.3.7.

3.2.4 In addition to the mandatory declaration under 3.2.1, 3.2.2 and 3.2.3, vitamins and minerals may be listed in accordance with the following criteria:

3.2.4.1 Only vitamins and minerals for which recommended intakes have been established and/or which are of nutritional importance in the country concerned should also be declared.

3.2.5 When nutrient declaration is applied, only those vitamins and minerals which are present in significant amounts should be listed.[3]

3.2.6 In the case where a product is subject to labelling requirements of a Codex standard, the provisions for nutrient declaration set out in that standard should take precedence over but not conflict with the provisions of Sections 3.2.1 to 3.2.5 of these guidelines.

[3] As a rule, 5% of the recommended intake (of the population concerned) supplied by a serving as quantified on the label should be taken into consideration in deciding what constitutes a significant amount.