codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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ALINORM 04/27/22

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION
Twenty-seventh Session
Rome, 28 June - 3 July 2004

REPORT OF THE THIRTY-SECOND SESSION OF THE CODEX COMMITTEE ON FOOD LABELLING

Montréal, Canada, 10 – 14 May 2004

Note: This document incorporates Circular Letter CL 2004/22-FL

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CX 5/15 **CL 2004/22-FL**
May 2004

TO: - Codex Contact Points
- Interested International Organizations

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

SUBJECT: **Distribution of the Report of the 32nd Session of the Codex Committee on Food Labelling (ALINORM 04/27/22)**

A. MATTERS FOR ADOPTION BY THE 27th SESSION OF THE CODEX ALIMENTARIUS COMMISSION

Draft Standards and Guidelines at Step 8 of the Procedure

1. Draft Amendment to the Standard for Quick Frozen Fish Sticks (Fish Fingers), Fish Portions and Fish Fillets, Breaded or in Batter (Labelling Section) (para. 11, Appendix II)
2. Draft Guidelines for Use of Nutrition and Health Claims (para. 52, Appendix III)
3. Draft Amendment to the Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods: Annex 2 – Permitted Substances :Tables 1 and 2 (para. 76, 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, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy **before 15 June 2004**.

B. REQUEST FOR COMMENTS AND INFORMATION

Proposed Draft Standard and Guidelines at Step 3 of the Procedure

4. Proposed Draft Amendment to the Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods: Proposed Draft Revised Annex 2 – Permitted Substances (para. 76, Appendix VIII)
5. Proposed Draft Amendment to the General Standard for the Labelling of Prepackaged Foods: Quantitative Declaration of Ingredients (para. 109, Appendix VII)
6. Proposed Draft Guidelines for the Labelling of Foods and Food Ingredients Obtained through Certain Techniques of Genetic Modification/Genetic Engineering : Labelling Provisions (para. 93, Appendix VI)

Governments and international organizations wishing to submit comments on point 4., 5. and 6 above should do so in writing to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy, with a copy to Mr. Ron B. Burke, Director, Bureau of Food Regulatory International and Interagency Affairs, Health Products and Food Branch, Health Canada, Bldg No. 7, Room 2395, Tunney's Pasture, Ottawa K1A 0L2, Canada, Fax No. 613.941.3537, E-mail: codex_canada@hc-sc.gc.ca, **before 15 November 2004.**

SUMMARY AND CONCLUSIONS

The summary and conclusions of the 32nd Session of the Codex Committee on Food Labelling are as follows:

Matters for adoption by the 27th Session of the Codex Alimentarius Commission:

The Committee:

- agreed to advance to Step 8 the Draft Amendment to the *Standard for Quick Frozen Fish Sticks (Fish Fingers), Fish Portions and Fish Fillets, Breaded or in Batter* (Labelling Section) (para. 11, Appendix II);
- agreed to advance to Step 8 the Draft Guidelines for Use of Nutrition and Health Claims (para. 52, Appendix III);
- agreed to advance to Step 8 the Draft Amendment to the *Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods*: Annex 2 – Permitted Substances :Tables 1 and 2 (para. 76, Appendix IV);
- agreed to undertake new work on the revision of the *Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods* (para. 78);
- agreed to ask the advice of the Commission on the need for new work on country of origin labelling (para. 116).

Other Matters of Interest to the Commission

The Committee:

- endorsed the labelling provisions in the Draft Standard for Salted Atlantic Herring and Salted Sprat (at Step 8) and returned the other labelling provisions for further consideration by the subsidiary bodies concerned (paras. 12-43);
- agreed to return to Step 6 for redrafting the Draft Amendment to the *Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods*: Annex 2 – Permitted Substances :Tables 3 and 4, and to return to Step 3 the Draft Amendment to Table 1 on Natural Sodium Nitrate (paras. 76-77, Appendix VIII);
- agreed to retain at Step 7 the Draft Amendment to the *General Standard for the Labelling of Prepackaged Foods* (Draft Recommendations for the Labelling of Foods Obtained through Certain Techniques of Genetic Modification/Genetic Engineering): Definitions and to return to Step 3 the Proposed Draft Guidelines for the Labelling of Food and Food Ingredients Obtained through Certain Techniques of Genetic Modification/Genetic Engineering: Labelling Provisions (paras. 93-94, Appendices V and VI);
- agreed to return to Step 3 the Proposed Draft Amendment to the *General Standard for the Labelling of Prepackaged Foods* (Quantitative Declaration of Ingredients) (para. 109, Appendix VII);
- agreed not to undertake new work on traceability/product tracing (para. 121) and misleading labelling (para. 127), and agreed to consider the advertising at its next session (para. 133).

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LIST OF APPENDICES

INTRODUCTION

1) The Codex Committee on Food Labelling held its Thirty-second Session in Montréal, Canada, from 10 to 14 May 2004, at the kind invitation of the Government of Canada. The Session was chaired by Dr. Anne MacKenzie, Senior Science Advisor, Science Branch, Canadian Food Inspection Agency. The Session was attended by 249 delegates representing 48 Member countries, one Member Organization (EC) and 32 international organizations. A complete list of participants is attached in Appendix I to this report.

OPENING

2) The Session was opened by Dr Judith Bossé, Vice-President, Science Branch, Canadian Food Inspection Agency, who welcomed the participants to Montréal, Québec, and expressed her appreciation to member countries for their active contribution and support to the work of the Committee. Dr Bossé highlighted the importance of the issues to be considered by the present session in order to develop international recommendations on various aspects of labelling so as to provide clear information to consumers, while ensuring the scientific basis of Codex standards and related texts. Recognizing the need for consensus in the decision making process, Dr Bossé wished every success to the delegates in their important work.

ADOPTION OF THE AGENDA (Agenda Item 1)[1]

3) The Delegation of Switzerland proposed to consider the revision of the Nutrient Reference Values for labelling purpose under Agenda 11- Other Business and Future Work. The Delegation of the United States proposed to discuss the definition of advertising on the basis of the discussion paper prepared by Canada under Agenda Item 11.

4) The Committee agreed with these proposals and adopted the Provisional Agenda as presented in CX/FL 04/1.

5) The Delegation of India, referring to its written comments, expressed the view that the Committee should not proceed with consideration of the Draft Guidelines on Health Claims until consensus had been reached on the definition of "advertising" and proposed to defer consideration of traceability/product tracing until the Proposed Draft Principles for Risk Analysis had been finalized in the Committee on General Principles. The Chairperson informed the Committee that the definition of traceability/product tracing had been finalized by the Committee on General Principles (see paras. 111 to 115)

6) The Delegation of the European Community presented CRD 18 on the division of competence between the European Community and its Member States according to Rule II.5 of the Rules of Procedure.

MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES (Agenda Item 2)[2]

7) The Committee noted that several matters arising from the Commission and some other Committees were for information only. The Committee noted that in reply to the question of the CCFL concerning vitamins and minerals declaration in the Guidelines on Nutrition Labelling (section 3.2.6.2), the Committee on Nutrition and Foods for Special Dietary Uses had confirmed the current threshold for the declaration of vitamins and minerals and the current provisions for the declaration of vitamins and minerals.

Committee on Fish and Fishery Products

8) The Committee recalled that its 28th Session had considered the Draft Amendment to the Standard for Quick Frozen Fish Sticks (Fish Fingers), Fish Portions and Fish Fillets, Breaded or in Batter and had agreed in principle that the declaration of fish content should be included in the labelling section. The Committee had agreed to hold the Draft Amendment at Step 7 and had asked the Committee on Fish and Fishery Products to consider the definition of fish content and the method for its determination.

9) The Committee considered the proposal for the definition and method of analysis proposed by the Committee on Fish and Fishery Products and endorsed by the Committee on Methods of Analysis and Sampling. Several delegations supported the finalization of the amendment, noting that it was the result of

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1 CX/FL 04/1, CRD 22 (comments of India)

2 CX/FL 04/2

detailed technical discussion in the CCFFP and provided a practical solution to the determination of fish content.

10) The Delegation of South Africa expressed its reservation on the use of chemical analysis for the determination of fish content as it could result in barriers to trade, especially as GMP principles were not defined, and the nitrogen factors of several important fish species in international trade, such as South African hake, were not specified.

Draft Amendment to the Standard for Quick Frozen Fish Sticks (Fish Fingers), Fish Portions and Fish Fillets, Breaded or in Batter (Labelling Section)

11) The Committee agreed to forward the Draft Amendment to Step 8 for adoption by the 27th Session of the Codex Alimentarius Commission (see Appendix II).

CONSIDERATION OF LABELLING PROVISIONS IN DRAFT CODEX STANDARDS (Agenda Item 3)[3]

12) The Delegation of India proposed to amend the section on Labelling of Non-retail Containers in all standards under consideration to reflect that the information required should be mentioned both on the container and in the accompanying documents, and to delete the second paragraph that allowed the use of an identification mark. The Committee however recalled that these standard provisions for the labelling of non-retail containers were included in the Procedural Manual and used in many Codex standards, and that any amendment in this respect would require a general discussion. The Committee therefore agreed to retain the current provisions for the labelling of non-retail containers.

Committee on Fish and Fishery Products

Draft Standard for Salted Atlantic Herring and Salted Sprat

13) The Delegation of the United States, while not objecting to the endorsement of the labelling provisions, expressed the view that the reference to "law and custom" required further clarification as to its interpretation and implications.

14) The Delegation of Canada supported the current reference to "law and custom" in the labelling section in order to recognize the use of local custom in the naming of fish, and recalled that this question had been discussed extensively in the Codex Committee on Fish and Fishery Products (CCFFP).

15) The Committee endorsed the labelling provisions in the Draft Standard and agreed to ask the CCFFP to consider how the reference to "custom" could be interpreted in relation to national legislation and whether this term should be retained in the standards for fish and fishery products.

Ad Hoc Intergovernmental Task Force on Fruit and Vegetable Juices

Draft General Standard for Fruit Juices and Nectars

16) The Delegation of Brazil, supported by the Delegations of the United States and Canada, expressed the view that the current text of section 7.1.1.7 did not represent the agreement reached during the Task Force due to an error in Appendix II to ALINORM 03/39A, and that the first paragraph concerning "blended" juices should therefore be deleted.

17) Other delegations pointed out that the text of section 7.1.1.7 had been agreed upon by the Task Force and should be retained as the name of the product should include the terms "mixed" or "blended", where applicable. It was noted that the text of the report referred to discussion only on the addition of the second paragraph of the section, and did not mention the first paragraph. The Delegation of Mexico suggested to respect the agreement reached by the Task Force.

18) The Committee could not come to a conclusion on this section and agreed that it should be further considered and clarified by the Task Force at its next session.

19) In section 7.1.2.2, the Delegation of India proposed to specify the name of the artificial sweeteners in conjunction with the name of the fruit juice/nectar and to add the statement "Not recommended for Children and Phenyketoneurics". The Delegation also proposed to amend section 7.1.2.8 on the use of pictorial representation of fruit, to ensure that consumers were not misled. Some delegations expressed the

[3] CX/FL 04/3, CRD 19 (comments of Canada), CRD 22 (comments of India)

view that these proposals would result in substantial changes to the labelling section and required further consideration.

20) The Committee could not reach a consensus on these proposals and agreed to refer sections 7.1.2.2 and 7.1.2.8 to the Task Force for further consideration.

21) The Delegation of Ireland, speaking on behalf of the Member States of the European Union present at the session, pointed out that the Task Force had agreed to add a footnote to section 7.1.2.11 of the draft standard indicating that for citrus fruit, pulp or cells are the juice sacs obtained from the endocarp.

22) In section 7.2, the Committee agreed to correct both paragraphs to read "distributor or importer" for consistency with the standard text for non-retail containers. The Committee endorsed all other sections as proposed.

Committee on Fats and Oils

Draft Standard for Fat Spreads and Blended Fat Spreads

23) The Delegation of Canada pointed out that the terms "blended spreads" and "blends" were not meaningful for consumers and proposed to refer to the type of fat in the name of the product, that would read "(naming the fat(s)) blended spreads" or "blended (naming the fat) spread". As an alternative, the Delegation proposed to modify the sentence to read "Where consumers would be mislead, the name of the product shall incorporate the name of the fats and oils". The Delegation of Brazil proposed to retain the second paragraph of section 7.1 without square brackets in order to allow a reference to the name of fats and oils in a generic or a specific manner. The Committee could not come to a conclusion on these proposals and agreed to return the section to the Committee on Fats and Oils for further consideration.

24) The Committee agreed that the declaration of milk fat content should not be limited to blended spreads and amended section 7.3.2 to read "The milk fat content shall be indicated in a manner that is clear and not misleading to the consumer".

25) The Committee endorsed the other sections as proposed in the Draft Standard for Fat Spreads and Blended Fat Spreads.

Committee on Nutrition and Foods for Special Dietary Uses

Proposed Draft Guidelines for Vitamin and Mineral Food Supplements

26) The Committee agreed that section 5.1 should read "Vitamins and minerals should be labelled…" for consistency with similar labelling sections in Codex texts.

27) The Delegation of Brazil proposed to delete the square brackets in section 5.4 and to refer to a single unit rather than a single use. The Delegation of Switzerland pointed out that the notion of "use" may cover more than one unit and supported the current text.

28) The Delegation of South Africa proposed to amend section 5.5 to the effect that information on vitamins and minerals "may" be expressed as a percentage of the NRV mentioned, for consistency with the *Guidelines on Nutrition Labelling*, and to refer to national legislation as the type of declaration used should be left to national authorities. Other delegations supported the current text as the percentage of the NRV was an important information for consumers.

29) The Committee agreed that sections 5.4 and 5.5 should be considered further by the CCNFSDU in the light of the above discussion and endorsed all other sections as proposed.

Proposed Draft Revised Standard for Infant Formula [and Formulas for Special Medical Purposes Intended for Infants]

30) The Committee noted that the sections related to health and nutrition claims section had been retained in square brackets pending further discussion on the general recommendations on health claims in the CCFL.

31) The Delegation of Ireland, speaking on behalf of the Member States of the EU present at the session, expressed the view that the section on health and nutrition claims should be consistent with section 1.4 of the Draft Guidelines for Use of Nutrition and Health Claims, that referred to health claims allowed in accordance with national legislation. This position was supported by several delegations and some observers, who pointed out that health claims could provide useful information when scientifically justified.

32) Other delegations proposed to retain the current text of section 9.1.5 without square brackets to reflect that health claims should not be allowed in infant formula. The Observer from IBFAN, supported by other observers, expressed the view that health claims should be prohibited in infant formula as they were not based on science and provided misleading information to consumers.

33) Some delegations questioned the inclusion of two sections on health claims in the labelling provisions (9.1.5 and 9.6.6) and indicated that this required further clarification. The Committee noted that these sections would need to be reviewed following the final adoption of the Draft Guidelines for Use of Nutrition and Health Claims, and agreed to refer them back to the CCNFSDU for further consideration.

34) The Delegation of the United States pointed out that the sections on ingredient declaration (9.2.1) and nutrient declaration (9.3) included several inconsistencies, respectively with the *General Standard for the Labelling of Prepackaged Foods* and the *Guidelines on Nutrition Labelling*.

35) As regards section 9.1.6, some delegations noted that further discussion in the CCNFSDU on the minimum and maximum levels for iron and its bioavailability might result in the deletion of section 9.1.6 on iron declaration. The Committee recognized that section 9.1.6 would be more adequately addressed directly by the CCNFSDU as it concerned a specific nutrient.

36) The Delegation of India proposed to amend the title of the standard to refer only to "infant formula"; to retain section 9.1.5 prohibiting health claims; and to delete section 9.1.3 on the labelling of infant formula based on cow's milk.

37) The Committee agreed to refer back sections 9.1.3, 9.1.5, 9.1.6, 9.2.1, 9.3, and 9.6.6 to the CNFSDU for further consideration in the light of the above discussion and endorsed all other sections as proposed.

Proposed Draft Revised Standard for Processed Cereal-Based Foods

38) The Delegation of Ireland, speaking on behalf of the Member States of the EU present at the session, expressed the view that the section on health and nutrition claims should be consistent with section 1.4 of the Draft Guidelines for Use of Health and Nutrition Claims.

39) The Delegation of the United States pointed out that the sections on ingredient declaration (8.3.1) and nutrient declaration (8.4) were inconsistent, respectively with the General Standard for the Labelling of Prepackaged Foods and the Guidelines on Nutrition Labelling and expressed the view that the CCNFSDU should consider these sections carefully.

40) The Delegation of Australia proposed to delete the requirement for the declaration of the presence or absence of gluten (8.6.3) as labelling of foods and ingredients that can cause hypersensitivity was adequately covered in the General Standard for the Labelling of Prepackaged Foods.

41) The Observer from ENCA, supported by the Observer from IBFAN, proposed to amend section 8.1.1 to read "the label shall have no pictures or text which idealizes or suggests an inappropriate age of use"; and to amend section 8.6.4 to indicate that health workers should be independent from commercial interest.

42) The Committee however recalled that the CCNFSDU had agreed to the current text of sections 8.1.1 (first paragraph) and 8.6.4 as a result of an extensive discussion, as reflected in the report (ALINORM 04/27/26, paras. 124 and 127), and endorsed these sections as proposed.

43) The Committee agreed to refer back the second paragraph of section 8.1.1, sections 8.3.1, 8.4 and 8.6.3 to the CCNFSDU for further consideration in the light of the above discussion and endorsed all other sections as proposed.

DRAFT GUIDELINES FOR USE OF NUTRITION AND HEALTH CLAIMS (Agenda Item 4)[4]

44) The Committee recalled that the last Session of the Committee had agreed to forward the Draft Guidelines to the 26th Session of Codex Alimentarius Commission for its adoption at Step 8, however, the Commission returned the Draft Guidelines to Step 6 since there was no consensus especially, as to the inclusion of "advertising" in paragraph 1.1.

45) The Delegation of the United States expressed its concern with the inclusion of "advertising" in paragraph 1.1 as it was of the view that this work is outside the terms of reference of the Committee and

[4] ALINORM 03/22A, Appendix IV; CL 2003/28-FL; CX/FL 04/4 (comments of Australia, Brazil, Iran, Malaysia, New Zealand, Spain, South Africa, CI, ISDI); CRD 2 (Canada, European Community, IBFAN); CRD 8 (Norway, Philippines, EFLA, ENCA, ICGMA), CRD 21 (Canada), CRD 22 (India)

would raise fundamental issues in various aspects. However, the Delegation supported the adoption of the Draft Guidelines since it could establish a framework to provide useful information on nutrition and health claims to consumers. As a compromise, the Delegation proposed to include the following text after "food labelling and" in paragraph 1.1: ".., consistent with appropriate national legislation in" so that member governments can regulate advertisement in accordance with their national legislation.

46) The Delegation of Canada, referring to the document prepared by Canada "Discussion Paper on Advertising" (CRD 21), supported the legal opinion expressed by the FAO and WHO in 1984 that advertisement was in the terms of reference of the Codex Alimentarius Commission. However, the Delegation supported the proposal by the United States in order to advance the text.

47) Many delegations and observers supported the view that advertising was in the terms of reference of the Committee and some of these supported the proposal of the United States as a compromise text. However, other delegations and observers supported the inclusion of a reference to "advertising" without any qualification in order to provide clear guidance to governments and to ensure consumer protection against misleading claims.

48) The Delegation of the European Community, while supporting the view that advertisement was in the terms of reference of the Committee, proposed a different compromise text to add after "food labelling and" in paragraph 1.1: ".., unless provided otherwise by national legislation, in advertising". This proposal was supported by many delegations and observers.

49) The Delegation of the United States expressed the view that the legal opinion by FAO was referring to the terms of reference of the Codex Alimentarius Commission, while the task to be undertaken by this Committee should be determined by its Terms of Reference in which advertisement was just mentioned in the context of "studying". The Delegation also stated that advertisement should be addressed by national legislation since the main target of advertisement is domestic consumers.

50) As a result of further discussion, the Committee agreed to amend paragraph 1.1 to read: "These guidelines relate to the use of nutrition and health claims in food labelling, and, where required by the authorities having jurisdiction, in advertising."

51) Several delegations and observers proposed to modify the text other than paragraph 1.1 and raised a number of questions. These included the request for the deletion of the reference to national legislation from paragraph 1.4: the inclusion of "ingredients" in the Section 7 "Health Claims" wherever the term "nutrients" is mentioned: the replacement of "constituent" in paragraphs under 2.2 with "nutrient" due to the vagueness of this term: the inclusion of "food constituents" after "nutrient or" in paragraph 1) of 7.1.1 in accordance with the definition described in paragraph 2.1.1: the deletion of paragraph 2.2.3 due to the view that 2.2.2 already covered the contents in 2.2.3: the inconsistency found between the paragraphs 2.2.1 and 7.1.6. However, the Committee agreed to retain the current text, recognizing that it resulted from intensive discussions and detailed consideration of each section in the earlier sessions of the Committee.

Status of the Draft Guidelines for Use of Nutrition and Health Claims

52) The Committee agreed to advance the Draft Guidelines, as amended at the current session, to Step 8 for adoption by the 27th Session of the Codex Alimentarius Commission (see Appendix III).

GUIDELINES FOR THE PRODUCTION, PROCESSING LABELLING AND MARKETING OF ORGANICALLY PRODUCED FOODS: DRAFT REVISED ANNEX 2 – PERMITTED SUBSTANCES (Agenda Item 5)[5]

53) The Committee recalled that the Commission had adopted the Draft Revised Annex 2 at Step 5 and that it had been circulated for comments at Step 6, with the understanding that comments were requested on all substances in the Table and the structure of the Tables.

54) The Chair of the Working Group held prior to the session, Ms. Carla Barry (Canada), presented the outcome of the discussions on the revised Annex 2 (CRD 24).

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5 ALINORM 03/22A, Appendix VI, CL 2003/28-FL, CX/FL 04/5 (comments of Australia, Denmark, EC, Japan, New Zealand, Norway, Paraguay, Poland, Switzerland, IFOAM, IPPA), CX/FL 04/5-Add.1 (comments of Chile: justification based on criteria - use of Natural Sodium Nitrate in organic farming), CX/FL 04/5-Add.2 (Brazil, Canada, France, United States, IDF), CRD 6 (EC, Philippines, Thailand), CRD 20 (IFOAM), CRD 24 (Report of the Working Group held prior to the Session)

General Issues

55) The Working Group discussed the process that would be used to update Annex 2. The Working Group identified the need for a defensible and transparent process within CCFL to evaluate substances for addition or removal to the tables in Annex 2.

56) It was recalled that the Substance Lists are indicative and intended to provide guidance to all member countries and that countries are to develop their own list based on their national legislation, taking into account the Codex Criteria for the Development of Lists of Substances for countries.

Tables 1 and 2

Table 1: Substances For Use In Soil Fertilizing and Conditioning

57) The square brackets were removed from the "description; compositional requirements; conditions of use" column for sawdust, bark and wood waste; wood ash and wood charcoal. In addition, wood ash and wood charcoal were amalgamated as one item.

58) It was noted that the zeolites were listed twice and in order to eliminate duplication this substance was retained only under the item "clay".

59) The Committee noted that there had been no consensus in the Working Group on the inclusion in Table 1 of Natural Sodium Nitrate (NSN) proposed by Chile, and had an extensive discussion on this question. Several delegations and the Observers from IFOAM and IACFO expressed their objections to the inclusion of this substance in the list as it was not in conformity with the principles of organic production. The Delegation of Chile recalled that it had provided substantial justification for the inclusion of NSN in document CX/FL 04/5-Add.1, including an assessment against the criteria of the Guidelines, and noted that other substances which were also controversial, such as nitrites were included in the list at Step 6.

60) In reply to some questions concerning the status of this substance, the Secretariat recalled that the Tables had been circulated at Step 6 and that comments for inclusion, deletion or amendment of substances had all been provided at Step 6, and that the last session had not made any provision for the inclusion of Natural Sodium Nitrate at a different Step. Several delegations therefore proposed to return Natural Sodium Nitrate to Step 3 and the Committee agreed with this proposal, noting that this was possible in application of the Procedure.

Table 2: Substances For Plant Pest and Disease Control

61) Iron phosphate was included in the table for use as a molluscicide without square brackets.

62) It was agreed to retain the general category of rodenticides and the text was corrected to delete the reference to "disease control". Furthermore, text was added to indicate that certification bodies and authority could specify usage.

Tables 3 and 4

63) The Working Group recognized that the Codex Committee on Food Additives and Contaminants (CCFAC) and the Joint Expert Committee on Food Additives (JECFA) have the mandate to review food additives from a health and safety point of view for all foods. Also, Section 1.4 of the Guidelines for Organically Produced Foods state that "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". The Codex Secretariat confirmed this role of the CCFAC and the role of CCFL which is to determine which additives should be used in organic production. Only those additives that have already been approved by CCFAC should be considered for evaluation against the criteria outlined in these Guidelines.

64) The Committee agreed that Tables 3 and 4 should be restructured to the format of the General Standard of Food Additives, i.e. INS number, additive function, condition of use and category of food in order to provide clarity to the specific condition for use in relation to both function and food. Due to the complexity of the table and recognizing that all information would not be available to complete the table during this session, it was agreed that an electronic working group led by Canada would carry out this revision.

Table 3: Ingredients of Non-Agricultural Origin referred to in Section 3 of the Guidelines

65) The square brackets were removed for Glycerol (INS 422) as it met the criteria of the Guidelines and the specific conditions were clarified to state that glycerol was to be obtained from plant origin and be used as a carrier for plant extracts.

66) The conditions for use of Gum Arabic (INS 414) in the plant products table were corrected to delete the reference to "milk" and retain only "fat and confectionery products".

67) There was considerable discussion regarding the necessity for the use of nitrites (INS 250) and nitrates (INS 252) in livestock products. As no consensus was reached, it was agreed that these additives would remain in square brackets. Since the use of ascorbates is tied to nitrites and nitrates, ascorbates (INS 301, 302,303) would also remain in square brackets pending the decision on the use of nitrites and nitrates in certain organically produced foods. The Observer from IACFO expressed the view that consumers expectations on organic food should be taken into account for further consideration of nitrates and nitrites and proposed to discuss such expectations at the next session of the Committee.

68) The specific conditions for ascorbic acid (INS 300) were corrected to retain the reference to dairy products without square brackets.

69) The Working Group could not come to a consensus on the use of phosphates (INS 339, 340, 450 and 452) and Nitrous oxide (INS 942) and they were retained in square brackets for further consideration. Clarification was required as to the availability of other alternatives and the Working Group discussed whether it was possible for some foods to be produced through organic practices. The Delegation of Denmark, supported by some observers, suggested that the general principles of organic production be revised in order to recognize that not all food products may be available from organic food processing.

Table 4: Processing Aids which may be used for the Preparation of Products of Agricultural Origin Referred to in Section 3 of the Guidelines

70) It was agreed that the specific conditions for sodium hydroxide should include oil production from rapeseed (*Brassica* spp.), as no alternatives are available.

71) The Codex Secretariat indicated that the status of additives had been verified and that five additives in the Table for plant products were not currently allowed under the conditions of use specified in the Table (sulphur dioxide, tartaric acid and its salts, and tocopherols). All other additives were included in Table 3 of the General Standard for Food Additives (Additives Permitted for use in Food in General, Unless Otherwise Specified, in Accordance with GMP) or their specific use corresponded to the uses defined in commodity standards (such as Mono calcium phosphate in flour).

72) The Committee discussed whether it should advance to Step 8 the substances in Table 3 and 4 on which consensus had been reached. The Delegation of Australia, supported by other delegations, proposed to defer the finalisation of the list of substances until the reformatting of the Tables had been completed. The Committee agreed with this proposal.

73) As regards the establishment of an acceptable interim process for the evaluation of all substances in square brackets for inclusion in all the Tables in Annex 2, the Committee agreed that an electronic Working Group coordinated by the Delegation of the United States would consider this question in order to make proposals for consideration by the next session.

74) The Committee noted that the Working Group had discussed the opportunity of undertaking an overall revision of the Guidelines in view of the requirement in section 8 of the Guidelines to conduct a review each 4 years. Several delegations supported this proposal, in order to improve the consistency between the sections and the overall structure of the document, and the Committee agreed to initiate the revision of the entire Guidelines. The Delegation of Australia proposed that during the revision process, consideration be given to reviewing the definitions relating to genetic modification to ensure consistency between the *Guidelines* and other Codex standards and guidelines.

75) The Committee expressed its appreciation to Ms. Carla Barry and to the Working Group for their excellent work and constructive proposals that had allowed substantial progress in the revision of Annex 2.

Status of the Draft Revised Annex 2 in the Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods

76) The Committee agreed to advance Tables 1 and 2, as revised at the current session, to Step 8 for adoption by the 27th Session of the Codex Alimentarius Commission (see Appendix IV). The Committee agreed to return Natural Sodium Nitrate to Step 3 (see Appendix VIII).

77) The Committee also agreed to return Tables 3 and 4, including the changes made at the current session, to Step 6 for revision by a working group coordinated by Canada, comments and consideration by the next session.

78) The Committee agreed to propose as new work the revision of the Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods, subject to the approval of the 27th Session of the Codex Alimentarius Commission, on the basis of a project document to be prepared by the Canadian and Codex Secretariats.

DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOODS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING (DRAFT AMENDMENT TO THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS): DEFINITIONS (Agenda Item 6a)[6]

PROPOSED DRAFT GUIDELINES FOR THE LABELLING OF FOODS AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING: LABELLING PROVISIONS (Agenda Item 6b)[7]

79) The Committee recalled that the 31st Session of the Committee had decided to establish a Working Group with a mandate to develop options for the management of this agenda item. The Working Group, which was held in Calgary, Canada from 28th to 30th October 2003, recommended that the Committee should continue to consider this item and retain it on the agenda. The Working Group also expressed considerable interest in maintaining a single document with a mandatory component and other provisions which would be considered optional, although no consensus could be reached on this issue. Noting concerns related to possible interpretations by a WTO dispute panel associated with the "optional" elements in Codex texts, the Working Group suggested that the Committee may consider it useful to bring this matter to the attention of the Commission and request the Commission to seek an opinion from the FAO, WHO and WTO. The Committee expressed its appreciation to the Government of Canada for hosting a very useful meeting.

80) The Delegation of the United States expressed the view that there was a consensus on the need for mandatory labelling in cases where significant changes in the product composition, characteristic, nutritional value or end use existed. The Delegation did not agree that a single document was the best way to move forward. The Delegation opposed the idea of labelling based solely on method of production. The Delegation expressed the view that no unsafe food should be allowed on the market. Further, labelling two identical products based only on method of production would be misleading as many consumers would perceive this as a safety warning. In this sense, the Delegation pointed out that such labelling would be an unfair practice in food trade and thus violate the fundamental principles of Codex.

81) The Delegation of the European Community supported a single document with mandatory and optional elements since the proposal to split the document was rejected twice, noting also that the Working Group in Calgary had agreed to maintain a single text, drawing on the existing format of the *General Standard.* The Delegation stressed that the purpose of labelling of foods is to provide consumers with useful information and not only to draw attention to health and safety information. The Delegation highlighted a number of provisions in the General Standard for the Labelling of Prepackaged Foods which were not related to health and safety such as common name, country of origin labelling and net weight. The Delegation also reminded the Committee of the situation as regards nutrition labelling which is optional in some countries and mandatory in others. In view of this, the Delegation supported to continue work on a single document

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6 ALINORM 03/22, Appendix III

7 ALINORM 03/22, Appendix IV, CX/FL 04/6 (Report of the Working Group), CRD 4 (Argentina), CRD 11 (Canada - Discussion Paper on Method of Production Labelling related to the *Proposed Draft Guidelines for the Labelling of Foods and Food Ingredients Obtained through Certain Techniques of Genetic Modification/Genetic Engineering*), CRD14 (Philippines, ENCA, ICGMA), CRD 22 (India), CRD 25 (European Community), CRD 26 (Malaysia), CRD 27 (Proposed Terms of Reference for Ad Hoc Working Group)

with both mandatory and optional components. The Delegation did not support the proposal of the Working Group to seek opinions of FAO, WHO, WTO on this matter. It also suggested that progress could be made with respect to the definition.

82) The Delegation of Canada, referring to its discussion paper in CRD 11, pointed out that the 25th (Extraordinary) Session of the Commission had confirmed that protection of consumer health was the first priority in the work of Codex. The Delegation stated that the 43rd Session of the Executive Committee had expressed the view that the Four *Statements of Principles* should be closely adhered to in considering the guidelines for labelling of foods derived from biotechnology and that the consumers claimed right to know could not be used by Codex as the primary basis for decision-making on appropriate labelling. The Delegation also pointed out that method of production labelling did not comply with the principle that only those other factors which can be accepted on a worldwide basis should be taken into account in the framework of Codex, as stipulated in the *Criteria for the Consideration of the Other factors referred to in the Second Statement of Principles*. Although there was considerable interest in maintaining a single document, the Working Group in Calgary had not reached a consensus on this. Therefore, the Delegation proposed to split the text and to advance the health and safety-related labelling since there appears to be consensus on this part of the guidelines. In addition, the Delegation proposed to develop principles to provide a framework for consideration of method of production labelling, in order to make progress in the discussion[8].

83) The Committee had a lengthy discussion on this issue. The Committee noted the written comments of Malaysia, that was not represented at the session. Many delegations, including Brazil, India, Norway and Switzerland, and observers supported the opinion of the European Community and stated that labelling of foods derived from biotechnology was not intended for health and safety as genetically modified products are evaluated for their safety before being placed on the market. These delegations, including Cameroon, stated that there was strong demand from consumers to label genetically modified foods based on method of production and many countries had already established national regulations. During the discussion, the Delegation of Switzerland, supported by the Observer from Greenpeace, recalled the mandate that had been given to the Committee by the Commission in 1991 "to provide guidance on how the fact that a food was derived from "modern" biotechnologies would be made known to the consumers" (ALINORM 91/40, para. 90). Some Delegations further stated that the credibility of the Committee would be lost if the Committee failed to respond to the enormous demand from consumers in this respect. These Delegations also pointed out that the Committee had already established method of production labelling such as organic and halal labelling. It was pointed out that the lack of method of production labelling on genetically modified foods was itself an unfair trade practice.

84) Other delegations and observers supported the view expressed by the Delegations of the United States and Canada. Some Delegations stressed the importance of taking into account the possible impact of the method of production labelling on food prices in developing countries and also the practicality of this labelling system as regards enforcement by the national authorities. It was pointed out that method of production labelling could be inconsistent with some provisions of the Agreement on Technical Barriers to Trade.

85) Some Delegations also highlighted the problems faced by developing countries, especially exporting countries, due to trade barriers resulting from differences in national regulations and lack of international harmonization regarding labelling of foods derived from biotechnology. It was also pointed out that several countries had difficulties in the development of their national regulations for the same reasons.

86) Concern was also expressed on the legal consequences that optional texts intended for governments in view of the relationship of Codex with the WTO.

87) The Delegation of the European Community expressed its concern that lack of international harmonization for the labelling of foods derived from modern biotechnology might harm the uptake of biotechnology, in particular in developing countries

88) The Observer from ICGMA, supported by other observers, expressed the view that labelling based on the method of production would discriminate against safe products and would provide limited and misleading information to consumers.

89) The Delegation of New Zealand proposed to continue consideration of a single document with provisions that might be advanced at different steps through the Codex Elaboration Procedure. In this regard,

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8 These principles are included in CRD 11.

the Chair requested interested delegations to develop a draft project plan for a proposed Ad hoc Working Group.

90) The Delegation of Canada reporting on behalf of the small group of interested delegations[9] indicated that the group had proposed the following Terms of reference for the proposed Ad hoc Working Group:

1) Lay out the most expeditious route forward on matters related to the draft guidelines, including time lines

2) Examine suggested and other appropriate options (e.g. principles approach, optional labelling) with a view to unravelling relevant questions, prioritizing work, and developing the most appropriate course forward, including the development of updated text, as appropriate.

A work schedule had also been proposed to allow the preparation of a revised document for consideration by the next session of the Committee (CRD 27). The Committee expressed its appreciation to the Delegations of New Zealand and Canada for their efforts to facilitate consensus on this complex issue.

91) The Delegation of the European Community expressed its objections to the establishment of the proposed Ad hoc Working Group which might result in reopening the discussion on management issues that had already taken place in the working group held in October 2003, and as it was preferable at this stage to discuss the text of the Proposed Draft Guidelines in the presence of Codex Members and Observers, focusing on the sections in square brackets. The Delegation of the United States supported the establishment of a working group with the proposed Terms of Reference as it would facilitate further progress in the discussion.

92) After some discussion, the Committee recognized that there was no consensus to convene a working group between sessions and agreed to return the Proposed Draft Guidelines to Step 3, as presented in ALINORM 03/22, Appendix IV, with the addition of Appendix V of CX/FL 04/6. The Committee agreed that there would be no working group prior to the session but that the next session would devote one entire day to review the text section by section, taking into account all comments received. The Committee also noted that all sections were open for comments and discussions at its next session.

Status of the Proposed Draft Guidelines for the Labelling of Foods and Food Ingredients Obtained through Certain Techniques of Genetic Modification/Genetic Engineering : Labelling Provisions

93) The Committee agreed to return the Proposed Draft Guidelines, as amended at the present session, to Step 3 for comments and consideration at the next session (see Appendix VI).

Status of the Draft Amendment to the General Standard for the Labelling of Prepackaged Foods (Draft Recommendations for the Labelling of Foods Obtained through Certain Techniques of Genetic Modification/Genetic Engineering : Definitions.

94) The Committee did not discuss the Definitions. They will be considered by the next session of the Committee at Step 7 (see Appendix V).

PROPOSED DRAFT AMENDMENT TO THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS: QUANTITATIVE DECLARATION OF INGREDIENTS (Agenda Item 7)[10]

95) The Committee recalled that the 31st Session had returned the Proposed Draft Amendment to Step 3 for further comments and consideration at the next session.

96) Several delegations expressed their objections to universal quantitative declaration of ingredients and supported quantitative declaration only when ingredients were emphasized on the label. Some delegations also highlighted the difficulties related to practical implementation of quantitative declaration and enforcement by national authorities.

97) The Delegation of the European Community and several other delegations supported quantitative declaration of ingredients, as it provided important information to meet consumers' demand. It was pointed out that implementation of quantitative declaration of ingredients in the European Union had not caused particular difficulties

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9 Argentina, Australia, Canada, India, Mexico, New Zealand, Thailand, United States, BIO, CI, CLI, EUROPABIO, ICGMA and ICC

10 CRD 1 (comments from EC, Norway, ENCA, IBFAN, IDF), CRD 12 (Philippines, ICGMA), CRD 13 (Canada)

98) The Delegation of Mexico, supported by several delegations, proposed to delete paragraphs b), c), and d) as their interpretation may vary significantly from country to country and such considerations should be addressed by national authorities. The Delegation also proposed to reword section a) for clarification purposes. The Delegation of the United States also proposed a rewording of section 5.1.1 to make it more generally applicable.

99) The Delegation of Norway, supported by the Observer from IACFO, proposed to add a new section on mandatory quantitative declaration of added free sugars, with a footnote defining "free sugars", in view of the conclusions of the WHO/FAO Expert Consultation on Diet, Nutrition and the Prevention of Chronic Diseases, that recognized high intake of free sugars as one of the issues in the developing of chronic disease. The Delegation pointed out that this would help consumers to make an informed choice and facilitate their understanding of nutritional information.

100) Several delegations and observers expressed their objection to this proposal for the following reasons: the text under consideration should address only ingredient declaration, while nutrient declaration and claims were addressed in the *Guidelines on Nutrition labelling* and the *Guidelines for Use of Nutrition Claims*; and information on "added sugars" would not provide additional meaningful information to consumers.

101) Some delegations and observers proposed to delete paragraph f) referring to national authorities, while other delegations proposed to retain it to allow additional requirements at the national level. Several delegations proposed to delete paragraph g) that established a link with claims concerning certain foods, while some delegations proposed to add other foods to the current list. The Observer from IACFO noted that FAO/WHO Expert Report No. 916 identified several foods (commonly used as ingredients in processed foods) which have effects, distinct from known nutrient effects, on major disease risks and therefore, national authorities should be permitted to require QUID for these ingredients regardless of whether claims are made.

102) Several delegations and some observers expressed the view that in general, section 5.1.1 should not include references to nutrition or health claims since such claims were adequately addressed in the *Guidelines on Nutrition Labelling* and the *Guidelines for Use of Nutrition Claims*, and were not relevant in the context of ingredient declaration.

103) The Observer from Consumers International, supported by several observers, proposed to retain the conditions for ingredient declaration specified in paragraphs a) to f) as they reflected consumers demand for additional information and would facilitate an informed choice.

104) Several delegations questioned the basis of a threshold of 2% for the declaration of ingredients, as proposed in paragraphs h) and i), and some delegations proposed to use a threshold of 5%, or to delete the reference to a specific figure. The Observer from IDF requested a clarification concerning the relationship between QUID labelling requirements in the General Standard for the Labelling of Prepackaged Foods and labelling requirements in the Codex commodity standards for milk and milk products.

105) After further discussion, the Chair noted that there was consensus at this stage only to delete paragraph b) on ingredients "associated by consumers with the food", and the Committee agreed with this proposal. The Committee could not come to a conclusion on the other amendments put forward in the discussion on section 5.1.1

106) In section 5.1.2, several delegations proposed to delete paragraphs a) and b) on minimum and maximum percentage, and to retain only paragraph c) referring to an average percentage.

107) The Committee agreed with the proposal of the Delegation of the European Community to add a new paragraph at the end of section 5.1.2 to clarify the declaration of ingredients for foods which have lost moisture following heat treatment or other treatment.

108) The Chairperson noted the large diversity of views put forward in the discussion and the difficulties to come to a conclusion at the present session. The Committee agreed that, in order to facilitate discussion, a Working Group would be held immediately prior to the next session, subject to confirmation of logistical arrangements by Canada and Malaysia.

Status of the Proposed Draft Amendment to the General Standard for the Labelling of Prepackaged Foods: Quantitative Declaration of Ingredients

109) The Committee agreed to return the Proposed Draft Amendment, as amended at the present session, to Step 3 for comments and further consideration at the next session (see Appendix VII).

CONSIDERATION OF COUNTRY OF ORIGIN LABELLING (Agenda Item 8)[11]

110) The Committee recalled that the last session of the Committee had agreed not to continue work since there was no consensus and decided to report this outcome to the Codex Alimentarius Commission. However, the 26th Session of the Commission did not approve this decision and asked the Committee to reconsider this issue and report back to the Commission as to whether the Committee should initiate new work.

111) The Delegation of the United Kingdom, referring to the discussion paper CX/FL 01/12 prepared by the UK, Switzerland, and Malaysia, reminded the Committee that the background of the proposal to consider country of origin labelling was that the current provision in section 4.5 of the *General Standard for the Labelling of Prepackaged Foods* based its criteria for labelling of country of origin on the place of processing which was not enough to prevent misleading labelling. Also an increasing number of consumers were requesting country of origin labelling for a wider range of products than those covered by Codex commodity standards to date.

112) The Delegation of Ireland, on behalf of the member states of the European Union present at the meeting, supported work on country of origin labelling and expressed the view that the work at the first stage should focus on the definition of criteria or guidelines allowing for a clear distinction between mandatory and voluntary cases. The Delegation of Japan also supported work of country of origin including the declaration of the origin of ingredients in response to the growing consumers' recognition that the quality of foods was related to their origins. This view was supported by the Observer from IACFO. Many delegations and observers supported new work in this area since in their view this would provide useful information which consumers had been requesting and the current provisions were too general and did not provide sufficiently clear guidance as to when and how the labelling of country of origin should be applied. While acknowledging work underway in the WTO with respect to Country of Origin Labelling, some of these delegations pointed out that the purpose of such work was to address tariff issues and was different from the issues dealt with in labelling for information purposes.

113) Many other delegations and observers opposed new work by the Committee since they considered that the current provisions sufficiently addressed consumer concern in this respect and fully achieved the purpose of protecting consumers from deceptive practices and therefore there was no need to further change the provisions. Some of these delegations also felt that the initiation of new work was premature in view of the ongoing work by WTO on the Harmonized Rules of Origin, which could significantly impact on the work by the Committee.

114) Several delegations expressed the concern that country of origin labelling, especially as regards ingredient origin would be impracticable, complicated, confusing and entail huge cost to food producers and industries and that this could be a source of trade barriers, especially for developing countries. Some delegations stressed the difficulties related to enforcement of such provisions by national authorities. It was also pointed out that the country of ingredient origin could cause practical difficulties for food manufacturers who purchase ingredients from a variety of sources.

115) The Delegation of Canada reminded the Committee of the *Critera for the Establishment of Work Priorities* and that the first priority is consumer protection from the point of view of health and fraudulent practices. The Delegation noted that the developing countries that spoke on that item opposed any new work and recalled that under the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*, the Commission and its subsidiary bodies should give particular attention to the circumstances of developing countries. The Delegation of Canada also noted that under the Criteria for the Consideration of Other Factors referred to in the Second Statement of Principle, the feasibility of risk management options especially in developing countries, may be considered. The Delegation of Switzerland reminded the Committee that during the 26th Session of the Commission, many developing countries had

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11 CX/FL 04/8, CRD 5 (comments of Canada, European Community, ENCA, IBFAN), CRD 15 (ICGMA), CRD 22 (India), CRD 26 (Malaysia)

supported the continuation of work on country of origin labelling. The Delegation of Argentina clarified that it had not supported this new work in the Commission.

116) The Committee recognized that there was no consensus on the need for new work on country of origin labelling. Therefore, the Committee decided to report back to the 27th Session of the Codex Alimentarius Commission that the Committee had had an extensive discussion but the opinion of the Committee was divided between those delegations and observers who supported new work and those who opposed it, in order to seek guidance from the Commission.

CONSIDERATION OF FOOD LABELLING AND TRACEABILITY/PRODUCT TRACING (Agenda Item 9)[12]

117) The Committee noted the information on current work related to traceability/product tracing in other Codex Committees presented in the document. In addition, the Secretariat indicated that the Committee on General Principles (CCGP) had finalized a definition of traceability/product tracing that would be submitted to the Commission for adoption and inclusion in the Procedural Manual.

118) The Delegation of Ireland, speaking on behalf of the member states of the EU present at the session, noted its support for the definition developed by the CCGP and expressed the view that traceability has broad applications that extend beyond health and safety matters.

119) The Delegation of Mexico, supported by several delegations, expressed the view that it was premature to initiate work on traceability/product tracing and food labelling until such time as the work currently underway in the Committee on Food Import and Export Inspection and Certification Systems had been completed. Some delegations also recalled that the current provisions in the General Standard for the Labelling of Prepackaged Foods adequately allowed to identify and trace back products when required.

120) The Observer from Consumers International stressed the importance of traceability not only to ensure food safety but to provide clear and accurate labelling to consumers.

121) The Committee agreed that work on food labelling and traceability/product tracing would be removed from its agenda. The Committee noted it may be required to reconsider this issue as an agenda item after the work of other relevant committees is completed. It was also noted that the Committee would be advised if the Commission or Executive Committee decided that specific work in this area was required.

DISCUSSION PAPER ON MISLEADING CLAIMS (Agenda Item 10)[13]

122) The Committee recalled that its last session had not reached consensus on the need for new work to address misleading labelling and had agreed that the Delegation of Australia would prepare a revised discussion paper to facilitate consideration of this issue.

123) The Delegation of Australia indicated that the discussion paper considered case studies identifying different types of misleading labels and their relationship with existing Codex labelling texts, and concluded that although truthful but misleading labelling was likely to become more evident in the future with greater sophistication in consumer demand for information, the capacity to progress this discussion objectively in the Committee was limited as several outstanding labelling issues remained to be addressed. Therefore the discussion paper recommended that the Committee retain a watching brief on the issue and reconsider its approach after some of these issues had been resolved.

124) The Committee expressed its appreciation to the Delegation of Australia and the working group for their detailed research and analysis of this complex issue.

125) The Delegation of the United States, supported by some delegations, proposed to consider this issue further at the next session. To facilitate further discussion, the Delegation offered to undertake a review of existing Codex texts to extract principles in order to identify gaps which could result in misleading labelling and report their findings. The Delegation of Cameroon indicated that the question of misleading labelling was already addressed in labelling texts and that it was advisable to carry out a review of these texts.

126) Several delegations and observers supported the conclusions of the paper and did not support new work on misleading labelling insofar as several substantial issues remained to be addressed in the

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12 CX/FL 04/9, CRD 7 (comments of Canada), CRD 10 (comments of Argentina), CRD 16 (comments of ICGMA), CRD 22 (comments of India), CRD 23 (ALINORM 04/27/33, Appendix V- definition of traceability/product tracing)

13 CX/FL 04/10, CRD 3 (comments of Canada, EC, IBFAN), CRD 9 (ENCA), CRD 22 (India)

Committee, especially country of origin labelling, quantitative declaration of ingredients, labelling of foods derived from biotechnology, and nutrition and health claims.

127) The Committee recognized that there was not sufficient support to proceed with new work on misleading labelling and agreed to discontinue consideration of this issue. The Committee noted that it was always possible to reconsider this question in the future if new proposals were put forward.

OTHER BUSINESS, FUTURE WORK AND DATE AND PLACE OF NEXT SESSION (Agenda Item 11)[14]

Discussion Paper on Advertising

128) The Committee recalled that the 26th Session of the Commission, while considering the Draft Guidelines for use of Nutrition and Health Claims, had requested the Committee to consider the development of a definition for advertising as related to health and nutrition claims. The Delegation of Canada introduced the discussion paper on advertising (CRD 21) that recalled earlier discussions in the Committee and in the Commission on advertising, including the legal opinion provided by the Legal Counsels of FAO and WHO in 1984. The discussion paper also considered the issues related to the elaboration of a definition of advertising, as complementary to labelling, and in view of the terms of reference of the Committee.

129) The Delegation of the United States expressed the view that the legal opinion provided in 1984 referred to the terms of reference of the Codex Alimentarius Commission; however the terms of reference of the Committee referred only to "studying problems associated with advertising" and the Committee might need to seek the advice of the Commission on whether it should develop specific texts on advertising. The Delegation also pointed out that the legal and practical issues associated with advertising should be considered carefully before undertaking new work in this area.

130) Several delegations and observers supported further work on advertising in relation to health and nutrition claims, as specifically requested by the Commission. Some delegations and observers also stressed the need for guidance to governments in the area of food advertising in view of the importance of this issue for consumers. It was pointed out that the lack of rules for advertising might lead to a situation where consumers might find statements in advertising that would not be allowed in labelling.

131) Several delegations pointed out that the Committee should not consider advertising from a broad perspective, but should focus on those aspects of advertising relevant to the mandate of Codex and of the Committee on Food Labelling.

132) Some delegations expressed the view that it was premature to take a decision at this stage as member countries needed more time to consider carefully this complex question at the national level.

133) The Committee recognized that no conclusion could be reached at the present session but that further discussion of advertising was needed in order to reply to the request of the Commission. The Committee therefore agreed to circulate the discussion paper prepared by Canada, with some editorial changes, for comments and to consider advertising as a separate Agenda Item at the next session with priority being given to the development of a definition for advertising as it relates to nutrition and health claims. The Committee expressed its appreciation to Canada for its excellent paper in order to facilitate discussion of this complex issue.

Proposal for the Revision of the Codex General Guidelines on Claims

134) The Delegation of South Africa, referring to its country comments, proposed a revision of the Section 3.4 of the Codex General Guidelines on Claims (CAC/GL 1-1979(Rev.1-1991)) to allow for the claims as to the suitability of a food for use in the prevention, alleviation, treatment, and in certain cases, cure of diseases. The Delegation pointed out that a large body of new scientific evidence had been available since the last revision to prove that foods and nutrients can offer an alternative option in the treatment of disease, can prevent diseases and in some cases can cure diseases. The Delegation further stated that provisions on "Other function claims " and "Reduction of disease risk claims " in the Draft Guidelines on Nutrition and Health Claims elaborated by the Committee at this session had embodied this principle that nutrients can prevent illness or improve health conditions. The Delegation noted that the Joint FAO/WHO Expert Consultation on

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[14] CX/FL 04/11 (Proposal of South Africa); CRD 21 (Discussion paper on Advertising), CRD 26 (comments of Malaysia)

Diet, Nutrition and the Prevention of Chronic Diseases acknowledges the fact that nutrients plays a role in the prevention of chronic diseases.

135) Many delegations expressed their objections to this proposal as a clear distinction should be established between claims that were acceptable for foods and those that applied to drugs, especially as regards treatment of disease. Some delegations noted that the General Guidelines on Claims might need to be revised to make them consistent with the Draft Guidelines for Use of Nutrition and Health Claims but expressed the view that the amendment proposed did not address this question. Some delegations, while recognizing the role of nutrition in the prevention of chronic disease, pointed out that the proposal referred to products that were regulated as drugs in several countries and that such claims should be considered on a case-by-case basis at the national level.

136) The Observer from CRN supported by the Observer from IADSA suggested that section 3.4 of the Codex General Guidelines on Claims should be revised to take into account recent scientific evidence on the role of nutrients in disease prevention.

137) The Committee appreciated the efforts made by South Africa in preparing the document which overviewed a very complicated issue. However, due to lack of support, the Committee decided not to initiate new work on this item.

Proposal for the Revision of Nutrient Reference Values (NRVs)

138) The Delegation of Switzerland proposed to update Nutrient Reference Values (NRVs) in the Table in the Guidelines for Nutrition Labelling as several essential nutrients were not included and the Guidelines stipulated that NRVs should be kept under review in order to take account of scientific developments. The Delegation recommended that the Committee should request the Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) to conduct this as a matter of priority.

139) The Delegation of South Africa reminded the Committee that the CCNFSDU at its last session had agreed to revise NRVs by means of a working group chaired by South Africa, and that a circular letter had been sent to ask for proposals to revise NRVs. In this regard, the Codex Secretariat informed the Committee about the consideration of NRVs in that Committee, especially in conjunction with the development of the Proposed Draft Guidelines for Vitamins and Minerals Supplements (ALINORM 04/27/26, paras. 54-55).

Other Matters

140) The Delegation of Cameroon, in its own behalf and on behalf of the delegations from African countries, expressed its thanks to FAO, WHO, the Secretariat of the Codex Alimentarius Commission and all donor countries involved in the Codex Trust Fund, that had allowed some of their delegates to participate in this important session. The Delegation encouraged these donors to continue their efforts in order to strengthen the participation of these countries in international standardization.

DATE AND PLACE OF NEXT SESSION

141) The Committee welcomed the offer of the Government of Malaysia to host the Committee, that would be held for the first time outside of Canada, and noted that its next session would be held in Kota Kinabalu, Sabah, Malaysia, from 9 to 13 May 2005.

SUMMARY STATUS OF WORK

Subject Matter	**Step**	**Action by**	**Document Reference in ALINORM 04/27/22**
Draft Amendment to the *Standard for Quick Frozen Fish Sticks* (Labelling Section)	8	Governments 27th CAC	para. 11 Appendix II
Draft Guidelines for Use of Nutrition and Health Claims	8	Governments 27th CAC	para. 52 Appendix III
Guidelines for Organically Produced Foods: Draft Revised Annex 2 : Tables 1 and 2	8	Governments 27th CAC	para. 76 Appendix IV
Guidelines for Organically Produced Foods: Draft Revised Annex 2 : Tables 3 and 4	6	Governments 33rd CCFL	para. 77
Guidelines for Organically Produced Foods: Proposed Draft Revised Annex 2: Table 1 (Natural Sodium Nitrate)	3	Governments 33rd CCFL	para. 76 Appendix VIII
Draft Amendment to the General Standard (Draft Recommendations for the Labelling of Foods obtained through certain techniques of GM/GE): Definitions	7	33rd CCFL	para. 94 Appendix V
Proposed Draft Guidelines for the Labelling of Foods obtained through certain techniques of GM/GE: Labelling Provisions	3	Governments 33rd CCFL	para. 93 Appendix VI
Proposed Draft Amendment to the General Standard (Quantitative Declaration of Ingredients)	3	Governments 33rd CCFL	para. 109 Appendix VII
Country of Origin Labelling		27th CAC	para. 116
Consideration of Advertising		Governments 33rd CCFL	para. 133

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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

6.1.3 The proportion of fish content should be declared on the label.

7. SAMPLING, EXAMINATION AND ANALYSIS

7.4 Estimation of Fish Content

According to AOAC Method 966.15. In cases where there is some remaining doubts over the composition of the fish core then the method of analysis as outlined below could be used, i.e. as a reference method.

Determination of Fish Content

The fish content of a fish finger (fish stick) is calculated by using the following equation

$$\%\text{Fish Content} = \frac{\text{Weight of ingoing fish}}{\text{Weight of final product}} x100$$

For most products therefore, the fish ingredient weight is that of the raw ingredient. Any figure placed or declared on a product label would be a typical quantity reflecting the producer's normal manufacturing variations, in accordance with good manufacturing practice.

Checking of fish content by chemical analysis

The percentage fish content, corrected for the non-fish flesh nitrogen contributed by the carbohydrate coating, is calculated as follows.

$$\%\text{Fish} = \frac{(\%\text{ total nitrogen} - \%\text{ non - fish flesh nitrogen}}{\text{N factor}^*} x100$$

* appropriate N (nitrogen) factor

The non-fish flesh nitrogen is calculated as follows:

% non-fish flesh nitrogen = % carbohydrate x 0.02

Where the carbohydrate is calculated by difference:

% carbohydrate = 100 – (% water + % fat + % protein + % ash)

References

Determination of nitrogen: ISO 937:1978

Determination of moisture: ISO 1442:1997

Determination of total fat: ISO 1443:1973

Determination of ash: ISO 936: 1978

Table 2: Interim Nitrogen factors to be used for white fish as an ingredient (i.e. after GMP)

SPECIES	Nitrogen %
White fish:	
Cod	2.66
Minced Cod	2.61
Coley/Saithe	2.69
European Hake	2.64
Haddock	2.72
Ling	2.78
Plaice	2.46
Alaskan Pollack	2.59
Whiting	2.68
White fish mean	2.65

DRAFT GUIDELINES FOR USE OF NUTRITION AND HEALTH CLAIMS

(At Step 8 of the Procedure)[1]

Nutrition claims should be consistent with national nutrition policy and support that policy. Only nutrition claims that support national nutrition policy should be allowed.

Health claims should be consistent with national health policy, including nutrition policy, and support such policies where applicable. Health claims should be supported by a sound and sufficient body of scientific evidence to substantiate the claim, provide truthful and non-misleading information to aid consumers in choosing healthful diets and be supported by specific consumer education. The impact of health claims on consumers' eating behaviours and dietary patterns should be monitored, in general, by competent authorities. Claims of the type described in section 3.4 of the Codex General Guidelines on Claims are prohibited.

1. SCOPE

1.1 These guidelines relate to the use of nutrition and health claims in food labelling and, where required by the authorities having jurisdiction, in advertising.

1.2 These guidelines apply to all foods for which nutrition and health claims are made without prejudice to specific provisions under Codex standards or Guidelines relating to Foods for Special Dietary Uses and Foods for Special Medical Purposes.

1.3 These guidelines are intended to supplement the Codex General Guidelines on Claims and do not supersede any prohibitions contained therein.

1.4 Nutrition and health claims shall not be permitted for foods for infants and young children except where specifically provided for in relevant Codex standards or national legislation.

2. DEFINITIONS

2.1 ***Nutrition claim*** means any representation which states, suggests or implies that a food has particular nutritional properties including but not limited to the energy value and to the content of protein, fat and carbohydrates, as well as the content of vitamins and minerals. The following do not constitute nutrition claims:

(a) the mention of substances in the list of ingredients;

(b) the mention of nutrients as a mandatory part of nutrition labelling;

(c) quantitative or qualitative declaration of certain nutrients or ingredients on the label if required by national legislation.

2.1.1 ***Nutrient content claim*** is a nutrition claim that describes the level of a nutrient contained in a food.

(Examples: "source of calcium"; "high in fibre and low in fat";)

2.1.2 ***Nutrient Comparative claim*** is a claim that compares the nutrient levels and/or energy value of two or more foods.

(Examples: "reduced"; "less than"; "fewer"; "increased"; "more than".)

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[1] Amendments to the *Guidelines for Use of Nutrition Claims* are underlined

2. 2 ***Health claim*** means any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health. Health claims include the following:

2.2.1 ***Nutrient Function Claims*** - a nutrition claim that describes the physiological role of the nutrient in growth, development and normal functions of the body.

Example:

"Nutrient A (naming a physiological role of nutrient A in the body in the maintenance of health and promotion of normal growth and development). Food X is a source of/ high in nutrient A."

2.2.2 ***Other Function Claims*** - These claims concern specific beneficial effects of the consumption of foods or their constituents, in the context of the total diet on normal functions or biological activities of the body. Such claims relate to a positive contribution to health or to the improvement of a function or to modifying or preserving health.

Examples:

"Substance A (naming the effect of substance A on improving or modifying a physiological function or biological activity associated with health). Food Y contains x grams of substance A."

2.2.3 ***Reduction of disease risk claims*** - Claims relating the consumption of a food or food constituent, in the context of the total diet, to the reduced risk of developing a disease or health-related condition.

Risk reduction means significantly altering a major risk factor(s) for a disease or health-related condition. Diseases have multiple risk factors and altering one of these risk factors may or may not have a beneficial effect. The presentation of risk reduction claims must ensure, for example, by use of appropriate language and reference to other risk factors, that consumers do not interpret them as prevention claims.

Examples:

" A healthful diet low in nutrient or substance A may reduce the risk of disease D. Food X is low in nutrient or substance A"

" A healthful diet rich in nutrient or substance A may reduce the risk of disease D. Food X is high in nutrient or substance A"

3. NUTRITION LABELLING

Any food for which a nutrition or health claim is made should be labelled with a nutrient declaration in accordance with Section 3 of the Codex Guidelines on Nutrition Labelling.

4. NUTRITION CLAIMS

4.1 The only nutrition claims permitted shall be those relating to energy, protein, carbohydrate, and fat and components thereof, fibre, sodium and vitamins and minerals for which Nutrient Reference Values (NRVs) have been laid down in the Codex Guidelines for Nutrition Labelling.

5. NUTRIENT CONTENT CLAIMS

5.1 When a nutrient content claim that is listed in the Table to these Guidelines or a synonymous claim is made, the conditions specified in the Table for that claim should apply.

5.2 Where a food is by its nature low in or free of the nutrient that is the subject of the claim, the term describing the level of the nutrient should not immediately precede the name of the food but should be in the form "a low (naming the nutrient) food" or "a (naming the nutrient)-free food".

6. COMPARATIVE CLAIMS

Comparative claims should be permitted subject to the following conditions and based on the food as sold, taking into account further preparation required for consumption according to the instructions for use on the label:

6.1 The foods being compared should be different versions of the same food or similar foods. The foods being compared should be clearly identified.

6.2 A statement of the amount of difference in the energy value or nutrient content should be given. The following information should appear in close proximity to the comparative claim:

6.2.1 The amount of difference related to the same quantity, expressed as a percentage, fraction, or an absolute amount. Full details of the comparison should be given.

6.2.2 The identity of the food(s) to which the food is being compared. The food(s) should be described in such a manner that it (they) can be readily identified by consumers.

6.3 The comparison should be based on a relative difference of at least 25% in the energy value or nutrient content, except for micronutrients where a 10% difference in the NRV would be acceptable, between the compared foods and a minimum absolute difference in the energy value or nutrient content equivalent to the figure defined as "low" or as a "source" in the Table to these Guidelines.

6.4 The use of the word "light" should follow the same criteria as for "reduced" and include an indication of the characteristics which make the food "light".

7. HEALTH CLAIMS

7.1 Health claims should be permitted provided that all of the following conditions are met:

7.1.1 Health claims must be based on current relevant scientific substantiation and the level of proof must be sufficient to substantiate the type of claimed effect and the relationship to health as recognised by generally accepted scientific review of the data and the scientific substantiation should be reviewed as new knowledge becomes available[2]. The health claim must consist of two parts:

1) Information on the physiological role of the nutrient or on an accepted diet-health relationship; followed by

2) Information on the composition of the product relevant to the physiological role of the nutrient or the accepted diet-health relationship unless the relationship is based on a whole food or foods whereby the research does not link to specific constituents of the food.

7.1.2 Any health claim must be accepted by or be acceptable to the competent authorities of the country where the product is sold.

7.1.3 The claimed benefit should arise from the consumption of a reasonable quantity of the food or food constituent in the context of a healthy diet.

7.1.4 If the claimed benefit is attributed to a constituent in the food, for which a Nutrient Reference value is established, the food in question should be:

(i) - a source of or high in the constituent in the case where increased consumption is recommended; or,

(ii) - low in, reduced in, or free of the constituent in the case where reduced consumption is recommended.

Where applicable, the conditions for nutrient content claims and comparative claims will be used to determine the levels for “high”, “low”, “reduced”, and “free”.

7.1.5 Only those essential nutrients for which a Nutrient Reference Value (NRV) has been established in the Codex Guidelines on Nutrition Labelling or those nutrients which are mentioned in officially recognized dietary guidelines of the national authority having jurisdiction, should be the subject of a nutrient function claim.

7.2 Health claims should have a clear regulatory framework for qualifying and/or disqualifying conditions for eligibility to use the specific claim, including the ability of competent national authorities to prohibit claims made for foods that contain nutrients or constituents in amounts that increase the risk of disease or an adverse health-related condition. The health claim should not be made if it encourages or condones excessive consumption of any food or disparages good dietary practice.

7.3 If the claimed effect is attributed to a constituent of the food, there must be a validated method to quantify the food constituent that forms the basis of the claim.

7.4 The following information should appear on the label or labelling of the food bearing health claims:

7.4.1 A statement of the quantity of any nutrient or other constituent of the food that is the subject of the claim.

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[2] Reference to the Scientific Criteria for Health Related Claims being developed by the CCNFSDU should be inserted here.

7.4.2 The target group, if appropriate.

7.4.3 How to use the food to obtain the claimed benefit and other lifestyle factors or other dietary sources, where appropriate.

7.4.4 If appropriate, advice to vulnerable groups on how to use the food and to groups, if any, who need to avoid the food.

7.4.5 Maximum safe intake of the food or constituent where necessary.

7.4.6 How the food or food constituent fits within the context of the total diet.

7.4.7 A statement on the importance of maintaining a healthy diet.

8. CLAIMS RELATED TO DIETARY GUIDELINES OR HEALTHY DIETS

Claims that relate to dietary guidelines or "healthy diets" should be permitted subject to the following conditions:

8.1 Only claims related to the pattern of eating contained in dietary guidelines officially recognized by the appropriate national authority.

8.2 Flexibility in the wording of claims is acceptable, provided the claims remain faithful to the pattern of eating outlined in the dietary guidelines.

8.3 Claims related to a "healthy diet" or any synonymous term are considered to be claims about the pattern of eating contained in dietary guidelines and should be consistent with the guidelines.

8.4 Foods which are described as part of a healthy diet, healthy balance, etc., should not be based on selective consideration of one or more aspects of the food. They should satisfy certain minimum criteria for other major nutrients related to dietary guidelines.

8.5 Foods should not be described as "healthy" or be represented in a manner that implies that a food in and of itself will impart health.

8.6 Foods may be described as part of a "healthy diet" provided that the label carries a statement relating the food to the pattern of eating described in the dietary guidelines.

TABLE OF CONDITIONS FOR NUTRIENT CONTENTS

COMPONENT	CLAIM	CONDITIONS
		NOT MORE THAN
Energy	Low	40 kcal (170 kJ) per 100 g (solids) or 20 kcal (80 kJ) per 100 ml (liquids)
	Free	4 kcal per 100 ml (liquids)
Fat	Low	3g per 100 g (solids) 1.5 g per 100 ml (liquids)
	Free	0.5 g per 100 g (solids) or 100 ml (liquids)
Saturated Fat	Low[3]	1.5 g per 100 g (solids) 0.75 g per 100 ml (liquids) and 10% of energy
	Free	0.1 g per 100 g (solids) 0.1 g per 100 ml (liquids)
Cholesterol	Low[3]	0.02 g per 100 g (solids) 0.01 g per 100 ml (liquids)
	Free	0.005 g per 100 g (solids) 0.005 g per 100 ml (liquids) and, for both claims, less than: 1.5 g saturated fat per 100 g (solids) 0.75 g saturated fat per 100 ml (liquids) and 10% of energy of saturated fat
Sugars	Free	0.5 g per 100 g (solids) 0.5 g per 100 ml (liquids)
Sodium	Low Very Low Free	0.12 g per 100 g 0.04 g per 100 g 0.005 g per 100 g

[3] In the case of the claim for "low in saturated fat", trans fatty acids should be taken into account where applicable. This provision consequentially applies to foods claimed to be "low in cholesterol" and "cholesterol free".

		NOT LESS THAN
Protein	Source	10% of NRV per 100 g (solids) 5% of NRV per 100 ml (liquids) or 5% of NRV per 100 kcal (12% of NRV per 1 MJ) or 10% of NRV per serving
	High	2 times the values for ”source”
Vitamins and Minerals	Source	15% of NRV per 100 g (solids) 7.5% of NRV per 100 ml (liquids) or 5% of NRV per 100 kcal (12% of NRV per 1 MJ) or 15% of NRV per serving
	High	2 times the values for "source"

DRAFT AMENDMENT TO THE GUIDELINES FOR THE PRODUCTION, PROCESSING, LABELLING AND MARKETING OF ORGANICALLY PRODUCED FOODS: DRAFT REVISED ANNEX 2 – PERMITTED SUBSTANCES
(At Step 8 of the Procedure)

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, e.g. 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

Substances	**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[4] sources not permitted.
Slurry or urine	If not from organic sources, need recognized by inspection body. Preferably after controlled fermentation and/or appropriate dilution. "Factory" farming sources not permitted"
Composted animal excrements, including poultry	Need recognized by the certification body or authority
Manure and composted farmyard manure	"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.
Compost and spent mushroom and Vermiculite substrate	Need recognized by the certification body or authority. The initial composition of the substrate must be limited to the products on this list
Composted or fermented home refuse	Need recognized by the certification body or authority.
Compost 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.
Seaweeds and seaweed products	Need recognized by the certification body or authority.
Sawdust, bark and wood waste	Need recognized by the certification body or authority, wood not chemically treated after felling.
Wood ash and wood charcoal	Need recognized by the certification body or authority, from wood not chemically treated after felling.
Natural phosphate rock.	Need recognized by the certification body or authority. Cadmium should not exceed 90mg/kg P_20_5
Basic slag	Need recognized by the certification body or authority.
Rock potash, mined potassium salts (e.g. kainite, sylvinite)	Less than 60% chlorine
Sulphate of potash (e.g. patenkali)	Obtained by physical procedures but not enriched by chemical processes to increase its solubility. Need recognized by the certification body or authority.

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

Calcium carbonate of natural origin (e.g. chalk, marl, maerl, limestone, phosphate chalk)	----
Magnesium rock	----
Calcareous magnesium rock	----
Epsom salt (magnesium-sulphate)	----
Gypsum (calcium sulphate)	Only from natural sources/origin.
Stillage and stillage extract	Ammonium stillage excluded
Sodium chloride	Only mined salt
Aluminium calcium phosphate	Cadmium should not exceed 90mg/kg P_20_5
Trace elements (e.g. boron, copper, iron, manganese, molybdenum, zinc)	Need recognized by the certification body or authority.
Sulphur	Need recognized by the certification body or authority.
Stone meal	----
Clay (e.g. bentonite, perlite, zeolite)	----
Naturally occurring biological organisms (e.g. worms)	----
Vermiculite	----
Peat	Excluding synthetic additives; permitted for seed, potting module composts. Other use as recognized by certification body or authority. Not permitted as a soil conditioner.
Humus from earthworms and insects	----
Chloride of lime	Need recognized by the certification body or authority.
Human excrements	Need recognized by the certification body or authority. The source is separated from household and industrial wastes that pose a risk of chemical contamination. It is treated sufficiently to eliminate risks from pests, parasites, pathogenic micro-organisms, and is not applied to crops intended for human consumption or to the edible parts of plants.
By-products of the sugar industry (e.g. Vinasse)	Need recognized by the certification body or authority.
By-products from oil palm, coconut and cocoa (including empty fruit bunch, palm oil mill effluent (pome), cocoa peat and empty cocoa pods)	Need recognized by the certification body or authority.
By-products of industries processing ingredients from organic agriculture	Need recognized by the certification body or authority.
Calcium chloride solution	Leaf treatment in case of proven calcium deficiency.

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. Exclusion of Piperonyl butoxide after 2005 as a synergist.
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	Need recognised by the certification body or authority. Not chemically treated.
Gelatine	---
Lecithin	Need recognized by the certification body or authority.
Casein	---
Natural acids (e.g. vinegar)	Need recognized by the certification body or authority.
Fermented product from Aspergillus	---
Extract from mushroom (Shiitake fungus)	---
Extract from Chlorella	---
Chitin nematicides	Natural origin
Natural plant preparations, excluding tobacco	Need recognized by certification body or authority.
Tobacco tea (except pure nicotine)	Need recognized by certification body or authority.
Sabadilla	---
Beeswax	---
II. Mineral	
Copper in the form of copper hydroxide, copper oxychloride, (tribasic) copper sulphate, suprous oxide, Bordeaux mixture and Burgundy mixture	Need, prescription and application rates recognized by certification body or authority. As a fungicide on condition that the substance be used in such a way as to minimize copper accumulation in the soil.
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.
Iron phosphates	As molluscicide.
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.
Homeopathic and Ayurvedic preparations	---
Herbal and biodynamic preparations	---
Sterilized insect males	Need recognized by certification body or authority.
Rodenticides	Products for pest control in livestock buildings and installations. 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.
Mineral oils	Need recognized by the certification body or authority.
Mechanical control devices such as e.g., crop protection nets, spiral barriers, glue-coated plastic traps, sticky bands.	---

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

(DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOODS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING)

DEFINITIONS

(At Step 7 of the Procedure)

SECTION 2. DEFINITION OF TERMS[5]

For the purpose of the General Standard:

"Food and food ingredients obtained through certain techniques of genetic modification / genetic engineering" means food and food ingredients composed of or containing genetically modified / engineered organisms obtained through modern biotechnology, or food and food ingredients produced from, but not containing genetically modified / engineered organisms obtained through modern biotechnology.

"Organism" means any biological entity capable of replication, reproduction or of transferring genetic material.

"Genetically modified / engineered organism" means an organism in which the genetic material has been changed through modern biotechnology in a way that does not occur naturally by multiplication and/or natural recombination.

"Modern biotechnology" means the application of:

a. In vitro nucleic acid techniques[6], including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

b. Fusion of cells[7] beyond the taxonomic family,

that overcome natural physiological, reproductive or recombination barriers and that are not techniques used in traditional breeding and selection

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5 **The terminology used in this section on definitions should not determine the terminology which is appropriate for use on food labels**

6 These include but are not limited to: recombinant DNA techniques that use vector systems and techniques involving the direct introduction into the organism of hereditary materials prepared outside the organism such as micro-injection, macro-injection, chemoporation, electroporation, micro-encapsulation and liposome fusion

7 Fusion of cells (including protoplast fusion) or hybridization techniques that overcome natural physiological, reproductive, or recombination barriers, where the donor cells/protoplasts do not fall within the same taxonomic family

PROPOSED DRAFT GUIDELINES FOR THE LABELLING OF FOOD AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING

(At Step 3 of the Procedure)

PURPOSE OF THE GUIDELINES

To provide guidelines to ensure that the labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering provides factual, verifiable, understandable and non-misleading information to protect consumer's health and to ensure fair practices in food trade. Food labelling plays an important role in providing information to consumers and thereby facilitating consumer choice.

These guidelines set out a number of approaches and related information that could be used for the labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering.

1.0 SCOPE

These guidelines recommend procedures for the labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering.

1.1 These guidelines apply to the labelling of such food and food ingredients:

1.1.1 when it is demonstrated, through an appropriate analysis of data, that the composition, nutritional value, or intended use of the food or food ingredient differ in comparison to that of corresponding conventional counterparts, having regard to accepted limits of natural variation[8]; and /or

1.1.2 when they are composed of or contain a genetically modified / engineered organism or contain protein or DNA resulting from gene technology[9]; and/or

1.1.3 when they are produced from, but do not contain, genetically modified / engineered organisms, protein or DNA resulting from gene technology.

2.0 DEFINITION OF TERMS[10]

(At Step 7 of the Procedure)

For the purpose of these Guidelines:

"Food and food ingredients obtained through certain techniques of genetic modification / genetic engineering" means food and food ingredients composed of or containing genetically modified / engineered organisms obtained through modern biotechnology, or food and food ingredients produced from, but not containing genetically modified / engineered organisms obtained through modern biotechnology.

"Organism" means any biological entity capable of replication, reproduction or of transferring genetic material.

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8 This would include products such as oils with altered fatty acid levels, but would not include products such as those with agronomic modifications which contain recombinant DNA and/or protein but no further overall change to composition, nutritional value or intended use.

9 [Gene Technology: Means a collection of techniques which are used to alter the heritable genetic material of living cell or organisms in a way that does not occur naturally by multiplication an/or recombination]

10 The terminology used in this section on definitions should not determine the terminology which is appropriate for use on food labels

"Genetically modified / engineered organism" means an organism in which the genetic material has been changed through modern biotechnology in a way that does not occur naturally by multiplication and/or natural recombination.

"Modern biotechnology" means the application of:

a. In vitro nucleic acid techniques[11], including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

b. Fusion of cells[12] beyond the taxonomic family,

that overcome natural physiological, reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

3.0 LABELLING PROVISIONS

In adopting a specific approach to the labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering the following provisions could be used:

3.1 When food and food ingredients obtained through certain techniques of genetic modification/genetic engineering, as defined in Section 2 are [no longer equivalent to / differ significantly] from the corresponding existing food and food ingredients, as regards:

-composition; and/or

-nutritional value; and/or

-intended use;

the characteristics or properties which make it different from the corresponding existing food and food ingredients should be clearly identified on the label as described in Subsection 6.l on label declarations.

3.2 The presence in any food or food ingredients obtained through certain techniques of genetic modification/genetic engineering of an allergen transferred from any of the products listed in Section 4.2.1.4 of the General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985 (Rev.1-1991) shall be declared[13]

3.3 [The presence of substances which may result in physiological or metabolic disorders for certain sections of the population and that are absent in corresponding existing foods[should][shall] be labelled].

3.4 In addition to the provisions of Subsection 3.1 to 3.3, when food and food ingredients obtained through certain techniques of genetic modification/genetic engineering as defined in Section 2, are labelled to indicate method of production, labelling declarations should apply (some examples of which are described in Subsection 6.2):

(a) When they are composed of or contain a genetically modified / engineered organism or contain protein or DNA resulting from gene technology; and/or

(b) When they are produced from, but do not contain, genetically modified /engineered organisms, protein or DNA resulting from gene technology even when they do not differ in composition, nutritional value and, intended use**.**

3.5 [Notwithstanding Section 4.2.2.2 of the General Standard[6], the presence of substances that are absent in corresponding existing food and food ingredients that could be the subject of dietary restrictions, based on religious objections or cultural practices, may be labelled. Where such labelling is used, member countries should establish criteria on how labelling decisions, based on dietary restrictions, will be decided and implemented in a manner that is fair, transparent and consistent.]

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11 These include but are not limited to: recombinant DNA techniques that use vector systems and techniques involving the direct introduction into the organism of hereditary materials prepared outside the organism such as micro-injection, macro-injection, chemoporation, electroporation, micro-encapsulation and liposome fusion

12 Fusion of cells (including protoplast fusion) or hybridization techniques that overcome natural physiological, reproductive, or recombination barriers, where the donor cells/protoplasts do not fall within the same taxonomic family

13 This provision was adopted at Step 8 by the Codex Alimentarius Commission at its 24rd Session (July, 2001)

[4.0 THRESHOLD LEVELS

4.1 Where food and food ingredients obtained through certain techniques of genetic modification/genetic engineering, are labelled to declare the method of production, consideration may be given to:

[Establishment of a threshold level in food and food ingredients for the presence of food and food ingredients obtained from certain techniques of genetic modification/genetic engineering, below which labelling would not apply[14]] and/or

[Establishment of a de minimis threshold level for adventitious or accidental inclusion in food and food ingredients, of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering, below which labelling would not apply]]

[5.0 EXEMPTIONS

5.1 Notwithstanding the provisions of Subsection 3.1 to 3.3, consideration may be given to the exemption from labelling of specific categories (for example highly processed food ingredients, processing aids, food additives, flavours) of food and food ingredients obtained through certain techniques of genetic modification / genetic engineering.]

6.0 LABEL DECLARATIONS

In accordance with the General Principles section of the Codex General Standard for the Labelling of Prepackaged Foods and the Codex General Guidelines on Claims, prepackaged food shall not be described on any label or in any labelling or presented in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character or safety in any respect.

6.1 Where food and food ingredients obtained through certain techniques of genetic modification/genetic engineering are labelled to indicate final product characteristics, the following requirements should apply:

(a) if the composition or nutritional value of food and food ingredients is [no longer equivalent to/ differs significantly] from the corresponding existing food and food ingredients, the label should provide, in conjunction with, or in close proximity to, the name of the food and food ingredients, such additional words or phrases as necessary to inform the consumer as to its changed composition or nutrient content in conformity with Sections 4.1 and 4.2.2 of the General Standard. In addition, nutrient declaration should be provided in conformity with the Codex Guidelines on Nutrition Labelling.

(b) if the mode of storage, preparation or cooking is [no longer equivalent to / differs significantly] from the corresponding existing food and food ingredients, clear instructions for use should be provided.

6.2 In accordance with Section 6.0 and in addition to the provisions in Subsection 6.1, food labels should be meaningful to the [intended] consumer. Where food and food ingredients obtained through certain techniques of genetic modification/genetic engineering are labelled to declare the method of production, examples of label declaration(s) include but are not limited to:

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[14] Consideration of a threshold must address existing provisions of the *Codex General Standard for the Labelling of Prepackaged Foods*, e.g. Section 4.2.1.3 (Compound Ingredients)

(a) ["Produced from genetically modified (naming the source)"] e.g. "produced from genetically modified soya"

(b) If the ingredient is already listed as produced from the source, ["genetically engineered (naming the food)"], e.g. "genetically engineered maize flour"

(c) ["Grown from seeds obtained through [modern] plant biotechnology"]

(d) If the ingredient is designated by the name of a category, ["contains (name of the ingredient) produced from genetically modified (source)"], e.g. starch ("contains starch produced from genetically modified maize")

(e) ["Genetically engineered (naming the characteristic) (naming the food)"] e.g. "genetically engineered high oleic soybean oil"

(f) ["Product of plant / animal biotechnology"]

(g) ["Naming the food/food ingredient (genetically modified)"] e.g. "soybean (genetically modified)"

(h) ["Naming the food/food ingredient (genetically modified food/food ingredient (not segregated)"] e.g. "soybean (genetically modified soybean not segregated)"

(i) ["Product of gene technology"]

6.3 Where the presence of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering is declared on the label, the following would apply:

(a) In the case of single-ingredient foods, or where there is no list of ingredients, the information should appear clearly on the label of the food; or

(b) In the case of a food ingredient(s) in a multi-ingredient food, the information should be shown in the list of ingredients or in parentheses immediately following the ingredient(s). Alternately, the ingredient(s) may be identified by an asterisk and the required wording should appear in a statement immediately following the list of ingredients.

[7.0 IMPLEMENTATION

Consistent with the approach(es) adopted under Section 3, additional consideration should be given to procedures and methodologies for the identification of food and food ingredients produced using certain techniques of genetic modification/genetic engineering and verification of label declarations. These include, but are not limited to: development of validated detection methods; establishment of verification (for example, documentation) systems; and efforts for the development of supporting capacity and infrastructure.]

ANNEX

[Optional Labelling: Without prejudice to the acceptance of the approach to method of production labelling as a "legitimate concern"* of governments in establishing their national legislation, the following is provided as optional considerations to member countries:]

[*Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which Other Factors are Taken Into Account]

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

(Quantitative Ingredient Declaration Labelling)
(At Step 3 of the Procedure)

5. ADDITIONAL MANDATORY REQUIREMENTS

5.1 Quantitative Ingredient Declarations

5.1.1 Every food sold as a mixture or combination shall disclose the ingoing percentage, by weight, of any ingredient (including ingredients of compound ingredients) that

(a) is emphasised on the label through words or pictures; or

(b) [is essential to characterise the food; or

(c) is essential to distinguish the food from others with which it may be confused; or]

(d) appears in the common or trade name of the food; or

(e) [the disclosure of which is deemed, by national authorities, to be necessary to enhance the health of consumers or prevent consumer deception].

(f) [is the subject of an express or implied claim about the presence of any fruits, vegetables, whole grains or added sugars]

Such disclosure is not required where

(g) [the ingredient comprises less than 2% of the total weight of the product and has been used for the purposes of flavouring; or]

(h) the ingredient comprises less than [2%] of the total weight of the product and consumers have no reasonable expectation of a nutritional or health effect related to the amount of that ingredient; or

(i) commodity-specific standards of Codex Alimentarius conflict with the requirements described here.

5.1.2 The information required in Section 5.1.1 shall be declared on the product label [as a numerical percentage rounded to the nearest percentage point].

The ingoing percentage, by weight, of each such ingredient [may be given on the label in close proximity to the words or images emphasising the particular ingredient, or beside the common name or class name of the food, or adjacent to each appropriate ingredient listed in the ingredient list as;].

(a) [a minimum percentage, where the emphasis is on the large amount of the ingredient present, or

(b) a maximum percentage, where emphasis is on the small amount of the ingredient present, or]

(c) an average percentage in all other cases

or

for foodstuffs which have lost moisture following heat treatment or other treatment, the quantity shall correspond to the quantity of the ingredient or ingredients used, related to the finished product. The quantity shall be expressed as a percentage. However, when the quantity of an ingredient or the total quantity of all the ingredients expressed on the labelling exceeds 100%, the percentage shall be replaced by the weight of the ingredient(s) used to prepare 100g of finished product.

PROPOSED DRAFT AMENDMENT TO THE GUIDELINES FOR THE PRODUCTION, PROCESSING, LABELLING AND MARKETING OF ORGANICALLY PRODUCED FOODS: PROPOSED DRAFT REVISED ANNEX 2 – PERMITTED SUBSTANCES
(At Step 3 of the Procedure)

ANNEX 2

PERMITTED SUBSTANCES FOR THE PRODUCTION OF ORGANIC FOODS

TABLE 1: SUBSTANCES FOR USE IN SOIL FERTILIZING AND CONDITIONING

Substances	**Description; compositional requirements; conditions of use**
[Natural Sodium Nitrate]	[text to be drafted]