codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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ALINORM 03/22A

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION
Twenty-sixth Session
Rome, Italy, 30 June - 7 July 2003

REPORT OF THE THIRTY-FIRST SESSION OF THE CODEX COMMITTEE ON FOOD LABELLING
Ottawa, Canada, 28 April - 2 May 2003

Note: This document incorporates Circular Letter CL 2003/18-FL

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CX 5/15 **CL 2003/18-FL**
May 2003

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 31st Session of the Codex Committee on Food Labelling (ALINORM 03/22 A)**

A. MATTERS FOR ADOPTION BY THE 26th SESSION OF THE CODEX ALIMENTARIUS COMMISSION

Draft Standards at Step 8 of the Procedure

1. Draft Amendment to the General Standard for the Labelling of Prepackaged Foods (class names) (para. 24, Appendix II)

Draft Guidelines at Step 8 of the Procedure

2. Draft Amendment to the Guidelines on Nutrition Labelling (para. 41, Appendix III)
3. Draft Guidelines for Use of Nutrition and Health Claims (para. 66, Appendix IV)
4. Draft Amendment to the Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods: Proposed Draft Revised Section 5 - Criteria (para. 80, Appendix V)

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 10 June 2003**.

Proposed Draft Guidelines at Step 5 of the Procedure

5. 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. 98, Appendix VI)

Governments wishing to submit comments on the implications which the Proposed Draft Amendment may have for their economic interests should do so in writing in conformity with the Procedure for the Elaboration of World-wide Standards at Step 5 to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy **before 10 June 2003**.

B. REQUEST FOR COMMENTS AND INFORMATION

Proposed Draft Standard at Step 3 of the Procedure

5. Proposed Draft Amendment to the General Standard for the Labelling of Prepackaged Foods: Quantitative Declaration of Ingredients (para. 113, Appendix VII)

Governments and international organizations wishing to submit comments on point 5. 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 2003 .**

SUMMARY AND CONCLUSIONS

The summary and conclusions of the 31st Session of the Codex Committee on Food Labelling are as follows:

Matters for adoption by the 26th Session of the Codex Alimentarius Commission:

The Committee:

- agreed to advance to Step 8 the Proposed Draft Amendment to the *General Standard for the Labelling of Prepackaged Foods* (class names) (para. 24, Appendix II);
- agreed to advance to Step 8 the Proposed Draft Amendment to the *Guidelines on Nutrition Labelling* (para. 41, Appendix III);
- agreed to advance to Step 8 the Draft Guidelines for Use of Nutrition and Health Claims (para. 66, Appendix IV);
- agreed to advance to Step 8 the Draft Amendment to the *Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods*: Draft Revised Section 5 - Criteria (para. 80, Appendix V);
- agreed to advance to Step 5 the 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. 98, Appendix VI).

Other Matters of Interest to the Commission

The Committee:

- endorsed the labelling provisions in the Draft Standards submitted for consideration (paras. 8-21);
- 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 at Step 4 the Proposed Draft Guidelines for the Labelling of Food and Food Ingredients Obtained through Certain Techniques of Genetic Modification/Genetic Engineering: Labelling Provisions (para. 74);
- 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. 113, Appendix VII);
- agreed not to work on the amendment of the *General Standard for the Labelling of Prepackaged Foods* concerning country of origin labelling as there was no consensus and to inform the Commission of its discussions (paras. 114-119);
- agreed to discuss the need for new work on traceability/product tracing (para. 125) and misleading claims (para. 129) at its next session.

TABLE OF CONTENTS

LIST OF APPENDICES

INTRODUCTION

1) The Codex Committee on Food Labelling held its Thirty First Session in Ottawa, Canada from 28 April to 2 May 2003, at the kind invitation of the Government of Canada. Dr. Anne MacKenzie, Associate Vice-President, Science Evaluation, Canadian Food Inspection Agency, chaired the meeting. The meeting was attended by 205 delegates and observers representing 38 Member Countries and 30 International Organizations. The full List of Participants is attached to this report as Appendix I.

OPENING OF THE SESSION

2) The Session was opened by Dr. André Gravel, Executive Vice-President, Canadian Food Inspection Agency who welcomed participants to the Thirty First Session of the Committee on behalf of the Government of Canada. Dr. Gravel noted that the recommendations of the Report of the *Joint FAO/WHO Evaluation of the Codex Alimentarius and Other FAO and WHO Work on Food Standards*, which was the outcome of the first comprehensive evaluation in Codex's forty-year history, would have a great importance for the future work of Codex. Canada would welcome the changes in order to improve the efficiency of the Codex process, while maintaining and strengthening the scientific basis of the risk analysis framework. Dr. Gravel also stressed that food labelling standards when they have an impact on consumer health and safety would fall within the first priority of Codex. Dr. Gravel also recalled that the Committee had been proactive in utilizing electronic communication to enlarge participation and stressed the need to facilitate the participation of developing countries in Codex. Finally Dr. Gravel wished a successful and productive session and encouraged all the participants to continue to seek creative and innovative solutions to the challenges put forward by complex labelling issues.

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

3) The Committee adopted the Provisional Agenda as its Agenda for the Session without amendment.

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

4) The Committee noted that most matters referred in the working documents would be considered specifically under the relevant Agenda items.

Committee on Nutrition and Foods for Special Dietary Uses

5) The Committee noted that in reply to its request to develop criteria for the scientific basis of health claims, in conjunction with the Draft Guidelines for Use of Health and Nutrition Claims, the Committee on Nutrition and Foods for Special Dietary Uses had agreed to initiate new work on the elaboration of Proposed Draft Recommendations on the Scientific Basis of Health Claims, with the understanding that further consideration would be given to the title and status of the document as a separate text or as a section of the Draft Guidelines.

Regional Coordinating Committee for Asia

6) The Committee noted that the 13th Session of the Regional Coordinating Committee for Asia had discussed a paper from the Coordinator for Asia concerning the need to commence work in the area of novel foods and functional foods. As proposed by many delegations, the Coordinating Committee had recommended that FAO and WHO organize an Expert Consultation on functional foods and noted that there was an urgent need to initiate work on functional foods in the near future (ALINORM 03/15, paras. 86-93).

7) The Committee noted that FAO and WHO were currently considering how to address this request and that the next session of the Commission would consider the requests for scientific advice put forward by Codex Committees in their respective areas of work.

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1 CX/FL 03/1

2 CX/FL 03/2, CX/FL 03/2-Add.1, CX/FL 03/2-Add.2 (comments of IBFAN)

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

COMMITTEE ON FRESH FRUITS AND VEGETABLES

8) The Committee endorsed the labelling provisions in the following Draft Standards: Sweet Cassava; Pitahaya; Oranges; and Revised Provisions for Commercial Identification in the Standards for Limes, Pummelos and Grapefruits.

COMMITTEE ON PROCESSED FRUITS AND VEGETABLES

9) The Committee endorsed the labelling provisions in the Draft Guidelines for Packing Media for Canned Fruits and in the following Draft Standards: Canned Bamboo Shoots; Canned Stone Fruits; and Aqueous Coconut Products – Coconut Cream and Coconut Milk.

COMMITTEE ON FATS AND OILS

Draft Standard for Olive Oils and Olive-Pomace Oils

10) The Delegations of Australia and New Zealand objected to the labelling section as it referred to Section 3 and the description of the products in that Section would not allow the marketing of their national production. The Committee however recalled that it was not competent to discuss technical aspects of the Draft Standard such as the description of the product, and that member countries had the possibility to submit comments at Step 8 in this respect. The Committee endorsed the labelling provisions in the Draft Standard for Olive Oils and Olive-Pomace Oils as proposed.

COMMITTEE ON FISH AND FISHERY PRODUCTS

Draft Standard for Dried Boiled Salted Anchovies

11) The Committee endorsed the labelling provisions with an amendment to Section 6.1 Name of the Food so that it would refer to the "national legislation" of the country in which the product is sold, instead of the "law and custom", in order to ensure consistency with other labelling provisions.

COMMITTEE ON MILK AND MILK PRODUCTS

Draft Standard for Cream and Prepared Creams

12) The Committee endorsed the labelling provisions and amended sections 7.1.2 and 7.2 to read "The milk fat content shall be declared *in accordance with national legislation*…" for clarification purposes.

Draft Standard for Whey Powders

13) The Committee endorsed the labelling provisions as proposed.

Draft Standard for Fermented Milks

14) The Committee discussed the provisions in section 7.1.2 concerning the use of the term "Heat Treated Fermented Milk" and noted the written comments provided by India in CRD 20 which stated that the words used are confusing and misleading for consumers. The Delegation of Spain proposed to amend the last sentence to allow the use of the term "heat-treated yoghurt" in addition to "heat treated fermented milk" in order to provide a clear description of the product. The Delegation of Mexico expressed the view that the document required further study.

15) The Delegation of Bolivia, supported by the Delegation of Indonesia, expressed the view that heat treatment was necessary when refrigeration could not be applied, especially in developing countries, and that the term "heat treated yoghurt" should therefore be allowed. The Delegation also pointed out that many developing countries had not been able to participate in the discussions of the CCMMP and that such concerns should be taken into account.

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[3] CX/FL 03/3, CX/FL 03/3-Add.1, CX/FL 03/3-Add.2, CRD 11 (comments of Germany and the Philippines), CRD 20 (comments of India), CRD 23 (IFAP)

16) The Observer from IFAP expressed the view that the current provisions did not describe the true nature of the product since "fermented milk" was too generic and that "heat treated" should therefore be followed by the specific name of the type of fermented milk, as described in section 2.1 of the Draft Standard and as stated in section 4.1.1 of the General Standard for the Labelling of Prepackaged Foods. The Observer also expressed the view that the wording in section 7.2.1 could create technical barriers to trade for developing countries.

17) Several delegations supported the current text as it reflected a compromise reached at the last session of the CCMMP following extensive discussions in earlier sessions, and as no new element had been put forward since that session. It was also pointed out that the labelling provisions were consistent with the General Standard for the Labelling of Prepackaged Foods and that the "name of the food" reflected the title of the Draft Standard, while allowing for the application of national legislation in the country of retail sale.

18) The Delegation of Ghana expressed the view that as there was no consensus, the Draft Standard should be referred back to the Committee on Milk and Milk Products.

19) The Committee endorsed the labelling provisions as proposed in the current Draft Standard for Fermented Milks. The Delegation of Bolivia expressed its objection to this decision.

COMMITTEE ON ADDITIVES AND CONTAMINANTS

Draft Revised General Standard for Irradiated Foods

20) The Committee noted the written comments of the Philippines concerning section *6.1.4 Post Irradiation Verification* to the effect that the Committee on Methods of Analysis and Sampling was the more appropriate Committee to address the issue of methods of analysis and sampling. The Secretariat indicated that the CCMAS was currently addressing this issue and had already developed methods for the detection of irradiated foods[4]. The Committee agreed that Section 6.1.4 should not be included under *Labelling* and noted that it could be included possibly under *Methods of Analysis and Sampling* or as a separate section.

21) The Committee endorsed the other labelling provisions as proposed (sections 6.1 to 6.3).

DRAFT AMENDMENT TO THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS : CLASS NAMES (Agenda item 4)[5]

22) The Committee recalled that the Draft Amendment had been returned to Step 6 to consider the appropriate percentage (30/35/50%) of the level of milk protein with the understanding that one class name "milk protein" would be retained.

23) The Chairperson proposed to apply a minimum level of 50% milk protein in dry matter as this had been proposed in many written comments and no objection to the use of this level had been expressed. The Committee agreed to use a single class name "milk protein" containing a minimum level of 50% milk protein in dry matter.

Status of the Draft Amendment to the *General Standard for the Labelling of Prepackaged Foods* : Class Names

24) The Committee agreed to forward the Draft Amendment to the *General Standard for the Labelling of Prepackaged Foods*: Class Names to the Commission for final adoption at Step 8 (see Appendix II).

DRAFT AMENDMENT TO THE GUIDELINES ON NUTRITION LABELLING (Section 3.2 Listing of Nutrients) (Agenda Item 5)[6]

25) The Committee recalled that the Draft Guidelines had been adopted at Step 5 by the 50th Session of the Executive Committee and circulated at Step 6 by CL 2002/37-FL. The Committee considered the text section by section and made the following amendments and comments.

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4 CODEX STAN 231-2001

5 ALINORM 03/22, Appendix V, CX/FL 03/4 (comments of Brazil, Spain, South Africa, European Community), CX/FL 03/4-Add.1 (Canada), CRD 3 (Indonesia), CRD 12 (Philippines), CRD 20 (India)

6 ALINORM 03/22, Appendix VI; CL 2002/37-FL; CX/FL 03/5 (comments of Australia, Brazil, Colombia, New Zealand, ICGMA, ISDC, WSRO); CX/FL 03/5-Add.1 (EC), CX/FL 03/5-Add.2 (Canada); CRD 2 (IDF); CRD 13 (Malaysia, Philippines), CRD 20 (India)

Section 3.2.1.4

26) The Committee agreed to add a reference to national dietary guidelines, in addition to national legislation, as proposed by the Delegation of Australia.

Section 3.2.2

27) The Delegation of Malaysia, supported by the Delegation of Mexico, proposed to delete the entire section listing additional nutrients for the following reasons: developing countries were still in the process of implementing the current nutrition labelling provisions, scientific data were insufficient to support the declaration of additional nutrients, and nutrition issues and consumer understanding of these issues differed widely among countries. The Delegation of Japan pointed out that the nutritional status of the population differed significantly from one country to another, and therefore the need for nutrient declaration should be left to national authorities. The Delegation of New Zealand expressed the view that this section was not necessary as additional nutrient declaration was covered in section 3.2.1.4.

28) The Delegation of the Netherlands, speaking on behalf of the Member States of the European Union present at the session, supported the additional declaration of the nutrients listed in section 3.2.2 as it would provide essential information for consumers. This position was supported by other delegations. The Observer from IACFO supported the extension of nutrition labelling irrespective of whether or not a marketing claim was made, especially for those nutrients that were relevant from the point of view of public health, as mentioned in the report of the Joint FAO/WHO Expert Consultation on *Diet, Nutrition and the Prevention of Chronic Diseases*. The Observer noted that in recent years, several countries have established such mandatory programmes.

29) The Observers from ISDC and ICGMA expressed the view that products with a fat content of zero should not have to declare the different types of fatty acids as zero because this did not provide meaningful information for consumers and would create practical difficulties for the industry due to the limited label space available. The Observer from WSRO expressed the view that the declaration of sugars should not be required as this was not supported by scientific evidence and contradicted the first *Statement of Principle*.

30) Following further discussion the Committee considered a revised text proposed by a small drafting group led by the Delegation of Canada. The revised section 3.2.2 addressed voluntary declaration of a specific nutrient, in addition to those listed in section 3.2.1, and section 3.2.3 covered nutrient declaration when a health or nutrition claim was made. These two sections replaced the current sections 3.2.2 to 3.2.2.3 and did not refer to specific nutrients.

31) The Committee noted a proposal to merge sections 3.2.2 and 3.2.3 in order to simplify the text but agreed that they addressed different aspects of nutrient declaration and should be retained as proposed. The Delegation of the United States questioned the need for section 3.2.2 as it appeared to duplicate the provisions of section 3.2.1.4. The Delegation of Canada indicated that section 3.2.1.4 concerned the declaration of an additional nutrient (in addition to the core nutrients), while section 3.2.2 specified how national legislation could trigger the declaration of relevant nutrients when a voluntary declaration was made.

32) The Committee agreed on the revised sections 3.2.2 and 3.2.3 with some amendments for clarification purposes and the following sections were renumbered accordingly.

Section 3.2.3 (now 3.2.4)

33) The Committee agreed to retain the current text of the Guidelines concerning the declaration of carbohydrates. The reference to dietary fibre was reintroduced in the text as it was no longer covered by other sections.

Section 3.2.4 (now 3.2.5)

34) Several delegations expressed their concerns with the proposal to replace the declaration of polyunsaturated fatty acids with a declaration of n-6 and n-3 polyunsaturated fatty acids and the Committee agreed to delete this sentence. The Committee agreed that the declaration of monounsaturated fatty acids, polyunsaturated fatty acids and cholesterol should be included and reordered the section to simplify the text.

35) The Committee had an extensive discussion on the declaration of trans-fatty acids. Several delegations proposed to delete the declaration of trans-fatty acids because the scientific basis for the declaration of trans-fatty acids was insufficient, a distinction should be established between different types of trans-fatty acids and their declaration was not meaningful for consumers. Other delegations and the Observers from the EC

and Consumers International pointed out that the declaration of trans-fatty acids was relevant for consumers and that substantial scientific evidence demonstrated their relationship with cardio-vascular diseases. Some delegations proposed to include a definition of trans fatty acids for the purposes of nutrient declaration and the Delegation of Canada proposed to include a footnote referring to "non-conjugated fatty acids". As it was not possible to reach a final conclusion at this stage, the Committee agreed that the declaration of trans-fatty acids should be left to national legislation and amended the text accordingly. The Committee also asked the Committee on Nutrition and Foods for Special Dietary Uses to provide a definition of trans-fatty acids for the purposes of the Guidelines and agreed to consider this question further when such advice became available.

Section 3.2.6 (now 3.2.7)

36) The Delegation of the Netherlands, speaking on behalf of the Member States of the European Union present at the session, proposed to set a minimum of 15% of the Nutrient Reference Value (NRV) for the declaration of vitamins and minerals as this would be consistent with the value for "source" in the *Guidelines for Use of Nutrition Claims*.

37) The Delegation of Brazil, supported by other delegations, pointed out that the section did not refer to claims but to a minimum level that would allow the declaration of vitamins and minerals on the label, and therefore the current value of 5% was appropriate. As a compromise, some delegations proposed to retain the value of 5% for liquids, but to increase the level to 10% for solids.

38) The Delegation of New Zealand, supported by some delegations, proposed to delete the reference to 100g or 100 ml and to retain only the reference to serving. The Committee noted that the current text reflected the differences in the references used at the national level by member countries.

39) The Committee could not come to a conclusion on these proposals and agreed to retain the current text of section 3.2.6 of the working document under consideration[7] at this stage. It also agreed to ask the Committee on Nutrition and Foods for Special Dietary Uses to clarify what is meant by "a significant amount" from the nutritional point of view and in particular what percentage of the NRV for vitamins and minerals should be required to allow nutrient declaration of vitamins and minerals. The CCNFSDU was also asked to consider whether the declaration should be made per serving or per 100g or 100 ml or both.

Section 3.4.7

40) The Committee agreed that the format for the declaration of fat should refer to "Total fat"; to correct the listing of nutrients; and to add "cholesterol", in conformity with the decisions made in section 3.2 concerning fat declaration.

Status of the Draft Amendment to the Guidelines on Nutrition Labelling (Section 3.2 Listing of Nutrients)

41) The Committee agreed to advance the Draft Amendment to Step 8 for adoption by the 26th Session of the Codex Alimentarius Commission (see Appendix III).

42) The Representative of WHO informed the Committee of the official launching of the Report of the Joint WHO/FAO Expert Consultation on *Diet, Nutrition and the Prevention of Chronic Diseases*[8]. The ranges of population nutrient intake goals (expressed in % of total energy) that are recommended by the Expert Consultation include: 15 - 30 % from fat while limiting saturated fatty acids to less than 10 %; 55 - 75 % from total carbohydrates, but free sugars should remain less than 10 %; and 10 – 15% from protein; salt, which should be iodised, should be restricted to less than 5 g/day, while the intake of fruit and vegetables should be at least 400 g/day.

43) The WHO Representative further noted that this Report serves as part of the scientific base for developing the Global Strategy on Diet, Physical Activity and Health, which will be finalized and submitted to the WHO Executive Board in January 2004, for addressing the global public health problems of chronic diseases. The strategic recommendations articulated in the Report would play a major role in placing diets and nutrition at the forefront of public health programmes and policies. Therefore, the work of CCFL in strengthening the guidelines on nutrition labelling, as well as the guidelines on nutrition and health claims, would be important instruments for implementing these global recommendations.

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7 ALINORM 03/22, Appendix VI

8 (http://www.who.int/nut/documents/trs_916.pdf or http://www.who.int/hpr/nutrition/ExpertConsultationGE.htm)

DRAFT GUIDELINES FOR USE OF NUTRITION AND HEALTH CLAIMS (Agenda Item 6)[9]

44) The Committee recalled that the Draft Guidelines had been adopted at Step 5 by the 50th Session of the Executive Committee and circulated at Step 6 in CL 2002/37-FL.

45) The Chair of the Working group that had met prior to the Session, Mrs Christina Zehaluk (Canada) presented the redrafted text and the main changes introduced following detailed discussion in the Working Group. It was noted that the Working Group had considered all written comments submitted, including those of the delegations that were not present at the session. The Committee considered the text section by section and made the following amendments and comments.

PREAMBLE

46) As proposed by the Working Group, the Committee agreed to delete the square brackets around the text in the second boxed preamble on health claims. It was also agreed that the impact of health claims on consumers' eating behaviours and dietary patterns should be monitored "in general, by competent authorities".

SCOPE

47) Many delegations supported the addition of the reference to advertising at the end of paragraph 1.1, as it was complementary to labelling and was important to protect consumers against misleading claims. These delegations considered this addition appropriate in view of the fact that the terms of reference of the Committee include a reference to advertisement and the term " labelling" only include advertisement at the point of sale of the food. Some delegations also pointed out that in some cases consumer deception was more likely to originate from advertising than from labelling itself. In view of the large support for this proposal, the Committee agreed to include a reference to advertising at the end of paragraph 1.1.

48) The Delegation of the United States objected to this decision as it fundamentally changed and significantly broadened the Scope of the Codex text on nutrition claims, whereas the mandate given to the Committee was only to incorporate provisions on health claims into the current text. This position was supported by the Delegation of Japan and the Observers from ICGMA and CropLife International. The Observer from ICGMA pointed out that the Terms of Reference of the Committee were limited to "study problems associated with the advertisement of food".

49) In paragraph 1.4, the Committee had an extensive discussion on the exclusion of health and nutrition claims for foods for infants and young children and noted that the text proposed by the Working Group was as follows: "*1.4 Nutrition and health claims ~~are not~~ shall only be permitted for foods for infants and young children ~~unless~~ where specifically provided for in relevant Codex standards*." The Delegation of Japan, supported by several delegations, proposed to amend the text to reflect that nutrition and health claims may be allowed by national legislation.

50) The Observer from IBFAN, supported by other observers, pointed out that WHA Resolution 54.2 on Infant and Young Child Nutrition urges Member States to "encourage the Codex Alimentarius Commission to take the International Code and relevant subsequent Health Assembly resolutions into consideration in developing its standards and guidelines" and that the current Guidelines should be consistent with the Resolution. For this purpose, according to IBFAN, nutrition and health claims should be generally prohibited in foods for infants and young children.

51) The Observer from IACFO sought clarification on whether there was consistency in this respect between the current standard and other Codex standards or the WHO Code of Marketing of Breast-Milk Substitutes. The Secretariat indicated that the Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) was currently in the process of revising two standards for foods for infants and children and was considering how to take into account the WHA Resolutions in the process, in view of the proposals of member countries in this respect. No provisions for nutrition or health claims were included in the Codex Standards for foods for infants and young children and no proposal had been made to include specific health or nutrition claims for individual nutrients.

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9 ALINORM 03/22, Appendix VII, CX/FL 03/6 (comments of Australia, Brazil, Columbia, Denmark, New Zealand, United Kingdom, CIAA, ICGMA, IDACE, ILSI, ISDC, ISDI); CX/FL 03/6-Add.1 (Canada, Norway, IBFAN); CRD 6 (South Africa, EFLA); CRD 14 (Malaysia, Philippines); CRD 20 (India); CRD 22 (Report of the Working Group).

52) The Delegation of Switzerland proposed that the CCNFSDU should revise the *Standard for Canned Baby Foods* and the *Standard for Follow-up Formula* in order to include provisions for either nutrition or health claims.

53) After some discussion, the Committee agreed to reword the text as follows: "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".

54) The Observer from the EC supported the proposal made by the delegation of Sweden in the Working Group to include a new section that would prohibit health claims for beverages with more that 1.2% alcohol by volume. However, it was considered that the principle was sufficiently addressed in section 7.2.

DEFINITIONS

55) The Committee agreed that section 2.1.2 should refer to "Nutrient comparative claim" for clarification purposes, as proposed by the Delegation of Japan.

56) In the examples under 2.2.1 Nutrient Function Claim, "a good/excellent source" was replaced with "a source of/ high in" as this was consistent with the terms used in the Table of Condition for Nutrient Contents.

57) In section 2.2 Health Claims, the Committee agreed to retain only the first sentence as a definition. As the second part of the section, as proposed by the Working Group and revised by the Committee, described how the health claim should be presented, it was transferred to section 7.1.1 under 7. Health Claims, as proposed by the Delegation of Australia.

58) The Committee had an extensive debate on section 2.2.2 Other Function Claims. Some delegations proposed to delete this section as the reference to constituents other than nutrients created confusion, and may be interpreted as allowing medicinal claims. Other delegations pointed out that the current text would exclude claims for nutrients relating to enhanced functions. After some further discussion, the Committee agreed on a revised text proposed by the Delegation of Canada in cooperation with other delegations and observers, referring to "..beneficial effects of food or their constituents, in the context of the total diet, on normal functions or biological activities of the body".

59) In the Examples under section 2.2.3 Reduction of Disease Risk Claims, it was agreed to refer to "nutrient or substance" in all examples.

SECTION 7. HEALTH CLAIMS

60) In section 7.1.2, the Observer from IACFO proposed to include a specific prohibition of product-specific claim to reflect the consensus of the Working Group that section 7.1.2 already permits governments to prohibit such claims. The Observer from IADSA proposed to delete the entire section as it was redundant with the Preamble. The Committee however retained the current text.

61) The Committee agreed that section 7.1.4 should apply to constituents for which a Nutrient Reference Value (NRV) is established and amended the text accordingly, as proposed by the Delegation of Denmark. An editorial amendment was also made to ensure consistency throughout the text.

62) The Observer from IACFO also proposed to include the concept of pre-market approval of health claims. Several delegations however pointed out that this was not necessary because the section clearly specified that health claims "must be accepted by or be acceptable to the competent authorities".

63) The Committee made some editorial amendments to sections 7.4.2, 7.4.3 and 7.4.6 in order to avoid repetition.

64) In section 7.4.3, the Committee agreed to retain the reference to "other dietary sources" proposed by the Working Group without square brackets as this was an important nutritional information. The Observers from ISDI and ICGMA requested that this provision be deleted as it would create practical difficulties for manufacturers without providing useful information to consumers.

65) The Delegation of New Zealand noted that the terminology of the document should reflect the fact that these are Guidelines and therefore "must" should be replaced by "should" throughout the text.

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

66) The Committee agreed to advance the Draft Guidelines, as amended at the current session, to Step 8 for adoption by the 26th Session of the Codex Alimentarius Commission (see Appendix IV).

67) The Committee expressed its appreciation to Mrs Zehaluk and to the Working Group for their excellent work in addressing complex issues, that had allowed the Committee to finalize the revision of the Guidelines.

68) While discussing the current amendments, the delegations of South Africa and Mexico made some proposals to amend the adopted sections on nutrition claims. However, the Committee noted that its mandate was limited to the consideration of provisions on health claims and consequential amendments throughout the text. It was noted that any proposal for amendment of the current Guidelines (other than health claims) could be brought forward for consideration as new work by the next session of the Committee.

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 7a)[10]

PROPOSED DRAFT GUIDELINES FOR THE LABELLING OF FOODS AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING: LABELLING PROVISIONS (Agenda Item 7b)[11]

69) The Committee recalled that the 30th Session of the Committee had extensive discussions on this agenda item, however, the Committee had returned the Draft Definitions to Step 6 and the Proposed Draft Guidelines to Step 3 for further comments and discussion in this session due to lack of consensus.

70) The Chair, recalling the history of the discussions on this agenda by the Committee for a long time, proposed to establish a Group of "Friends of the Chair" as an intersessional mechanism to break through the difficulty the Committee had been facing, in order to develop options to manage the issue for consideration by all Committee members at the next session. The Chair expressed the view that the Group would better function with a smaller number of participants than the full Committee. The Chair also referred to the importance of the transparency and participation in a balanced geographical representation, and between developed and developing countries.

71) The Committee supported this proposal and many delegations expressed their willingness to participate in this Group. These delegations and observers pointed out that transparency in the process, appropriate composition as regards participants, clear mandate for this Group and attention to the interests of developing countries were very important elements to take into account and also essential factors for a successful conclusion of this Group. Some delegations requested to distribute to all members of the Committee the summary of the discussion of the Group in order to ensure transparency. Regarding the inclusiveness, the Committee recognized that differing views were voiced such as that participation should be open to all members or that the Group should be limited to a smaller number of participants.

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10 ALINORM 03/22, Appendix III, CX/FL 03/7 (comments of Brazil, CI), CX/FL 03/7-Add.1(IBFAN), CRD 15 (Philippines)

11 ALINORM 03/22, Appendix IV, CX/FL 03/8 (comments of Brazil, South Africa, CI), CX/FL 03/8-Add.1 (discussion paper by Canada), CX/FL 03/8-Add.2 (IBFAN), CRD1 (EUROPABIO), CRD4 (Indonesia), CRD 9 (South Africa, CI), CRD16 (Philippines), CRD 20 (India)

72) In this context, the delegation of Norway recalled that the mandate given to the Committee by the Codex Alimentarius Commission in 1991 "to provide guidance on how the fact that a food derived from "modern biotechnologies" could be made known to the consumers" still holds (Paragraph 90 ALINORM 91/41) and expressed its expectation that the Committee and the Group under discussion would pay attention to this aspect in their future work. The Delegation also made a comment on CX/FL 03/8-Add.1 presented by Canada in relation to the Extraordinary Session of the Commission held in February 2003 on the priority for Codex that was mentioned in the Recommendations from the Codex Evaluation. The Delegation indicated that although the Commission emphasized the priority of the development of standards having an impact on consumer health and safety, this did not imply that Codex should not take fair practices into account when establishing standards.

73) The Committee agreed to establish a Working Group composed of the following member countries based on their interest to participate; Argentina, Australia, Barbados, Bolivia, Brazil, Canada, China, Egypt, France, India, Indonesia, Japan, Kenya, Korea, Mexico, Netherlands, New Zealand, Norway, Sweden, Switzerland, South Africa, United States, European Community. The Committee also agreed that the mandate of this Group would be to develop options for management of this agenda item and that the summary of the discussions by the Group as well as the proposals submitted to this Group would be circulated to all Codex members. The Chair invited interested countries to submit proposals to the Canadian Secretariat and indicated that the Group could meet between the sessions as required, the exact arrangement to be determined by the host country.

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

74) The Committee, bearing in mind the above decision, agreed to retain the Draft Definitions and the Proposed Draft Guidelines at Step 7 and 4 respectively for further discussions in the next session of the Committee.

GUIDELINES FOR THE PRODUCTION, PROCESSING, LABELLING AND MARKETING OF ORGANICALLY PRODUCED FOODS: A) DRAFT REVISED SECTION 5 - CRITERIA (Agenda Item 8a)[12]

75) The Committee recalled that the 50th Session of the Executive Committee had adopted at Step 5 the Draft Revised Criteria, that were subsequently circulated for comments at Step 6 in CL 2002/37-FL.

76) The Chair of the Working Group held prior to the session, Ms Ruth Lovisolo (Canada) presented the outcome of the discussions on Section 5 and Annex 2 (see also Agenda Item 8b). As regards Section 5, the Working Group had considered the written comments and had focused on the sections that remained in square brackets for further discussion.

77) The Working Group considered a proposal for the competent authority to compile a list of related regulations and make them available to all interested parties and stakeholders. It was noted that such transparency requirements had already been accommodated in the Codex texts on food import and export inspection and certification[13]. It was agreed to add a clause at the end of 5.1 first paragraph to read "and make them available to other countries upon request".

78) Following the discussions of the last session, the Working Group considered how to clarify the reference to "exceptional circumstances" to allow chemical extraction processes. It was agreed that recourse to chemical processes should occur only when substances from other processes had been exhausted and only for the extraction of carriers and binders and the text was amended accordingly. It was also noted, in this context, that there was a need to address the non-active portion of fertilizers and that, although the proposed revised text went some way in offering a solution, a similar issue would arise when considering specific substances for inclusion in Table 1 of Annex 2 of the Guidelines. It was agreed that this should be an interim measure and subject to future review and, hence, a footnote was added to this effect.

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12 ALINORM 03/22, Appendix II, CL 2002/37-FL; CX/FL 03/9 (comments of New Zealand, European Community); CX/FL 03/9-Add.1 (Canada, IACFO), CRD 17 (Philippines), CRD 21 (India), CRD 24 (Report of the Working Group)

13 CAC/GL 20-1995, para 14.

79) The Committee concurred with the above recommendations and recognized the essential importance of the revised criteria in order to evaluate substances in the Codex lists and for countries to develop their national lists, and generally to ensure the authenticity of organically produced foods.

Status of the Draft Revised Section 5 – Criteria in the *Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods*

80) The Committee agreed to advance the Draft Revised Section 5 – Criteria to Step 8 for adoption by the 26th Session of the Codex Alimentarius Commission (see Appendix V).

GUIDELINES FOR THE PRODUCTION, PROCESSING, LABELLING AND MARKETING OF ORGANICALLY PRODUCED FOODS: B) PROPOSED DRAFT REVISED SECTION: ANNEX 2 – PERMITTED SUBSTANCES (Agenda Item 8b)[14]

81) The Committee recalled that its last session had considered the Proposed Draft Revised Annex 2 and agreed to re-circulate it at Step 3 inviting submissions for amendments together with justification against the current criteria and taking into account the intent of the draft revised criteria. It had been agreed that an electronic drafting group would consider the comments and proposals submitted and propose a revised version of Annex 2.

82) The Chair of the Working Group held prior to the session, Ms Ruth Lovisolo (Canada), presented the outcome of the discussions on the revised Annex 2 as presented in CL 2003/9-FL.

General Issues

83) As regards the nature of the lists, the Working Group had recalled that countries should develop their own lists according to their national requirements taking into account the Codex criteria. It was stressed that the criteria had primacy over the indicative lists whilst recognising the value of the lists in providing guidance to member countries, especially developing countries. It was further noted that it had not been the intention for the Working Group to become a technical assessment committee, hence, the amendments proposed to the lists had to be justified against the criteria.

84) The Delegation of the United States recalled earlier discussions concerning the need for the lists and recognized that the development of indicative lists was important for several countries. However, the Delegation pointed out that it was not the role of the Committee or the Working Group to carry out technical assessment or review of the submissions put forward for new substances.

85) The Observer from IFOAM expressed its appreciation of the considerable work accomplished by the Working Group in the elaboration of the criteria and stressed that the lists should remain restricted in order not to deceive consumers of organic foods. In particular, traditional and innovative alternatives to the generalized use of additives should be considered. The Observer recommended that the future review process be developed with the assistance of the private sector, in view of its experience with the technical assessment of such substances, and proposed to discuss the management of the review process in the Working Group at the next session. The Observer from CI supported retaining indicative lists but noted that they should not be too extensive in order to ensure the authenticity of the "organic" claim.

86) It was recalled that a matrix had been developed in the electronic working group in order to allow the presentation of technical justification for new substances in a consistent manner and the Committee noted that this was only provided for information purposes and to facilitate the decision process but that the matrix was not intended to become a part of the Guidelines.

87) The Working Group had agreed that proposals for inclusion of new substances in the lists should not be addressed if they had not been accompanied with justification against the Criteria. The substances proposed were considered in detail and the following amendments were proposed.

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[14] ALINORM 03/22, Appendix VIII, CL 2002/15-FL; CL 2002/50-FL; CL 2003/9-FL; CX/FL 03/10 (comments of Australia, Canada, Denmark, New Zealand, Poland, European Community, IFOAM); CX/FL 03/10-Add.1 (Switzerland), CRD 5 (Indonesia), CRD 21 (India); CRD 24 (Report of the Working Group)

Table 1: Substances for Use in Soil Fertilizing and Conditioning

88) It was agreed that eight additions and/or clarifications should be retained in the proposed revised draft. It was noted that some proposals, such as plant extracts and biodynamic preparations, were already covered in other parts of the Guidelines. It was noted that the proposal of Chile to include sodium nitrate had not been supported by justification against the Criteria, and it was agreed that Chile would present such justification for consideration at the next session of the Committee on Food Labelling.

89) It was also agreed that, as a general rule, time limits or maximum permitted levels should not be set for any of the substances or their components as it was considered to not be sufficiently specific for all situations and/or too detailed for indicative lists.

Table 2: Substances for Plant Pest and Disease Control

90) The Working Group had considered 16 proposals against Table 2 which resulted in the incorporation of a number of new entries, clarifications to the conditions for use, and proposed deletions from the list. Some proposals such as 'repellants of plant and animal origins' were not included in the Table 2 as they were too general in nature and already addressed in other parts of the Guidelines.

91) As regards 'inorganic compounds', it was recognized that copper accumulation in the soil had become a world-wide concern and it was therefore required that accumulation from copper-based substances and other heavy metals in the soil should be minimized.

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

92) It had been difficult to reach consensus in the Working Group on the proposals put forward for additives due to variations in national regulations and traditional practices. Some delegations and the Observer from IFOAM were strongly opposed to the use of all phosphates in processed organic products. In addition, all of the nitrates (250 Sodium nitrite, 252 Potassium nitrate, etc) were placed in square brackets together with a proposed condition restricting their use to instances where no alternative technology exists to ensure the safety of livestock products. Since the use of nitrates is tied to the use of ascorbates, it was agreed that the ascorbates 301, 302, and 303 would be also placed in square brackets pending a decision on the role of nitrates in certain organically produced foods.

93) It was further agreed that the substance list for livestock products should be appended to the main table, as this was the intent of the original drafting of the second part of the Table.

94) The Delegation of Sweden expressed the view that the additives should be submitted to the Committee on Food Additives and Contaminants (CCFAC) for endorsement. The Committee however noted that this was not required as all the additives under consideration and in the current Guidelines had been evaluated by JECFA and levels of use had been established or endorsed by the CCFAC in a number of foods. The responsibility of the Committee on Food labelling was to decide whether these additives were acceptable in the framework of an organic system.

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

95) Following extensive discussions on the substances that were listed as processing aids but also had functions as additives, the current listings were retained although, technically speaking, some substances could be listed in both Tables. Following the earlier decision in respect of Table 3, the processing aids for livestock and bee products were appended to the body of the main Table.

Status of the Tables

96) The Committee noted that there had been consensus in the Working Group to advance Tables 1 and 2 to Step 5, while a number of substances in Tables 3 and 4 still required further consideration. The Committee discussed whether all Tables should be advanced to Step 5, with a view to their finalization at the next session.

97) The Delegation of France recalled that there had been no time to discuss the substances in Tables 3 and 4 in detail in the Working Group and that they were initially intended to be retained at Step 3, since detailed discussion was still required on several substances, especially additives. The Delegation was not opposed the advancement of Tables 3 and 4 to Step 5, provided member countries had the opportunity to comment on all substances and not only on those in square brackets. The Committee noted that following the adoption of the Proposed Draft Amendment at Step 5, the entire revised Annex 2 would be circulated and open to comments from member countries and international organizations on all substances included in the lists and the structure of the Table.

Status of the Proposed Draft Revised Annex 2 – Permitted Substances in the *Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods*

98) The Committee agreed to advance the Proposed Draft Revised Annex 2 – Permitted Substances for adoption to Step 5 by the 26th Session of the Codex Alimentarius Commission (see Appendix VI).

99) The Committee expressed its thanks to Ms. Lovisolo and to the Working Group for their excellent work and constructive approach to complex issues, that had allowed the finalisation of the criteria and substantial progress on the revision of the list.

100) The Committee agreed that the Working Group would be reconvened prior to the 32nd Session of CCFL to consider and make further recommendations on the elaboration of the Tables and matters pertaining to the Tables.

PROPOSED DRAFT AMENDMENT TO THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS: QUANTITATIVE DECLARATION OF INGREDIENTS (Agenda Item 9)[15]

101) The Committee recalled that the Proposed Draft Amendment to the General Standard for the Labelling of Prepackaged Foods on Quantitative Declaration of Ingredients (QUID) had been returned to Step 3 for redrafting by a Working Group coordinated by the United Kingdom. The Committee noted that written comments had been provided by Costa Rica, Czech Republic and Philippines that were not present at the meeting.

102) In reply to a question from the Delegation of India, the Committee recalled that the title of section 5.1 *Additional Mandatory Requirements* was not open for discussion and covered other labelling provisions in the *General Standard for the Labelling of Prepackaged Foods*. Only section 5.1 *Quantitative Labelling of Ingredients* was open for discussion as a Proposed Draft Amendment to the *General Standard*.

103) Many delegations and Observer organizations did not support the QUID proposal for the following reasons: it was already possible to provide important and useful information to consumers in accordance with the present Codex *General Standard for the Labelling of Prepackaged Foods* and Codex *Guidelines on Nutrition Labelling*; QUID could impose an economic burden on both industry and consumers; it could breach the intellectual property rights of manufacturers without any health or safety benefit to the consumers; and it would create unnecessary barriers to trade. It was also stressed that QUID declaration would be difficult to enforce in practice without adequate methodology. Some delegations also pointed out that QUID could be applied for specific cases when it was necessary for a clear product description.

104) Many other delegations and Observer organizations supported the proposed draft amendment to expand QUID and expressed their view that QUID would be useful for both aspects of Codex's mandate as protecting the health of the consumer and ensuring fair practices in the food trade, that QUID would be helpful for consumer's choice and especially in view of the increased interest in nutritional information. The Observer from the European Food Law Association also stated that there had been no legal problem to apply QUID in the European Union.

105) The Committee considered the Proposed Draft Amendment attached as Annex 1 of document CX/FL 03/11 and made the following amendments.

106) Many delegations and observer organizations supported section 5.1.1 (a). Some delegations proposed to refer to the "quantity" or "presence" of an ingredient but the Committee agreed to retain the current text after some debate. The Delegation of Mexico expressed its concern with the expression "any

[15] CX/FL 03/11, CX/FL 03/11 Add 1 (comments of Australia, Canada, Costa Rica, Czech Republic, European Community, CIAA, IACFO, IBFAN, ICGMA, ISDC), CRD 7 (comments of South Africa), CRD 18 (comments of Philippines), CRD 20 (comments of India)

ingredient that is emphasized on the label through words or pictures" as it considered that this was confusing and open to various interpretations.

107) The Delegation of Canada supported by some delegations proposed to delete section 5.1.1(b),(c),(d) as these provisions are vague and open to interpretation. The Delegation of Japan also proposed to delete sections 5.1.1 b) and d). However, some delegations and observers proposed to retain these provisions because they addressed the indirect emphasis on ingredients on the label. The Delegation of Belgium proposed to delete section 5.1.1 f). The Committee agreed to retain these sections in square brackets. The Committee also agreed to refer to "the common or trade name of the food" in section 5.1.1 (e) as proposed by the Delegation of Canada.

108) The Delegation of Japan proposed to add square brackets to the new section 5.1.1.(g) and (h) (now section 5.1.1(h) and (i)) stating that there was no basis for the figure of "2%". The Committee agreed to place in square brackets new section 5.1.1(h) and "2%" in new section 5.1.1 (i).

109) In section 5.1.2, the Committee agreed to place in square brackets "as a numerical percentage rounded to the nearest percentage point" and deleted the end of the sentence, as the numerical percentage would now be rounded to the nearest percentage point in all cases.

110) Some delegations proposed to delete sub-sections 5.1.2 (a) and (b) as it was not necessary to declare the minimum and maximum percentages. The Committee did not come to a conclusion on this question and agreed to retain both sub-sections in square brackets for further discussion. The Committee agreed to retain 5.1.2 (c) and to replace the "approximate percentage" with an "average percentage" as this was more accurate.

111) The Committee agreed to delete Section 5.1.3 with the understanding that section 5.1.3 (a) was already covered by section 5.1.1 (a) and that section 5.1.3 (b) would be moved to section 5.1.1 as a new sub-section (g). The Delegation of Belgium and the Observer from IACFO pointed out that merging these two sections would not be appropriate because section 5.1.3 referred to the location of the declaration while 5.1.2 referred to the percentage declared.

112) The Committee agreed to move the last sentence from section 5.1.3 to become the second sentence of section 5.1.2, with some amendments for clarification purposes. The Committee discussed the need to declare QUID information in proximity to the word or images emphasizing an ingredient or in the list of ingredients. Some delegations supported the declaration in the list of ingredients in order to prevent duplication and confusion for consumers. The Observer from IACFO stressed the need for additional quantitative declarations in conjunction with the presence of ingredients related to health such as fruits and vegetables and whole grains, or any emphasis on the presence of a specific ingredient. The Committee agreed to retain the relevant provisions in square brackets for further consideration.

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

113) The Committee, recognizing that the text still required further consideration of substantial issues, agreed to return the Proposed Draft Amendment as revised at the current session to Step 3 for further comments and consideration at the next session (see Appendix VII).

DISCUSSION PAPER ON COUNTRY OF ORIGIN LABELLING (Agenda Item 10)[16]

114) The Committee recalled that the 49th (Extraordinary) Session of the Executive Committee had not approved new work on an amendment to the General Standard for the Labelling of Prepackaged Foods in relation to provisions for labelling of country of origin but suggested that further discussion on the need for such an amendment was appropriate. The Committee at its last session had had an extensive discussion based on the paper prepared by the Secretariat including the initial proposal by the United Kingdom, however, the views of the delegations and observers were widely divergent. The Committee had therefore decided to circulate the paper prepared by the Secretariat for further comments and discussion at this session.

[16] CL 2002/25-FL, CX/FL 03/12(comments of Brazil, Costa Rica, Denmark, France, Italy, New Zealand, Spain, United States, CIAA, European Community), CX/FL 03/12-Add.1 (Canada, IBFAN), CRD 10 (South Africa), CRD 19 (Paraguay)

115) Many delegations and the Observers from CI and IACFO supported continuation of the work on country of origin labelling since this would provide useful information for consumers and the current provisions were too general and required clarification. These delegations and observers stressed the importance to respond to increasing consumers' demand for more information on country of origin. The Delegation of Norway, supported by the Delegation of Switzerland, pointed out that section 4.5.3 of the *General Standard* might result in a labelling of country of origin that might mislead the consumer.

116) However, many other delegations and the observers from IFFA and ICGMA opposed further work by the Committee. These delegations and observers expressed the view that the current provision in section 4.5.1 of the *General Standard for the Labelling of Prepackaged Foods* 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 provision. They expressed concern that the work in the Committee would duplicate the difficult and complicated work currently undertaken by WTO and WCO on the rules of origin, and that the expanded labelling for country of origin would not comply with the TBT Agreement by creating unnecessary trade barriers especially for developing countries. The Delegation of Bolivia indicated that the inclusion of this subject could have legal implications in the WTO. It was also pointed out that country of origin labelling would entail significant cost implications for industries and country of origin labelling requirement for ingredients would create practical difficulties for food manufactures due to the diversified and varying origins from which they purchase ingredients.

117) In response to those concerns, some delegations stated that the purpose of the work underway in WTO had been addressing tariff issues that were different from the issues dealt with in Codex, and the absence of detailed harmonised provisions in Codex on country of origin could be a source of trade barriers.

118) The delegation of India, referring to the current work conducted in the Committee on Fresh Fruits and Vegetables and the Committee on Milk and Milk Products, suggested that the existing provisions of the *General Standard* should be retained.

119) The Committee agreed not to continue work since there was no consensus and decided to report the discussion held in this session to the Codex Alimentarius Commission.

CONSIDERATION OF FOOD LABELLING AND TRACEABILITY (Agenda Item 11)[17]

120) The Committee recalled that its last session had had an extensive discussion on whether or not and if so how the Committee would proceed with work on traceability under the Agenda Item *Matters Referred from the Commission and other Codex Committees,* based on a background document papered by Canada presenting current discussions in various Codex Committees. As no consensus had been reached in the session, the Committee had decided to discuss this item further in the current session.

121) The Committee was updated on discussions of traceability/product tracing underway in various Codex Committees. The Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) at its 10th Session decided to establish a Woking Group on traceability/product tracing. CCFICS at its 11th Session considered the outcome of the Working Group that was held in August 2002. The 18th Session of the Committee on General Principles (CCGP) in April 2003 agreed to develop a definition of traceability/product tracing for consideration at its next session and for this purpose an electronic Woking Group was established. The 4th Session of the Codex *Ad Hoc* Intergovernmental Task Force on Foods Derived from Biotechnology held in March 2003 also conducted an open discussion on traceability.

122) Many delegations, while acknowledging the importance of traceability/product tracing in the context of food labelling, expressed the view that new work at this stage was premature and the Committee should wait for the outcome of the work undertaken by the other committees, especially CCGP to provide a definition, in order to ensure a coordinated and systematic approach to this issue. The Delegation of South Africa expressed the view that the CCGP should provide general guidance in addition to providing a definition. It was also stated that the present labelling provisions could well assure accurate labelling and the introduction of traceability/product tracing would entail additional imposition of costs on producers and manufacturers, especially in developing countries. The Delegation of Bolivia proposed to change the title of the item to "traceability/product tracing" as this was the wording used in other Codex Committees.

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17 CL 2002/24-FL, CX/FL 03/13 (comments of Brazil, Spain, CIAA, CI), CX/FL 03/3-Add.1 (Canada, European Community), CRD 8 (South Africa)

123) Some delegations expressed the view that product tracing should be used as a risk management tool to ensure food safety where necessary but that its application to ensure authenticity of labelling should not be generalized. Some delegations pointed out that traceability systems should be clearly distinguished from identity preservation systems that were driven by the market demand.

124) Many other delegations and the Observer from CI supported initiation of work by the Committee since traceability/product tracing was an important measure not only for risk management but also for ensuring authenticity of the food labelling. These delegations stressed the importance of traceability/ product tracing in facilitating fair practices in trade by protecting consumers from deceptive practices. The view was also expressed that traceability/product tracing was an important feature in quality production systems such as organic products and could alleviate the burden and cost of verification on the end products. In relation to the work conducted by the other Committees, several delegations pointed out that the work by the Committee would facilitate and assist the general debate conducted by CCGP and CCFICS through inputs from this Committee. The Delegation of Switzerland informed the Committee of the progress of the work undertaken by the Working Group of the CCFICS on traceability/product tracing. The Working Group had identified three elements which could be relevant to traceability/product tracing: 1) product identification; 2) product information (one step back and one step forward); and 3) the linkages between product identification and product information. The Committee was informed that the work in CCFICS had been in progress with the acknowledgement by that Committee that the CCGP was responsible for the development of the Codex definition for traceability/product tracing.

125) The Committee agreed to continue the discussion on traceability/product tracing at the next session taking into account the progress made by other Committees.

DISCUSSION PAPER ON MISLEADING CLAIMS (Agenda Item 12)[18]

126) The Committee recalled that its last session had considered a document prepared by the United States on misleading food labelling and had agreed that the Delegation of Australia, with the assistance of a drafting group, would prepare a discussion paper examining concrete examples and proposing a set of principles to address this issue. The Delegation of Australia indicated that the discussion paper reviewed case studies presented by several countries and listed the Codex texts addressing misleading labelling. However, no specific proposal was put forward at this stage and this issue would require further consideration.

127) Some delegations supported further work with a view to developing overarching principles that would cover misleading claims or labelling. Several delegations noted that it might be premature to define principles at this stage but supported further consideration of this complex issue in order to develop options to address the problem of misleading labelling.

128) Several delegations and observers pointed out that the concept of "misleading" evolved with time and differed according to the country or the group of consumers concerned, and therefore it would not be possible to develop general principles in this area. They expressed the view that the problems associated with "truthful but misleading" labelling should be considered on a case-by-case basis for individual products. Some delegations pointed out that current Codex labelling texts provided clear principles concerning the prevention of misleading claims and that they should be reflected in specific standards. In addition, some delegations expressed the view that the existence of misleading labels on the market was an enforcement problem and did not warrant a review of current labelling texts.

129) The Committee recognized that there was no consensus on the need for further work in this area but agreed with the proposal of the Chair to discuss it further at the next session, in order to determine whether specific work on Codex labelling texts was required. The Committee agreed that the Delegation of Australia would prepare a revised paper in order to facilitate further consideration of this issue.

130) With due respect to the conclusions made by the Chairperson, the Delegation of Switzerland questioned the manner in which the decision to pursue work on misleading claims had been taken, noting that it was not consistent with the decision to discontinue work on country of origin labelling in a similar situation where consensus could not be reached on the need for future work.

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[18] CX/FL 03/14, CX/FL 03/14-Add.1 (Comments of Canada, IBFAN), CRD 20 (comments of India)

OTHER BUSINESS, FUTURE WORK AND DATE AND PLACE OF THE NEXT SESSION (Agenda Item 13)

DATE AND PLACE OF THE NEXT SESSION

131) The Committee was informed that the next session was tentatively scheduled to be held in Montréal from 10 to 14 May 2004, the exact arrangements to be determined between the host country and the Codex Secretariat.

SUMMARY STATUS OF WORK

Subject Matter	**Step**	**Action by**	**Document Reference in ALINORM 03/22A**
Draft Amendment to the General Labelling Standard (class names)	8	Governments 26th CAC	para. 24 Appendix II
Draft Amendment to the Guidelines on Nutrition Labelling	8	Governments 26th CAC 25th CCNFSDU	para. 41 Appendix III
Draft Guidelines on Use of Nutrition and Health Claims	8	Governments 26th CAC	para. 66 Appendix IV
Guidelines for Organically Produced Foods: Draft Revised Section 5 - Criteria	8	Governments 26th CAC	para. 80 Appendix V
Guidelines for Organically Produced Foods:Proposed Draft Revised Annex 2 - Permitted Substances	5	Governments 26th CAC	para. 98 Appendix VI
Draft Amendment to the General Standard (Draft Recommendations for the Labelling of Foods obtained through certain techniques of GM/GE): Definitions	7	32nd CCFL	para. 74
Proposed Draft Guidelines for the Labelling of Foods obtained through certain techniques of GM/GE: Labelling Provisions	4	32nd CCFL	para. 74
Proposed Draft Amendment to the General Standard (Quantitative Declaration of Ingredients)	3	Governments 32nd CCFL	para. 113 Appendix VII
Consideration of other issues: 1) Country of Origin Labelling			paras. 114-119
2) Traceability		32nd CCFL	para. 125
3) Misleading Claims		Australia/Governments 32nd CCFL	para. 129

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DRAFT AMENDMENT TO THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS (CLASS NAMES)

(**At Step 8 of the Procedure**)

Section 4.2 List of Ingredients

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

Milk Protein: Milk products containing a minimum of 50% of milk protein (m/m) in dry matter *.

* Calculation of milk protein content : Kjeldahl nitrogen x 6.38

DRAFT AMENDMENT TO THE GUIDELINES ON NUTRITION LABELLING
(At Step 8 of the Procedure)[1]

3.2 Listing of Nutrients

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

3.2.1.1 Energy value; and

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

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

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

3.2.2 When a voluntary declaration of specific nutrient, in addition to those listed in section 3.2.1, is applied, national legislation may require the mandatory declaration of the amount of any other nutrients considered relevant for maintaining a good nutritional status.

3.2.3 Where a specific nutrition or health claim is applied, then the declaration of the amount of any other nutrient considered relevant for maintaining a good nutritional status as required by national legislation or national dietary guidelines should be mandatory.

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

3.2.5 Where a claim is made regarding the amount and/or type of fatty acids **or the amount of cholesterol**, the amounts of saturated fatty acids, **monounsaturated fatty acids** and polyunsaturated fatty acids **and cholesterol** should be declared, **and the amount of trans fatty acid may be required according to national legislation**, in addition to the requirements of Section 3.2.1 and in accordance with Section 3.4.7.

3.2.**6** In addition to the mandatory declaration under 3.2.1, 3.2.3 and 3.2.4 vitamins and minerals may be listed in accordance with the following criteria:

3.2.**6.**1 Only vitamins and minerals for which recommended intakes have been established and/or which are of nutritional importance in the country concerned should also be declared.

3.2.**6**.2 When nutrient declaration is applied, **vitamins and minerals which are present in amounts less than 5% of the Nutrient Reference Value or of the officially recognized guidelines of the national authority having jurisdiction per 100 g or 100 ml or per serving as quantified on the label should not be declared.**

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

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[1] Amendments are indicated in bold

3.4.7 Where the amount and/or type of fatty acids **or the amount of cholesterol** is declared, this declaration should follow immediately the declaration of the total fat in accordance with Section 3.4.3.

The following format should be used:

Total Fat		... g
of which	saturated **fatty acids**	... g
	trans fatty acids	... g
	monounsaturated fatty acids	... g
	polyunsaturated **fatty acids**	... g
Cholesterol		..mg

DRAFT GUIDELINES FOR USE OF NUTRITION AND HEALTH CLAIMS
(At Step 8 of the Procedure)[2]

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 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".)

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.

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

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[3]. 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.

7.1.4 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.

7.1.5 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”.

7.1.6 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.

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

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

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

7.5.2 The target group, if appropriate.

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

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

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

7.5.6 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[4]	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
		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"

[4] 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".

DRAFT AMENDMENT TO THE GUIDELINES FOR THE PRODUCTION, PROCESSING, LABELING AND MARKETING OF ORGANICALLY PRODUCED FOODS

DRAFT REVISED SECTION 5 – CRITERIA

(At Step 8 of the Procedure)

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

5.1 At least the following criteria should be used for the purposes of amending the permitted substance lists referred to in Section 4. In using these criteria to evaluate new substances for use in organic production, countries should take into account all applicable statutory and regulatory provisions and make them available to other countries upon request.

Any proposals for the inclusion in Annex 2 of new substances must meet the following general criteria:

i) they are consistent with principles of organic production as outlined in these Guidelines;

ii) use of the substance is necessary/essential for its intended use;

iii) manufacture, use and disposal of the substance does not result in, or contribute to, harmful effects on the environment;

iv) they have the lowest negative impact on human or animal health and quality of life; and

v) approved alternatives are not available in sufficient quantity and/or quality.

The above criteria are intended to be evaluated as a whole in order to protect the integrity of organic production. In addition, the following criteria should be applied in the evaluation process:

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

- they are essential for obtaining or maintaining the fertility of the soil or to fulfil specific nutrition requirements of crops, or specific soil-conditioning and rotation purposes which cannot be satisfied by the practices included in Annex 1, or other products included in Table 2 of Annex 2; and
- the ingredients will be of plant, animal, microbial, or mineral origin and may undergo the following processes: physical (e.g., mechanical, thermal), enzymatic, microbial (e.g., composting, fermentation); only when the above processes have been exhausted, chemical processes may be considered and only for the extraction of carriers and binders[5]; and
- their use does not have a harmful impact on the balance of the soil ecosystem or the physical characteristics of the soil, or water and air quality; and
- their use may be restricted to specific conditions, specific regions or specific commodities;

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

- they should be essential for the control of a harmful organism or a particular disease for which other biological, physical, or plant breeding alternatives and/or effective management practices are not available, and
- their use should take into account the potential harmful impact on the environment, the ecology (in particular non-target organisms) and the health of consumers, livestock and bees; and

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[5] The use of chemical processes in the context of these Criteria is an interim measure and should be reviewed in line with the provisions as set out in Section 8 of these Guidelines.

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

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

- their use may be restricted to specific conditions, specific regions or specific commodities;

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

- these substances are used only if it has been shown that, without having recourse to them, it is impossible to:
  .. produce or preserve the food, in the case of additives, or
  .. produce the food, in the case of processing aids
  in the absence of other available technology that satisfies these Guidelines;

- these substances are found in nature and may have undergone mechanical/physical processes (e.g. extraction, precipitation), biological/enzymatic processes and microbial processes (e.g. fermentation),

- or, if these substances mentioned above are not available from such methods and technologies in sufficient quantities, then those substances that have been chemically synthesized may be considered for inclusion in exceptional circumstances;

- their use maintains the authenticity of the product;

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

- the additives and processing aids do not detract from the overall quality of the product.

In the evaluation process of substances for inclusion on lists all stakeholders should have the opportunity to be involved.

5.2

Countries should develop or adopt a list of substances that meet the criteria outlined in Section 5.1.

The open nature of the lists

5.3 Because of the primary purpose of providing a list of substances, the lists in Annex 2 are open and subject to the inclusion of additional substances or the removal of existing ones on an ongoing basis. When a country proposes inclusion or amendment of a substance in Annex 2 it should submit a detailed description of the product and the conditions of its envisaged use to demonstrate that the requirements under Section 5.1 are satisfied. The procedure for requesting amendments to the lists is set out under Section 8 of these Guidelines.

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PROPOSED DRAFT AMENDMENT TO THE GUIDELINES FOR THE PRODUCTION, PROCESSING, LABELING AND MARKETING OF ORGANICALLY PRODUCED FOODS: PROPOSED DRAFT REVISED ANNEX 2 – PERMITTED SUBSTANCES

(At Step 5 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[18] 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	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.
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.

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

Stillage and stillage extract	Ammonium stillage excluded
Sodium chloride	Only mined salt
Aluminium calcium phosphate	Maximum 90 mg/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	----
Zeolites	----
Wood charcoal	[Only charcoal from wood not chemically treated after felling.]
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 or disease control in livestock buildings and installations.]

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.	---

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

3.1 Food additives, including carriers

INS	Name	Specific conditions
	For plant products	
170	Calcium carbonates	----
220	Sulfur dioxide	Wine products
270	Lactic acid	Fermented vegetable products
290	Carbon dioxide	----
296	Malic acid	----
300	Ascorbic acid	If not available in natural form
306	Tocopherols, mixed natural concentrates	----
322	Lecithin	Obtained without the use of bleaches and organic solvents
330	Citric acid	Fruit and vegetable products
335	Sodium tartrate	cakes/confectionery
333	Calcium citrate	Acidity regulator, stabiliser, dispersing agent, antioxidant.
334	Tartaric acid	---
336	Potassium tartrate	cereals/cakes/confectionery
341i	Mono calcium phosphate	only for raising flour
400	Alginic acid	----
401	Sodium alginate	----
402	Potassium alginate	----
406	Agar	----
407	Carageenan	----
410	Locust bean gum	----
412	Guar gum	----
413	Tragacanth gum	----
414	Arabic gum	Milk, fat and confectionary products
415	Xanthan gum	Fat products, fruit and vegetables, cakes & biscuits, salads.
416	Karaya gum	----
440	Pectins	----
[422]	[Glycerol]	[From plant extracts.]
500	Sodium carbonates	Cakes & biscuits, confectionery
501	Potassium carbonates	Cereals/cakes & biscuits/confectionary
503	Ammonium carbonates	----
504	Magnesium carbonates	----
508	Potassium chloride	Frozen fruit and vegetables/canned fruit and vegetables, vegetable sauces/ketchup and mustard

509	Calcium chloride	Fruits and vegetables/soybean products
511	Magnesium chloride	Soy bean products
516	Calcium sulphate	Cakes & biscuits/soy bean products/bakers yeast. Carrier
524	Sodium hydroxide	Cereal products
551	Silicon dioxide	Anti-caking agent for herbs and spices.
938	Argon	----
941	Nitrogen	----
948	Oxygen	----

For livestock and bee products

The following is a provisional list for the purposes of processing livestock and bee products only. Countries may develop a list of substances for national purposes that satisfy the requirements of these Guidelines as recommended in Section 5.2.

153	Wood Ash	Specified traditional cheeses as recognized by the certification body or authority.
170	Calcium carbonates	Milk products. Not as colouring agent.
[250]	[Sodium nitrite]	[Where no alternate technology exists for certain products, may be used for: pickling salt for meat products except sausages for frying, minced meat products, products made of fish, crustaceans and molluscs.]
[252]	[Potassium nitrate]	[Where no alternate technology exists for certain products, may be used for: raw pickled products and raw cured meat products.]
270	Lactic acid	Sausage casings/milk products.
290	Carbon dioxide	---
300	Ascorbic Acid	In meat [and dairy] products, provided insufficient natural sources are available.
[301]	[Sodium ascorbate]	[In meat products, provided insufficient natural sources are available.]
[302]	[Calcium ascorbate]	[In meat products, provided insufficient natural sources are available.]
[303]	[Potassium ascorbate]	[In meat products, provided insufficient natural sources are available.]
306	Tocopherols, mixed natural concentrates	As an antioxidant in mixed products to prevent fat oxidation.
322	Lecithin	Obtained without the use of bleaches or organic solvents. Milk products/milk based infant food/fat products/mayonnaise.
327	Calcium lactate	Stabilizer for thickening pasteurised milk and cream products.
330	Citric acid	As coagulation agent for specific cheese products and for cooked eggs.
331	Sodium citrate	Sausages/pasteurisation of egg whites/milk products, emulsified sausage and melted cheese. Stabilizer for thickening pasteurised milk and cream products, and emulsifying salt for processed cheese.
332	Potassium citrate	---

333	Calcium citrate	Stabilizer for thickening of pasteurised milk and cream.
[339]	[Sodium phosphate]	[Stabilizer for pasteurised milk and cream products.]
[340]	[Potassium phosphate]	[Emulsifying salt for melted and processed cheese and stabilizer for pasteurised creams]
400	Alginic acid	As a thickener for milk based and mixed products.
401	Sodium alginate	As a thickener for milk based and mixed products.
402	Potassium alginate	As a thickener for milk based and mixed products.
406	Agar	---
407	Carrageenan	Milk products
410	Locust bean gum	Milk products/meat products
412	Guar gum	Milk products/canned meat/egg products
413	Traganth gum	---
414	Arabic gum	Milk products/fat/confectionery/glazing agent
440	Pectin (unmodified)	Milk products
[450[	[Diphosphates]	[Emulsifying salt for melted and processed cheese and stabilizer for pasteurised creams.]
[452]	[Polyphosphate]	[Emulsifying salt for melted and processed cheese and stabilizer for pasteurised creams.]
500	Sodium carbonates	Milk products for pH regulation in traditional cheese varieties prepared out of sour milk.
509	Calcium Chloride	Milk products/meat products
938	Argon	---
941	Nitrogen	---
[942]	[Nitrous Oxide]	[Packaging gas, propellant for whipped cream]
948	Oxygen	---

3.2 Flavourings

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

3.3 Water and salts

Drinking water.

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

3.4 Preparations of Microorganisms and Enzymes

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

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

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

Substance	**Specific conditions**
For plant products Water	----
Calcium chloride	coagulation agent
Calcium carbonate	----
Calcium hydroxide	----
Calcium sulphate	coagulation agent
Magnesium chloride (or nigari)	coagulation agent
Potassium carbonate	drying of grape raisins
Carbon dioxide	----
Nitrogen	----
Ethanol	solvent
Tannic acid	filtration aid
Egg white albumin	----
Casein	----
Gelatine	----
Isinglass	----
Vegetable oils	greasing or releasing agent
Silicon dioxide	as gel or collodial solution
Activated carbon	----
Talc	----
Bentonite	----
Kaolin	----
Diatomaceous earth	----
Perlite	----
Hazelnut shells	----
Beeswax	releasing agent
Carnauba wax	releasing agent
Sulphuric acid	pH adjustment of extraction water in sugar production
Sodium hydroxide	pH adjustment in sugar production.[Oil production for rape seed *(Brassica spp).]*
Tartaric acid and salts	----
Sodium carbonate	sugar production
Preparations of bark components	----

Potassium hydroxide	pH adjustment for sugar processing
Citric Acid	pH adjustment. Oil production and hydrolysis of starch.
For livestock and bee products The following is a provisional list for the purposes of processing livestock and bee products only. Countries may develop a list of substances for national purposes that satisfy the requirements of these Guidelines as recommended in Section 5.2.	
Calcium carbonates	---
Calcium Chloride	Firming, coagulation agent in cheese making.
Kaolin	Extraction of propolis.
Lactic acid	Milk products: coagulation agent, pH regulation of salt bath for cheese.
Sodium carbonate	Milk products: neutralizing substance.
Water	---

Preparations of microorganisms and enzymes

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

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 associated by consumers with the food; or
(c) is essential to characterise the food; or
(d) is essential to distinguish the food from others with which it may be confused; or]
(e) appears in the common or trade name of the food; or
(f) [the disclosure of which is deemed, by national authorities, to be necessary to enhance the health of consumers or prevent consumer deception].
(g) [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

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