codex alimentarius commission

FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD HEALTH
ORGANIZATION

JOINT OFFICE: Via delle Terme di Caracalla 00100 ROME Tel.: 57971 Telex: 625852-625853 FAO I Cables: Foodagri Rome Facsimile: (6) 57973152-5782610

ALINORM 93/22

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION
Twentieth Session
Geneva 28 June - 7 July 1993

REPORT OF THE TWENTY-SECOND SESSION OF THE
CODEX COMMITTEE ON FOOD LABELLING
Ottawa, Canada, 26 - 30 April 1993

Note: This document incorporates Codex Circular Letter 1993/12-FL

W/V0705

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CX 4/15.2

CL 1993/12-FL
May 1993

TO: - Codex Contact Points
- Participants at the 22nd Session of the Codex Committee on Food Labelling
- 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 22nd Session of the Committee on Food Labelling (ALINORM 93/22)

A. MATTERS FOR ADOPTION BY THE 20th SESSION OF THE CODEX ALIMENTARIUS COMMISSION

Draft Guidelines at Step 8 of the Procedure

1. Draft Amendment to Section 3.3.4 of the Codex Guidelines on Nutrition Labelling (Draft Nutrient Reference Values for Labelling Purposes) (para. 23, Appendix II)

Governments wishing to propose amendments or comments on the above document should do so in writing in conformity with the Guide to the Consideration of Standards at Step 8 (see Procedural Manual of the Codex Alimentarius Commission) to the Secretary, Joint FAO/WHO Food Standards Programme, FAO, via delle Terme di Caracalla, 00100 Rome, Italy, **before 20 June 1993**.

Proposed Draft Guidelines at Step 5 of the Procedure

2. Proposed Draft Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (para. 88, Appendix V).

Government wishing to submit comments on the implications which the above document may have for their economic interests should do so in writing in conformity with the Procedure for the Elaboration of Worldwide Standards at Step 5 to the Secretary, Joint FAO/WHO Food Standards Programme, FAO, via delle Terme di Caracalla, 00100 Rome, Italy, **before 20 June 1993**.

B. DOCUMENTS TO BE ELABORATED FOR GOVERNMENT COMMENTS PRIOR TO THE NEXT SESSION OF THE COMMITTEE

Proposed Draft Amendment at Step 3 of the Procedure

3. Proposed Draft Amendment to the Codex General Guidelines on Claims on the Use of the Term "Natural" (para. 95)

C. REQUEST FOR COMMENTS AND INFORMATION

Proposed Draft Guidelines at Step 3 of the Procedure

4. Propsed Draft Guidelines for the Use of Health and Nutrition Claims (paras. 48-49, Appendix III)

Governments are invited to submit specific comments on Sections 6. Nutrient Function Claims and 7. Health Claims and the relevant definitions thereof (points 2.1.3 and 2.2).

5. Proposed Draft Recommendations for the Labelling of Potential Allergens (Amendment to the General Standard for the Labelling of Prepackaged Foods) (para. 56, Appendix IV)

Governments are invited to submit comments on the proposals concerning labelling and the identification of potential allergens, and to provide scientific information on the occurrence of food allergies and their national approach to this question.

Other Matters

6. Implications of Biotechnology on International Foods Standards and Codes of Practice

Governments are invited to provide information on their national approach and policies with regard to the labelling of foods and food ingredients or additives produced through biotechnology.

Governments and international organizations wishing to submit comments and information on points 5. and 6. are invited to do so **not later than 31 October 1993** to the Chairman of the Committee at the following address:

Mrs. K. Gourlie, Director
Consumer Products Branch
Consumer and Corporate Affairs
50 Victoria Street
Hull, Quebec K1A OC9
Canada

with a copy to the Secretary, Joint FAO/WHO Food Standards, FAO, via delle Terme di Caracalla, 00100 Rome, Italy.

SUMMARY AND CONCLUSIONS

The summary and conclusions of the 22nd Session of the Codex Committee on Food Labelling are as follows:

Matters for consideration by the Commission:

The Committee:

- agreed to advance to Step 8 the Draft Proposal for the amendment of Section 3.3.4 of the Codex Guidelines on Nutrition Labelling (**Draft Nutrient Reference Values for Labelling Purposes**) (para. 23, Appendix II)

- agreed to advance to Step 5 the **Proposed Draft Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods** (para. 88, Appendix V)

- endorsed the labelling provisions of Proposed Draft (or Draft) Standards elaborated by CCTFFV, CCFFP, CCPL (para. 14) and recommended that CCNFSDU amend the labelling provisions of the Proposed Draft Standard for Formula Foods for Use in Very Low Energy Diets (at Step 5) (paras. 14-18)

- proposed that the **Proposed Draft Guidelines for the Use of the Term "Natural"** (at Step 3) become an amendment to the General Guidelines on Claims (para. 89)

- agreed to circulate at Step 3 the **Recommendations for the Labelling of Potential Allergens in Foods** (amendment to the General Standard for the Labelling of Prepackaged Foods) (para. 56, Appendix IV)

Other matters of interest to the Commission:

The Committee:

- agreed to return to Step 3 the **Proposed Draft Guidelines for the Use of Health and Nutrition Claims** for further comments and to have a new draft prepared by Canada for consideration by the next session of the Committee, in the light of the advice provided by CCNFSDU (paras. 48-49, Appendix III)

- agreed to return to Step 3 the **Proposed Draft Guidelines for the Use of the Term "Natural"** for redrafting by Canada as an amendment to the General Guidelines on Claims in the light of the discussions of the Committee (para. 95)

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INTRODUCTION

1. The Codex Committee on Food Labelling held its 22nd Session in Ottawa, Canada, from 26 to 30 April 1993 by courtesy of the Government of Canada. The Session was chaired by Mrs. Katharine Gourlie, Director, Consumer Products Branch, Consumer and Corporate Affairs Canada. The Session was attended by 124 participants, representing 29 member countries and 10 international organizations. A complete list of participants is given in Appendix I to this report.

OPENING OF THE SESSION (Agenda Item 1)

2. The Session was opened by the Honourable Pierre H. Vincent, Minister of Consumer and Corporate Affairs, who welcomed the delegates and observers to Ottawa on behalf of the Government of Canada.

3. Mr. Vincent noted that the 22nd Session of the Committee on Food Labelling fittingly coincided with Canada's National Consumer Week and that countries involved in producing or trading foodstuffs acknowledged that the role of consumers was now more dynamic and important than ever before. Consumers, industry and governments recognized the need for new national and international agreements in which it was essential to take into account consumers' concerns. Mr. Vincent stated that the Codex Alimentarius Commission had a leading role in serving and protecting the consumer, since it was responsible for establishing international standards for foods and ensuring fair practices in trade.

4. Mr. Vincent pointed out that the Canadian government was reviewing its consumer policies in response to a greater interdependence between consumers, industry and governments, and a constantly changing technological, economic and social environment. He noted that increased international trade gave consumers access to a greater variety of products, and that moreover they were increasingly aware of health concerns and looked for health and nutrition-related information on food labels such as the nutritional content.

5. Mr. Vincent also noted that the globalization of markets and the adoption of international trade agreements aimed at improving service to consumers, and that, when developing labelling requirements, governments wanted to ensure that label information was scientifically valid and easily understandable.

6. In conclusion, Mr. Vincent expressed his hope that the Committee's deliberations would result in greater international harmonization and agreement with regard to food labelling, and wished the Committee success in its work.

ADOPTION OF THE AGENDA (Agenda Item 2)

7. The Committee agreed to the adoption of the Provisional Agenda (CX/FL 93/1) as proposed. In order to facilitate its discussions concerning the consideration of Proposed Draft Guidelines for the Production, Processing, Labelling and Marketing of Organically and Biologically Produced Foods (Agenda Item 9), the Committee appointed an *Ad Hoc* Working Group to discuss this subject under the direction of Mrs. R. Lovisolo, FAO Consultant. The Committee also agreed to admit a representative of the Press (Food Chemical News) to the meeting, with the understanding that informal remarks presented by delegations would not be attributed to the Government concerned as an official position.

MATTERS OF INTEREST ARISING FROM CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES (Agenda Item 3)

8. The Committee had for its consideration documents CX/FL 93/2 and CX/FL 93/2-Add. 1 when discussing this agenda item, which summarized matters of interest arising from the Codex Alimentarius

Commission and other Codex Committees. The Secretariat also provided a verbal summary of the consideration of inspection and certification with regard to religious requirements, as discussed at the First Session of the Codex Committee on Food Import and Export Inspection and Certification Systems (paras. 48-50, ALINORM 93/30). As it was noted that most of the items in the working papers were for information only or were scheduled for discussion elsewhere, the Committee focused its discussions on the following matter.

Implications of Biotechnology on International Food Standards and Codes of Practice

9. As indicated in Conference Room Document 1 (CX/FL 93/2-Add. 1), the Committee was informed of the request of the 19th Session of the Codex Alimentarius Commission that CCFL should provide guidance on the possibilities to inform the consumer that a food had been produced through "modern" biotechnologies (paras. 88-92, ALINORM 91/40). The Committee also noted discussions held at the 25th Session of the Codex Committee on Food Additives and Contaminants concerning this subject, and especially that the competence of CCFL with respect to the labelling of food additives produced through biotechnology had been reasserted (paras. 81-93, ALINORM 93/12A).

10. In view of the complexity and importance of the issue of biotechnology as related to food labelling, the Committee welcomed the offer of the Delegation of the United States to prepare a discussion paper concerning this subject for circulation and government comments well before the next Session. It was also agreed that general comments and information on national policies concerning this issue would be requested by Circular Letter for consideration by the Delegation of the United States.

11. The Committee was further informed of the conclusions of the Committees on Food Hygiene, on Food Additives and Contaminants, on General Principles, on Food Import and Export Inspection and Certification Systems, on Nutrition and Foods for Special Dietary Uses, and on Methods of Analysis and Sampling. The Committee noted that the Table of Proposed Conditions for Claims for Nutrient Contents, agreed upon by CCNFSDU as part of the proposed Draft Guidelines on Nutrition and Health Claims for Food Product Labelling, would be considered under Agenda Item 6.

ENDORSEMENT OF LABELLING PROVISIONS IN CODEX STANDARDS (Agenda Item 4)

12. The Committee had for its consideration document CX/FL 93/3, containing labelling provisions submitted by various Codex Committees for endorsement in accordance with the Revised Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985).

13. The Committee noted that the labelling provisions were being submitted in accordance with revised procedures concerning the Format for Codex Commodity Standards and Relations Between Commodity Committees and General Committees (pages 79 and 129-131, respectively, Codex Alimentarius Procedural Manual).

14. The Committee endorsed the labelling provisions of the following Codex Standards as submitted, with the understanding that those recommendations noted below would be considered by the Committee(s) concerned.

Codex Committee on Tropical Fresh Fruits and Vegetables
3rd Session, ALINORM 93/35

- Draft Standard for Pineapple (Step 8) (Appendix II)
- Draft Standard for Papaya (Step 8) (Appendix III)
- Draft Standard for Mango (Step 8) (Appendix IV)
- Proposed Draft Standard for Nopal (Step 5/8) (Appendix V)
- Proposed Draft Standard for Prickly Pear (Step 5/8) (Appendix VI)
- Proposed Draft Standard for Carambola (Step 5/8) (Appendix VII)

4th Session, ALINORM 93/35A

- Proposed Draft Standard for Litchi (Step 5/8) (Appendix II)
- Proposed Draft Standard for Baby Corn (Step 5/8) (Appendix III)
- Proposed Draft Standard for Banana (Step 5) (Appendix IV)
- Proposed Draft Standard for Avocado (Step 5) (Appendix V)

Codex Committee on Cereals, Pulses and Legumes

8th Session, ALINORM 93/29

- Proposed Draft Standard for Wheat (Step 5) (Appendix III)
- Proposed Draft Standard for Durum Wheat (Step 5) (Appendix IV)
- Proposed Draft Standard for Peanuts (Step 5) (Appendix V)
- Proposed Draft Standard for Oats (Step 5) (Appendix VI)

Codex Committee on Fish and Fishery Products

20th Session, ALINORM 93/18

- Proposed Draft Standard for Quick Frozen Squid (Step 5) (Appendix IV)
- Revised Codex Standard for Canned Shrimps or Prawns (Step 5) (Appendix V)
- Revised Codex Standard for Canned Salmon (Step 5) (Appendix VI)
- Revised Codex Standard for Canned Crab Meat (Step 5) (Appendix VII)
- Revised Codex Standard for Canned Sardines and Sardine-Type Products (Step 5) (Appendix VIII)
- Revised Codex Standard for Canned Tuna and Bonito (Step 5) (Appendix IX)
- Revised Codex Standard for Canned Finfish (Step 5) (Appendix X)
- Revised Codex Standard for Quick Frozen Shrimps or Prawns (Step 5) (Appendix XI)
- Revised Codex Standard for Quick Frozen Blocks of Fish Fillets, Minced Fish, Minced Fish Flesh and Mixtures of Minced Fish Flesh (Step 5) (Appendix XII)
- Revised Codex Standard for Quick Frozen Fish Sticks (Fish Fingers), Fish Portions and Fish Fillets Breaded or in Batter (Step 5) (Appendix XIII)
- Revised Codex Standard for Quick Frozen Lobsters (Step 5) (Appendix XIV)
- Revised Codex Standard for Quick Frozen Uneviscerated and Eviscerated Finfish (Step 5) (Appendix XV)

15. The Committee agreed to recommend that the CCFFP should simplify the labelling provisions of the above standards, as many of these requirements were already included in the General Labelling Standard. In other cases, it was also noted that some sections were missing (e.g., Sections 6.2 - 6.4, Codex Standard for Quick Frozen Shrimps and Prawns).

16. The Observer from the EEC informed the Committee about the observations they had made at the last session of CCFFP; certain provisions in the above Draft Standards differed from the EEC regulations in this area, especially the indication of net weight of glazed products, the Scope of the Standard for Sardine and Sardine-type product and the association of the terms tuna and bonito on the label in the Revised Codex Standard for Tuna and Bonito and that these observations had been made at the last session of CCFFP. The Delegation of France reserved their position on the endorsement of the labelling provisions of several of the above Quick Frozen Products as the Net Content provisions for Glazing differed from EEC requirements. France also reserved their position on the use of the dual product name "Bonito-Tuna" in the Standard for Canned Tuna and Bonito as well as the use of the product name "Sardines" for Pilchard Sardines. It was agreed that these comments would be communicated to the Committee on Fish and Fishery Products.

17. With regard to the suggestions concerning the addition of species to the standards, it was noted that these comments could be directed to the CCFFP at Step 6.

Codex Committee on Nutrition and Foods for Special Dietary Uses

18th Session, ALINORM 93/26

- Proposed Draft Standard for Formula Foods for Use in Very Low Energy Diets (Step 5) (Appendix II)

18. The Committee agreed to recommend that the CCNFSDU should remove sections 9.2 and 9.4 of the proposed draft labelling section, as these provisions were already covered under the General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses (CODEX STAN 146-1985). The Committee also recommended that when referring to Sections 9.1 and 9.6 in section 9.7, the applicable requirements should be explicitly indicated, as it was not clear which labelling provisions applied to the label of the package and/or the sachet, and which statements might appear on an accompanying leaflet.

PROPOSED DRAFT NUTRIENT REFERENCE VALUES FOR FOOD LABELLING PURPOSES (Agenda Item 5)

19. The Committee had for its consideration Appendix V of ALINORM 91/22, presenting a draft amendment to Section 3.3.4 of the Codex Guidelines on Nutrition Labelling (i.e. Draft Nutrient Reference Values) as adopted at Step 5 by the 19th Session of the Commission. Government comments at Step 6 in reply to CL 1992-5/FL were contained in document CX/FL 93/4 (Austria, Denmark, New Zealand, United States) and CX/FL 93/4-Add.1 (Malaysia). A document containing extracts from a report of the Scientific Committee for Food of the EEC on "Nutrient and Energy Intakes for the European Community"was distributed as an unnumbered Room Document.

20. The Committee recalled that Section 3.3.4 of the Codex Guidelines on Nutrition Labelling had been amended by incorporating the Nutrient Reference Values (NRVs) recommended by the Joint FAO/WHO Expert Consultation on Recommended Allowances of Nutrients for Food Labelling Purposes (1988, Helsinki). The Committee noted that it was not competent to set reference values for recommended nutritional intake and that expert advice should be sought on such aspects, and that the values under consideration were intended for labelling purposes only.

21. Some delegations pointed out that as a number of source materials existed, with different values for women and children in certain cases, appropriate guidelines or principles would be needed to ensure that the establishment of NRVs was based on appropriate scientific data. Moreover, new evaluations were currently being carried out at the national and international levels and significant evolutions had taken place in recent years in this particular field. In this perspective, some delegations suggested that the Nutrient Reference Values should not be adopted at the present time but that further guidance should be sought from the Committee on Nutrition and Foods for Special Dietary Uses, especially as regarded principles. Other delegations stressed that these values had been proposed as a result of the Helsinki expert consultation and were supported by CCNFSDU. It was well understood that the definition and review of such values was an ongoing process, subject to revision in the light of new scientific data, as the footnote to the list of NRVs presented in Appendix V of ALINORM 91/22 clearly indicated. The Committee was also reminded that the last Session of CCNFSDU had requested government comments on this matter, for consideration at its next Session (September 1994).

22. While recognizing the need for general principles to guide the choice and amendment of reference values, the Committee felt that the adoption of the revised list, which represented an updating of the previous list, should not be delayed until such time as these principles were elaborated. The Committee therefore agreed to advance to Step 8 the draft reference values and to request the guidance of CCNFSDU

on guidelines which should be followed to establish and revise such reference values. The Committee was of the opinion that an indication of the purpose for which these guidelines were needed should be given to CCNFSDU. After an extensive exchange of views on this issue, the Committee agreed that the following elements should be taken into consideration by CCNFSDU when elaborating "Principles for the Consideration of NRVs for Labelling Purposes":

1. While establishing Nutrient Reference Values (NRVs), the Principles for Nutrition Labelling as contained in the Codex Guidelines on Nutrition Labelling should be followed.

2. The primary purpose of nutrient reference values is to give meaningful and not misleading information to the consumer.

3. The composition of the list should be carefully considered and justified in terms of the consumers' needs.

4. A list of NRVs for foods targeted to the general population should be established. The need to establish NRVs for specific groups such as infants and children should also be considered.

5. NRVs should be based as far as possible on nutrient intakes recommended by FAO and/or WHO. The source of values should be indicated and justified.

Status of the Draft Nutrient Reference Values for Food Labelling Purposes (Proposal for the amendment of Section 3.3.4 of the Codex Guidelines on Nutrition Labelling)

23. The Committee agreed to advance the aforesaid Draft NRVs, as contained in Appendix II of the present report, to Step 8 of the Procedure for adoption by the Commission.

PROPOSED DRAFT GUIDELINES FOR THE USE OF HEALTH AND NUTRITION CLAIMS IN FOOD PRODUCT LABELLING (Agenda Item 6)

24. The Delegation of Canada introduced working paper CX/FL 93/6, containing the Proposed Draft Guidelines, which took into account the proposals of the previous session of the Committee. Government comments were presented in document CX/FL 93/6-Add. 1 (Denmark, Poland), Add.2 (Malaysia, Sweden, International Special Dietary Foods Industries), Add. 3 (International Dairy Federation), Add.4 (Joint Nordic comments of Finland, Iceland, Norway and Sweden), Add.5 (Brazil), Add.6 (International Organization of Consumers Unions).

25. The Committee agreed to amend the title of the Guidelines so as to harmonize it with the "General Guidelines on Claims" by removing "in food product labelling", and pointed out that the terms of reference of the Committe explicitly referred to Food Labelling.

Section 1. SCOPE

26. Some delegations expressed the view that the Guidelines should not include foods for special dietary uses, as specific provisions applied in their case. Other delegations pointed out that claims of a general nature relating to nutrient content could still be made for these foods. The Committee agreed to indicate that the Guidelines applied to all foods "without prejudice to specific provisions under Codex standards or guidelines relating to Foods for Special Dietary Uses and Foods for Special Medical Purposes".

Section 2. DEFINITIONS

27. The Committee decided to use the wording of the General Guidelines on Nutrition Labeliing for the definition of Nutrition Claim in point 2.1., and to delete the reference to "standardized terminology"

in point 2.1.1. It was further agreed that energy value should be specifically mentioned in the definition of comparative claims (point 2.1.2).

28. The Committee agreed to amend the definition of Nutrient Function Claim so as to indicate that "it sets out in general terms the nutritional consequences for good health of the intake of a particular nutrient".

29. The Committee had an exchange of views on the conditions under which health claims relating to food might be used, and discussed a proposal to add in 2.2 Health claims "that this relationship be expressed only within the context of the total diet".

30. With respect to the definitions of Nutrient Function Claim and Health claim, some delegations expressed the view that the distinction between these types of claims was very difficult to establish and that they should be considered jointly. Other delegations were of the opinion that distinct definitions should be retained.

31. The observer from the EEC informed the Committee that claims relating to the cure of diseases were prohibited in the Community except in the framework of the specific legislation on mineral waters and foods for special dietary uses. Some delegations indicated that health claims establishing relationships between a nutrient and the prevention of a disease could be allowed within the context of a total dietary pattern. Other delegations did not accept any reference to diseases.

Section 4. NUTRIENT CONTENTS CLAIMS

32. Some delegations questioned the intention expressed in point 4.1 as to claims which did not fall within the scope of the definition and the Table, judging that it was too restrictive to limit nutrient content claims to the descriptors proposed. They pointed out that reference might be made to a percentage or quantity of a nutrient, without qualifying it as «low» or «high» for example, or without any other claim. The Committee therefore agreed to amend the definition as follows, to make it clear that the values indicated in the Table applied to the specific claims presented therein:

> «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.»

33. The Committee had an exchange of views on point 4.2 and the Delegation of Norway, on behalf of the Nordic countries, proposed that claims should be permitted only when the nutrient was naturally present in the food, in order not to mislead the consumer. The Committee did not accept this proposal, as such a provision appeared too restrictive.

Section 5. COMPARATIVE CLAIMS

34. On the suggestion of the observer from IOCU, the Committee agreed to indicate that claims applied to the end-products as sold and not to their ingredients.

35. In point 5.1, the Committee agreed that «foods which replace each other in the diet» was not explicit enough and that reference should be made to «different versions of the same food or similar foods».

36. In point 5.2.1, the Committee considered the requirements which should apply when the claim referred to an absolute amount, as opposed to a percentage or fraction. Some delegations stressed that the consumer should not be mislead and questioned whether the total value of the nutrient present in the food should be indicated so as to provide an adequate basis for comparison or if any absolute amount should refer to 100g of the food. After an exchange of views on this question, the Committee agreed to refer to «the amount of difference, related to the same quantity, expressed as a percentage, a fraction or an absolute

amount», to delete the second sentence and to replace it with a general mention covering all possible cases, to the effect that «Full details of the comparison should be given».

37. With respect to point 5.3, some delegations were of the opinion that the relative difference should be increased to allow a comparative claim. The Committee noted that the differences should be nutritionally significant and that this aspect was addressed in the last part of 5.3, referring to a minimum absolute difference.

38. Some delegations pointed out that the percentages used for the purposes of comparison should be different for macronutrients and micronutrients. It was also suggested that a numerical indication should be permitted for a different amount of reduction provided no qualifying claim was made. Some delegations indicated that provisions should be made for the use of the term "light", when used as a claim for reduction. The Committee agreed to take these proposals into account in point 5.3 and to add a new point 5.4 in square brackets:

> [«the use of «reduced» (e.g. light) or «increased» should be restricted to changes of at least 25% of energy or macronutrients or 10% of the NRVs for micronutrients. This should not preclude factual numerical statements about smaller changes.»]

The Observer from IOCU noted that claims relating to "goodness" such as "good for you", "full of goodness" were common health claims and needed to be included in the Guidelines. The Committee agreed to consider this question at the next session.

Section 6. NUTRIENT FUNCTION CLAIMS

39. The Committee agreed to add a new point 6.1.3 to the effect that "the food for which the claim is made should be a significant source of the nutrient in the diet", so as to avoid misleading the consumer.

40. Some delegations expressed the view that such claims should not be allowed. It was also pointed out that point 6.1 was similar to point 7.1 relating to health claims and that there was no clear distinction between these definitions. The Committee noted that clarification was needed as to the amount of a nutrient necessary to justify such a claim and the definition of the function of nutrients, and agreed to refer this question to CCNFSDU for guidance. The Delegation of the United Kingdom indicated that it appeared necessary to merge Sections 6. Nutrient Function Claims and 7. Health Claims and the Committee agreed to request specific government comments on this issue, and noted that no consensus could be reached at this stage.

Section 7. HEALTH CLAIMS

41. The Chairman pointed out that the provisions of point 7.2 were already included in the General Guidelines on Claims (Section 3.4), and the Committee agreed to delete it.

42. Some delegations were of the opinion that health related claims could be allowed in relation to a total dietary pattern and if they could be substantiated by scientific evidence. Other delegations and the observer of the EEC expressed the view that no claim establishing a relation between a food or nutrient and a disease or health-related condition should be allowed. The Committee had an extensive exchange of views on this question but could not reach a consensus on the claims which should be allowed. The Committee consequently agreed to ask the advice of CCNSDFU on the health effects of nutrients as specifically related tc claims, (Points 7.1 and 7.3). It was further agreed to establish a drafting group including Australia, Canada, Denmark, France, Japan, New Zealand, Norway, Sweden, Switzerland, United Kingdom, United States, CIAA, IDF, IFGMA, IOCU, under the direction of the Delegation of Canada, to consider the provisions of Sections 6. and 7. and the related definitions (points 2.1.3 and 2.2) and prepare a revised proposal for consideration by the next Session.

Section 8. CLAIMS RELATED TO DIETARY GUIDELINES OR HEALTHY DIETS

43. On the suggestion of the Delegation of Germany, the Committee agreed to refer to "a national authority" and delete "having jurisdiction", as dietary guidelines might be established by scientific bodies with no regulatory power. On the suggestion of the observer of the IOCU, the Committee agreed to amend the wording of 8.4 to make it more explicit.

TABLE

44. The Secretariat indicated that CCFL was not mandated to amend the values in the Table, as the responsibility of establishing the values of nutrients relating to claims rested with CCNFSDU, as indicated by the 36th Session of the Executive Committee, and that the comments of the Committee would be communicated to CCNFSDU.

45. Several delegations made comments on the figures proposed to describe claims, especially on the following aspects: most references in the Table were expressed in relation to a fixed quantity of food, whereas the reference to serving was often more useful to the consumer; all nutrient values were not expressed with the same criteria and more consistency should be sought in this matter; modifications were suggested to the figures for "free", "source" or "high" for certain nutrients. Some delegations were of the opinion that "cholesterol free" should be retained, as Codex guidance was needed for this type of claim when used. The Delegation of the United Kingdom pointed out that in view of the changes proposed to point 4.1, the Table would no longer be exclusive and therefore where no criteria were indicated, the industry would be free to choose their own. The Delegation of Switzerland suggested to consider specifically the following values: 0.5g for "fat free"; 1g for "sugars free"; for vitamins and minerals, 15% of the NRV for "source" and 50% for "high". The Delegation of Norway suggested that the conditions for claims should refer to the energy unit (e.g. per 100kcal) instead of a fixed quantity or a serving. In reply to these concerns, the Secretariat recalled the last CCNFSDU Session had come to its conclusions after detailed consideration of these issues; in particular, it had been decided to delete the reference to "cholesterol free" as of no nutritional significance, and that the level of cholesterol in a food should be considered in relation to the energy derived from saturated fats. The Committee was also informed that the proposed values reflected the compromise reached between different approaches, especially as to the description of "free", and that many levels were indicated in square brackets and might be revised in the light of further comments. The Committee agreed that CCNFSDU should be informed of these comments, so as to reconsider the nutrient contents proposed if necessary.

46. The observer of the IDF expressed concern regarding the requirements proposed for "low", pointing out that provisions relating to fat could not be met for dairy products where the fat content was originally very high, as a reduction of 50% was already very significant and consumers should be informed of it. It was also pointed out that Codex standards or Draft standards referring to "low fat" already existed. The Delegations of Denmark and Norway as well as the Observer from IOCU, were of the opinion that the same requirements for "low" should apply to all foods.

47. The Committee noted that a Proposed Draft Standard for Fat Spreads was scheduled for consideration by the next Session of the Committee on Fats and Oils (September 1993), and that questions specifically related to dairy products would be considered by the Committee on Milk and Milk Products.

48. The Committee decided that as agreement could not be reached regarding the nutrient function claims and health claims, the Proposed Draft Guidelines should remain at Step 3 and be circulated for further comments. It was agreed to append to the report the text as amended by the Committee, in the sections where consensus existed. The Drafting Group, under the direction of the Delegation of Canada, would consider Sections 6. and 7. and the related definitions (point 2.1.2 and 2.3) in order to prepare a revised proposal for consideration by the next session. The Committee further agreed to seek the advice and guidance of CCNFSDU on these sections, and to inform CCNFSDU of the comments made with respect to the Table of nutrients.

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

49. The Committee agreed to return the Proposed Draft Guidelines, as contained in Appendix III to Step 3 for further comments.

CONSIDERATION OF LABELLING OF POTENTIAL ALLERGENS (Agenda Item 7)

50. The Committee had before it document CX/FL 93/5, which was prepared by Norway on the above subject in co-operation with Finland, Iceland and Sweden. Comments submitted by Austria were summarized in an unnumbered Conference Room Document.

51. The Committee recalled its previous discussions concerning this subject, whereby it was decided to examine the labelling of potential allergens which were included as components of composite ingredients in foods, and thus were not included in the ingredients list. The Committee noted that this issue would require the examination of Section 4.2.1.3 of the General Labelling Standard which addressed the labelling of composite ingredients, especially as related to the 25% rule (paras. 146-147, ALINORM 91/22).

52. The Delegation of Norway introduced the paper, which included a detailed summary of information concerning hypersensitivity (allergy and intolerance) problems and improvements associated with labelling in relation to hypersensitivity, issues related to the carry-over of food additives into foods and recommendations concerning amendments to the General Labelling Standard. The Delegation pointed out that labelling with regard to potential allergens should not give a false sense of security to affected consumers; however, although practical solutions might be difficult to find in this respect, the problems of hypersensitive consumers could not be solved without adequate labelling, which in itself provided a essential basis for other or complementary measures.

53. Several delegations noted that the matter of food hypersensitivity was both a public health and labelling issue, and that hypersensitive consumers relied on labelling to avoid certain foods. The Delegation of the United States pointed out in particular that the 25% rule should be revised. Certain delegations stated that the principle of complete and accurate ingredient declarations was generally accepted by governments and industry alike, but that additional industry co-operation was required, especially where second and third generation ingredients of foods were concerned. It was also noted that the recent Joint FAO/WHO International Conference on Nutrition recognized problems associated with food allergies, especially as related to infants and children.

54. A number of delegations suggested that actions required should be relative to the amount of risk, and that attempts should be made to define the ingredients and additives involved, as a balance was required to provide adequate, as opposed to burdensome, labelling information. The difficulties of establishing guidelines on a worldwide basis were also noted, as food allergies were often associated with specific sub-groups or regions. The relative costs associated with labelling and the categorization of potential allergens were also highlighted, as was the importance of justifying any changes to composite labelling requirements with appropriate criteria resting on a scientific basis. It was also noted that care should be taken not to create a sense of false security by action on labelling.

55. The Observer from the Association of European Celiac Societies (AOECS) noted the importance of labelling information for gluten sensitive individuals, as this group required in addition to the special gluten-free diet products, totally gluten-free foods for normal consumption. The Observer stated that detailed information was necessary because gluten was often added to foodstuffs where it normally was not expected (e.g., ham), or was part of a composite ingredient which was not required to be sub-listed in the ingredients list. The identification of ingredients such as starch should also be more explicit (e.g. wheat starch).

56. The Committee, while noting the importance of continuing discussions concerning this subject, agreed to append the recommendations for the amendment of the General Standard for the Labelling of Prepackaged Foods and the attached background document to the present report, as contained in Appendix IV, for circulation and government comments at Step 3.

CONSIDERATION OF NATIONAL STRATEGIES REGARDING THE APPLICATION OF THE LIST OF NUTRIENTS IN THE CODEX GUIDELINES ON NUTRITION LABELLING (Agenda Item 8)

57. The Committee had for its consideration document CX/FL 93/7 when discussing this agenda item, which contained government comments submitted by the United States in response to CL 1991/11-FL.

58. The Committee recalled that at its previous session it was agreed to request government comments on the type of nutrients they considered to be relevant for maintaining good nutritional status, as required by national legislation.

59. The Observer of the EEC informed the Committee that in application of Directive 90/496/EEC (24 September 1990), when nutrition labelling was provided, the following information would be required:

- As of 1 October 1993: energy value, protein, carbohydrate and fat;

- As of 1 October 1995: sugars, saturated fat, fiber and sodium (i.e., in addition to the above categories) whenever voluntary nutrition labelling existed or a nutrition claim was made for one of these nutrients.

REVISED PROPOSED DRAFT GUIDELINES FOR THE PRODUCTION, PROCESSING, LABELLING AND MARKETING OF ORGANICALLY/BIOLOGICALLY PRODUCED FOODS (Agenda Item 9)

60. The Committee had for its consideration document CX/FL 93/8 presenting the comments (Cuba, Denmark, Germany, Japan, New Zealand, Spain, United States, AMFEP, EEC, IFOAM) received in reply to CL 1991/23-FL, containing the first draft of the Guidelines (ALINORM 91/37), document CX/FL 93/8-Add. 1, which was a revised version of the Proposed Draft Guidelines for the Production, Processing, Labelling and Marketing of Organically/ Biologically Produced Foods, amended on the basis of the comments. The Committee also considered comments on the current draft as contained in CRD 2 (IFOAM) and CRD 3 (Japan).

61. The Committee was informed of discussions held at the 19th Session of the Commission concerning this issue, whereby it was agreed that the CCFL would be responsible for the future development of the guidelines presented (ALINORM 91/37) based on comments received from governments and Codex Regional Coordinating Committees (para. 103, ALINORM 91/40). The Committee also noted discussions held at the Coordinating Committees for North America and the South-West Pacific (paras. 87-90, ALINORM 93/32) and for Europe (paras. 80-84 and 88-89, ALINORM 93/19) concerning this subject.

62. The current Guidelines (CL/FL 93/8-Add.1) were presented by Ms. R. Lovisolo, FAO Consultant, who gave a brief summary of the background and elements suggested for organic foods. In this regard, several delegations noted that the work of the CCFL should be restricted to labelling, as other elements of the guidelines more appropriately rested with other Committees, such as the Codex Committee on Food Import and Export Inspection and Certification and the Codex Committee on Food Additives and Contaminants. It was also suggested that each country should decide whether it was appropriate to establish mandatory requirements for organic foods, while other delegations noted that the guidelines, as applied to international trade, were of an advisory nature.

63. The Committee agreed that its primary responsibilities were related to labelling and similar areas, as it was recognized that certain aspects of this work would be addressed more adequately by other Codex Committees.

64. The Committee also agreed to discuss the recommendations contained in the report of the Working Group on Organics which was chaired by the FAO Consultant and attended by Australia, Canada, France, Germany, Japan, Lithuania, Netherlands, Norway, Sweden, Switzerland, United States, EEC, IFOAM and IOCU. As a result of these discussions, the Committee agreed to the following changes to the Revised Proposed Draft Guidelines (CX/FL 93/8-Add.1):

SECTION 1. SCOPE

65. Paragraph 1.1 (b) should read:

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

as there are organically-produced products destined for purposes other than human consumption.

66. The term **"bio-dynamic"** or reference to other specific terms such as **"biological"** should be included only in a list of reserved terms and the square brackets be deleted as this would prevent deceptive labelling. The title of the Guidelines would therefore refer only to "organically produced foods". Paragraph 1.2 (b) should also be deleted.

SECTION 2. DESCRIPTION AND DEFINITIONS

67. As the term "agricultural origin" (paras. 3.3 (b); 3.4; 3.4 (a) and (b); and 3.6 (a) and (b)) could be applied differently between countries, (eg. some countries exclude fish products from the term) the definition for "agricultural product" was modified as follows:

"agricultural product" means any product or commodity, raw or processed, that is marketed for human consumption.

It was suggested that a definition for the term "veterinary drug" should be provided.

68. It was agreed that 2.2 (c) be altered to read:

"marketing" means holding for sale or displaying for sale ....

in order to clarify the definition. The definition for the term "bio-dynamic" should be removed as this term should not be isolated in this regard.

SECTION 3. LABELLING

69. As a means of protecting consumers against deceptive practices, a restriction on the blending of an ingredient derived from an organic and non-organic source within a single product should be included in the guidelines. The following statement was included in paragraph 3.3, between the present sub-points (c) and (d):

The same ingredients shall not be derived from both organic and non-organic origin.

70. The substance of paragraphs 3.4 (a) and (b) were amalgamated to read:

- are of agricultural origin and are not produced in the country or in sufficient quantity in the country in accordance with the requirements of Section 4 of these guidelines.

71. As promotional limitations could be imposed on the industry by paragraph 3.6 in that product containing up to 50% organic ingredients should be restricted to using organic product indications solely on the ingredients list, specific country comments should be sought on the feasibility of allowing other descriptive statements on products containing between 50% and 95% of organically-derived ingredients.

72. Paragraph 3.7 relating to conversion labelling was deleted as there would be limited advantage in utilizing such labelling provisions that could add new potential labels likely to be confusing to consumers.

SECTION 4. RULES OF PRODUCTION

73. Paragraph 4.2 covered an aspect of the specific principles of organic production and was moved to Annex 1.

SECTION 5. REQUIREMENTS FOR INCLUSION OF SUBSTANCES IN ANNEX 2

74. Point 4 of Annex 2 was moved to Section 5, paragraph 5.1 (d), third dash, as this should be a criterion for determining substances included on national lists, as follows:

> **- they are preferably nature identical and it is impossible to produce or preserve such food products without having recourse to such ingredients.**

75. The guideline should include criteria for the inclusion of substances in national lists which was covered by paragraph 5.1. This was, therefore, amended as follows:

> **Countries should develop a list of substances which satisfy the requirements of this guideline. The following criteria should be used for the purposes of amending these lists of substances not authorized for the purposes indicated in Section 4.**

As a consequence of the amendment to paragraph 5.1, paragraph 5.2 would set out the criteria for countries to make application to Codex for additions or amendments to the Codex list. Paragraph 5.2 should then to read:

> **Member countries should provide the following for any substance proposed for inclusion in Annex 2.**

SECTION 6. INSPECTION AND CERTIFICATION SYSTEMS

76. The use of the term "country" in paragraphs 6.2, 6.4 and 6.5 should be changed to read: "**competent authority**" in paragraph 6.2 and "**country authority**" in paragraph 6.4 and 6.5. As the designated authority responsible for the approval and supervision of private bodies should be able to delegate this function to an agent an additional provision should be included:

> **The authority may delegate this function to its agent.**

SECTION 7. INDICATIONS THAT PRODUCTS ARE COVERED BY AN INSPECTION SYSTEM

77. This section of the revised draft guidelines which related to provision for the use of a logo was considered not appropriate in the context of the Codex guidelines and was deleted.

SECTION 8. IMPORTS (becomes Section 7.)

78. The principle of equivalency within the guidelines may need further amplification, and should be considered in the light of further comments. It was considered appropriate to include for further discussion

the IFOAM proposal that countries might rely on non-governmental organizations for the determination of bilateral equivalency decisions.

ANNEX 1: PRINCIPLES OF ORGANIC PRODUCTION

Plants and Plant Products

79. It was recommended that the square brackets should be retained in paragraphs 1 and 2 so as to provide all countries with an opportunity for further comments.

Livestock Production

80. Paragraph 7 would be too restrictive in terms of requiring that livestock be maintained as part of an organic farm unit and was redrafted as follows:

> **Where livestock are maintained, they should be an integral part of the organic farm unit and should be raised and held according to these guidelines.**

81. In order to clarify conversion aspects of livestock production paragraph 9 was deleted and the following included:

> 9. **Animal products must not be sold as organic unless the animal has been raised according to these guidelines for a period of at least one year.**
>
> 10. **Up to 10% of adult animals of a herd or flock may be brought-in annually from non-organic sources for expansion or replacement purposes.**
>
> 11. **All brought-in animals from non-organic sources must be produced according to these guidelines for a period of a minimum of one year before their products may be sold under an organic label. Exceptions may be allowed for:**
>
> (a) **calves up to 14 (or 7?) days which have received colostrum and do not come from livestock markets;**
>
> (b) **dairy animals provided that milk is kept separate for a period of 12 (or 4?) weeks;**
>
> (c) **day old poultry; and**
>
> (d) **laying hens, provided that eggs are kept separate for a period of 30 days.**

Processing, Storage and Transport

82. A section on processing, storage and transport was developed and included in square brackets in the amended draft guidelines. Specific provisions for transport would not be necessary as national governments have extensive controls in place in this regard.

ANNEX 2. PERMITTED SUBSTANCES FOR THE PRODUCTION OF ORGANIC FOODS

83. Paragraph 4 was moved to 5.1(d) third dash point. The feasibility of an approach based on generic categories of substances as an alternative to the development of lists was considered. As the structure of the proposed lists had already achieved a substantial degree of consensus, it was recommended that further comments should be sought on this matter.

ANNEX 3. MINIMUM INSPECTION REQUIREMENTS AND PRECAUTIONARY MEASURES UNDER THE INSPECTION SYSTEM

84. Paragraph 8 should be amended as follows to prevent confusion:

" ... should be transported in a manner which would prevent ...."

Status of the Proposed Draft Guidelines on the Production, Processing, Labelling and Marketing of Organically/Biologically Produced Foods

85. The Committee agreed that the Proposed Draft Guidelines, as contained in Appendix V, would be advanced to Step 5 for adoption by the 20th Session of the Commission. This decision was made with the understanding that other relevant Codex committees would be informed.

CONSIDERATION OF PROPOSED DRAFT GUIDELINES FOR THE USE OF THE TERM "NATURAL" (Agenda Item 10)

86. The Committee had before it the Proposed Draft Guidelines for the Use of the Term "Natural" (CL 1992/28-FL) as prepared by Canada, as well as comments submitted at Step 3 on this proposal, presented in documents CX/FL 93/9 (Denmark, Spain), CX/FL 93/9-Add. 1 (Australia), Add.2 (Switzerland). Add.3 (USA), Add.4 (GISEM-UNISEM European Union of Natural Mineral Water Sources of the Common Market), Add.5 (Sweden), Add.6 (IDF)

87. The Committee recalled that the proposed draft guidelines were first considered at its 21st Session (paras. 87-106, ALINORM 91/22), after which Canada prepared revised guidelines based on written comments and discussions at the meeting. While introducing the revised guidelines, Canada noted that its provisions were significantly more restrictive than the first draft.

88. Several delegations stated that they did not support the development of guidelines for single words such as "natural", as it was felt that the use of such terms were already addressed by provisions in the Codex General Guidelines for Claims (i.e, Section 5.1 (iii)). Differences in the meaning of "natural" in various languages were also noted as a problem in the development of the guidelines, as were the difficulties in establishing exact meanings. The Committee, however, favoured preparation of guidelines in view of the widespread use of this term and the potential to mislead the consumer.

89. The Committee considered several options on how to proceed and decided to amend the General Guidelines for Claims with a new section on the use of the term "natural", as opposed to the continued development of separate guidelines, with the understanding that the Scope of the document would remain inchanged. It was further noted that Section 5.1 (iii) (Conditional Claims) of the General Guidelines, referring to "natural", would have to be amended in consequence. The Committee also agreed to discontinue the consideration of a definition for "traditional processes" and as a consequence, removed all references to this term from the text.

90. The Committee accepted the offer of the Delegation of Canada to elaborate amendments to the Codex General Guidelines on Claims relating to the use of the term "natural". In this regard, it was agreed that written comments received on CL 1992/28-FL as well as the following discussions would be taken into consideration when preparing these amendments.

Section 2. Criteria for the Use of "Natural"

91. In point 2.1.2, the Committee noted that irradiated foods would not qualify for natural labelling. The Delegation of Germany pointed out that provisions concerning pesticides and veterinary drugs should be included. The Committee agreed to remove the square brackets around the terms [food additives], [vitamins], [minerals], [colors] and [flavors] in view of their prohibition for use in "natural foods".

Section 3. Additional Labelling Requirements

92. The Committee agreed that the requirement set out in point 3.2 should not be made in view of the difficulties in including such a burdensome statement on product labels and the possibility to mislead consumers.

Minimal Processes

93. Several delegations took the position that processes such as pasteurization, roasting, cooking, blanching and baking should be considered as "minimal" as they were necessary in many cases to make the food fit for human consumption. Other delegations felt that such processes should be limited to those that involved minimal manipulation of the food and that cooking and pasteurization should be excluded. The Committee agreed to add the following words to the end of the definition of minimal processes: "... and include those processes necessary to make the food fit for human consumption." The Committee had an exchange of views on the examples to be included; it was also suggested that they should not be included in the definition, as a consensus could not be reached. The observer from I.D.F. stressed the need for the Committee to address the definition of permitted processes which would otherwise be left to individual countries. The Delegations of Norway, Sweden and Switzerland disagreed with this decision as they regarded the definition of minimal processes as too wide.

94. It was pointed out that specific provisions existed for mineral waters and that a statement on the exclusion of specific Codex standards should be included.

95. The Committee agreed that the proposed draft amendments to the General Guidelines on Claims on the use of the term "natural" would be prepared by Canada, on the basis of the comments received and the above discussion and circulated for further comments at Step 3 prior to the next session.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 11)

96. The Committee noted that the following matters would be considered at its 23rd Session:

- Consideration of Labelling Provisions in Codex Standards;
- Proposed Draft Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (at Step 7);
- Proposed Draft Guidelines for the Use of Health and Nutrition Claims (at Step 4);
- Recommendations for the Labelling of Potential Allergens (at Step 4);
- Proposed Draft Amendments to the Codex General Guidelines on Claims on the Use of the Term "Natural" (at Step 4);
- Principles for the Consideration of Nutrient Reference Values for Labelling Purposes
- Consideration of Labelling as Related to Biotechnology.

DATE AND PLACE OF THE NEXT SESSION (Agenda Item 12)

97. The Committee was informed that its 23rd Session was tentatively scheduled to be held from 24-28 October 1994 in Ottawa, Canada, pending a final decision by the Codex Alimentarius Commission.

SUMMARY STATUS OF WORK

Subject Matter	Step	Action by	Document Reference in ALINORM 93/22
Endorsement of Labelling Provisions in Codex Standards	-	20th CAC CCNFSDU CCFFP 23rd CCFL	paras. 12-18
Section 3.3.4 (Draft NRVs) of the Codex Guidelines on Nutrition Labelling	8	Governments 20th CAC	para. 23 Appendix II
Proposed Draft Guidelines for the Use of Health and Nutrition Claims	3	Governments Canada CCNFSDU 23rd CCFL	para. 48-49 Appendix III
Labelling of Potential Allergens	3	Governments 23rd CCFL	para. 56 Appendix IV
Proposed Draft Guidelines for Organically Produced Foods	5	20th CAC Governments 23rd CCFL	para. 88 Appendix V
Proposed Draft Guidelines for the Use of the Term "Natural"	3	Canada Governments 23rd CCFL	para. 95

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DRAFT NUTRIENT REFERENCE VALUES FOR FOOD LABELLING PURPOSES[1]
(At Step 8 of the Procedure)

(Proposal for amendment to Section 3.3.4 of the Codex Guidelines on Nutrition Labelling)

3.3.4 Numerical information on vitamins and minerals should be expressed in metric units and/or as a percentage of the Nutrient Reference Value per 100 g or per 100 ml or per package if the package contains only a single portion. In addition, this information may be given per serving as quantified on the label or per portion provided that the number of portions contained in the package is stated.

In addition, information on protein may also be expressed as percentages of the Nutrient Reference Value.

The following Nutrient Reference Values should be used for labelling purposes in the interests of international standardization and harmonization:

Protein	(g)	50
Vitamin A	(μg)	800[2]
Vitamin D	(μg)	5[3]
Vitamin C	(mg)	60
Thiamine	(mg)	1.4
Riboflavin	(mg)	1.6
Niacin	(mg)	18[3]
Vitamin B_6	(mg)	2
Folic acid	(μg)	200
Vitamin B_{12}	(μg)	1
Calcium	(mg)	800
Magnesium	(mg)	300
Iron	(mg)	14
Zinc	(mg)	15
Iodine	(μg)	150[3]
Copper	Value to be established	
Selenium	Value to be established	

[1] In order to take into account future scientific developments, future FAO/WHO and other expert recommendations and other relevant information, the list of nutrients and the list nutrient reference values should be kept under review.

[2] Proposed addition to Section 3.2.7 (Calculation of Nutrients) of the Codex Guidelines on Nutrition Labelling: "For the declaration of ß-carotene (provitamin A) the following conversion factor should be used: 1 μg retinol = 6 μg ß-carotene

[3] Nutrient Reference Values for Vitamin D, Niacin and Iodine may not be applicable for countries where national nutrition policies or local conditions provide sufficient allowance to ensure that individual requirements are satisfied. See also section 3.2.4.1 of the Codex Guidelines on Nutrition Labelling.

PROPOSED DRAFT GUIDELINES FOR THE USE OF HEALTH AND NUTRITION CLAIMS
(At Step 3 of the Procedure)

1. SCOPE

1.1 These guidelines relate to the use of nutrition and health claims in food labelling.

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.

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.

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

(Examples:[1] "source of calcium";
"high in fibre and low in fat";)

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

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

2.1.3 Nutrient function claim is a nutrition claim that sets out in general terms the nutritional consequences for good health of the intake of a particular nutrient.

(Examples: "Calcium aids in the development of strong bones and teeth";
"Protein helps build and repair body tissues";
"Iron is a factor in red blood cell formation";
"Vitamin E protects the fat in body tissues from oxidation";
"Sugars provide a source of quick energy for the body".)]

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

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[1]Examples included for clarification of definitions.

(Examples:

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

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

"X bran lowers blood cholesterol levels."

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

"Contains soluble fibre that lowers blood cholesterol levels."

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

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

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

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

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

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

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

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. NUTRIENT CONTENT CLAIMS

4.1 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.

4.2 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".

5. COMPARATIVE CLAIMS

Comparative claims should be permitted subject to the following conditions and based on the food as sold:

5.1 The foods being compared should be different versions of the same food or similar foods.

5.2 The foods being compared should be clearly identified. 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:

5.2.1 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.

5.2.2 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.

5.3 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[1].

5.4 [The use of "reduced" (e.g. light) or "increased" should be restricted to changes of at least 25% of energy or macronutrients or 10% of the NRVs for micronutrients. This should not preclude factual numerical statements about smaller changes.]

6. NUTRIENT FUNCTION CLAIMS

6.1 Claims relating to the function of a nutrient in the body should be permitted provided the following conditions are fulfilled:

6.1.1 The claim is for a generally recognized and accepted action or effect of a nutrient;

6.1.2 The claim is to the effect that the nutrient is a factor or an aid in maintaining the structure and functions of the body necessary to normal growth and development and the maintenance of good health and of activity; and

6.1.3 The food for which the claim is made should be a significant source of the nutrient in the diet.

7. HEALTH CLAIMS

7.1 A health claim that a food or a nutrient or substance contained in a food has a health-related effect on the body [should/should not] be permitted.

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

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 aspect of the food. They should be required to 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[2]

COMPONENT	CLAIM	CONDITIONS
A.		**NOT MORE THAN**
Energy	Low	40 kcal (170 kJ) per 100 g (solids) or 20 kcal (80 kJ) per 100 ml (liquids)
Fat	Low	3 g per 100 g (solids) or 1.5 g per 100 ml (liquids)
	Free	0.15 g per 100 g/ml
Saturated Fat	Low	1.5 g per 100 g (solids) or 0.75 g per 100 g (liquids) and 10% of energy
Cholesterol	Low	20 mg per 100 g (solids or 10 mg per 100 ml (liquids) and 1.5 g per 100 g (solids) or 0.75 g per 100 g (liquids) and 10% of energy
Sugars	Free	0.5 g per 100 g/ml
Sodium	Low [Very Low] [Free]	120 mg per 100 g [40 mg per 100 g] [5 mg per 100 g]
B.		**NOT LESS THAN**
Fibre	Source	[2 g per serving]
	High	[4 g per serving]
Protein	Source	[10% of reference RDA/100 g]
	High	[20% of reference RDA/100 g]
Vitamins and Minerals	Source	[10-15% of reference RDA/100 g]
	High	[20-30% of reference RDA/100 g]

[2]As amended by Codex Committee on Nutrition and Foods for Special Dietary Uses, their 18th Session September 28 - October 2, 1992.

CONSIDERATION OF POTENTIAL ALLERGENS IN FOODS

(Working paper prepared by Norway, in cooperation with Finland, Iceland and Sweden)

1. TERMS OF REFERENCE AND SCOPE OF THE DOCUMENT

At its 21st Session, the Codex Committee on Food Labelling (CCFL) agreed to discuss a working paper at its next session which would examine the labelling of potential allergens which were included as components of composite ingredients in foods, and thus were not included in the ingredients list. The working paper would be prepared under the direction of Norway, with assistance provided by Finland, Iceland and Sweden.

The Committee noted that this issue would require examination of Section 4.2.1.3 of the General Labelling Standard, which addressed the labelling of composite ingredients, especially as related to the "25% rule". The working paper would examine this issue in detail, and would include possible recommendations to the Committee for their consideration. It was also concluded that the CCEXEC would be informed of CCFL deliberations in this area (ALINORM 91/22, paras. 146-147).

At its thirty-eighth session, the Executive Committee expressed "concern as to the practicality of the proposal, as almost all foods contained potential allergens. With this in mind, the Executive Committee recommended that the CCFL should proceed cautiously when examining this subject" (ALINORM 91/4, paras. 49-50).

The present working paper summarises the main issues of the matter. These are considered in more depth in the annex to the paper, which also contains a list of references.

In accordance with the above terms of reference, the main emphasis of the present document is on problems associated with the declaration of composite ingredients. However, certain other aspects of labelling which are of concern to consumers with hypersensitivity problems have also been addressed, in particular the use of class names.

2. INTRODUCTION

The Codex General Labelling Standard provides the basis for national food labelling regulations in many countries throughout the world.

Because of the widespread occurrence of hypersensitivity problems, often of a serious nature, and of the ever-increasing variety of food products, often unfamiliar, offered to the consumer, the need for more informative labelling to help those affected is also increasing. The Provisions of the General Standard should reflect this situation.

3. HYPERSENSITIVITY - ALLERGY AND INTOLERANCE

Hypersensitivity reactions can be divided into allergy, which is a condition in which the immune response is altered, and intolerance for which no immunological cause has been detected. Intolerance may arise in association with metabolic disorders, such as lactose intolerance, or may be of unknown etiology. Coeliac disease involves the immunesystem but is not an allergic disease. The mechanism is not fully known.

Common allergens are proteins, whereas a variety of substances may cause intolerance.

In this document hypersensitivity is used as a collective term to denote both allergy and intolerance.

3.1 Occurrence

Data and estimates concerning the occurrence of hypersensitivity in general vary considerably from just a few to more than 40% of the population. Even the most conservative estimates imply that a large number of consumers are affected by hypersensitivity in some form or another. If only 2% were actually to suffer from such reactions, which is probably an underestimation, this would mean millions of affected consumers in Europe alone.

A Swedish official report concludes that food hypersensitivity occurs in about 20% of children up to three years old, 8% among six-year olds, about 15% among young adults, and is probably just as common in older people.

Hypersensitivity to food additives is uncommon in people who are not otherwise affected by allergic conditions. A Danish study reports a prevalence of 1-2% among school children.

Lactose intolerance is very common on a world basis, in some countries 90% of the population being reported to have this intolerance.

Coeliac disease has also a very high occurrence in some countries, for example in Sweden, where 1 in 300 are reported to suffer from the condition. The prevalence of both types of intolerance, however, varies considerably from country to country.

A reasonable estimate of the overall incidence of food hypersensitivity in some form would seem to be about 10% of the population.

3.2 Food which most commonly give rise to hypersensitivity

A number of commmon foods cause symptoms in many people in many parts of the world, which may be unpleasant and reduce the quality of life. Other allergies and intolerances are not so common, but nevertheless very serious for those concerned. Normal foods can induce reactions of a crippling, even life-threatening, nature.

It is difficult to make a complete and exhaustive list because hypersensitivity reactions are very individual, and because hypersensitivity reactions are related to patterns of consumption and dietary habits, especially in childhood. For instance, allergy to rice in Japan and to corn (maize) and peanuts in USA is more common in these countries than in Scandinavia. This means that there will be differences between population groups and countries as regards the foods most commonly giving rise to allergy and intolerance.

The foods and ingredients which have been well-documented and generally accepted to give rise to hypersensitivity reactions in people are: cereals; eggs; fish; legumes; milk; nuts, almonds etc.; fish; shellfish/crustacea. These foods may cause manifest symptoms in a large

number of people, and may be life-threatening or cause long-standing medical problems in small amounts in susceptible people.

Several types of fruit and vegetable give rise to symptoms in people with pollen allergies. Aspects such as amount, severity, effects of processing etc., have, however, not been fully elucidated.

As regards food additives, it has been documented that sulphites at levels down to 10 ppm may cause severe reactions in susceptible individuals. It is also known that colours, especially azo-colours, preservatives such as benzoates, and antioxidants such as BHA and BHT, give rise to hypersensitivity. The effects of these and other substances, especially concerning the amounts necessary to trigger off reactions, appear not to have been fully clarified.

4. PROBLEMS ASSOCIATED WITH LABELLING REGULATIONS

The essential requirements which hypersensitive consumers have as regards food labelling are:

a) that the declaration of ingredients must be sufficiently precise so as to enable the avoidance of food components which are not tolerated, and

b) that the labelling designations used must be familiar, unequivocal, and not subject to misunderstanding.

The main rule for the declaration of ingredients in the Codex General Standard on Labelling as contained in Section 4.2.1.2 is that there shall be a complete and detailed declaration.

However, less specific declaration of ingredients is permissible in certain cases. Especially important in this connection are the so-called 25% rule (4.2.1.3), and the use of class names (4.2.2.1).

4.1. Compound ingredients - the 25%-rule

Section 4.2.1.3 of the General Standard reads:

> "Where an ingredient is itself the product of two or more ingredients, such a compound ingredient may be declared, as such, in the list of ingredients provided that it is immediately accompanied by a list in brackets of its ingredients in descending order of proportion (m/m). Where a compound ingredient for which a name has been established in a Codex standard or in national legislation constitutes less than 25% of the food, the ingredients other than food additives which serve a technological function in the finished product need not be declared."

The 25% rule means that a substance which is present in only a small amount as an ingredient in a food has to be declared, while the same substance present in fairly large amounts as a component of a compound ingredient need not be declared.

According to the General Standard, the rule shall only be applied to products for which there is a Codex standard, or which are defined in the national legislation of the country in which the food is sold. This must mean that the compound ingredients which are not declared in full as to their component ingredients, must have a composition which is the same at all times in all products. This also presumes that the composition of the ingredient is familiar to the consumer, or that the necessary information is readily available.

The current trend in food legislation policy away from vertical commodity standards and towards general horizontal legislation with emphasis on labelling, implies the presence on the market of an increasing number of products and ingredients without the standardised composition which is the prerequisite for being able to omit the declaration of the components of a compound ingredient according to the 25% rule.

The 25% rule is in many countries also being applied to products which are produced according to custom or tradition, without the composition necessarily being specified in a standard.

Increasing international trade and greater efforts to achieve international harmonisation of food regulations, has resulted in a tendency for countries to accept products which are in accordance with other countries' standards or traditions. If these are included as compound ingredients in another product, there is every likelihood that specification of these compound ingredients will not be required. Consumers will usually not be aware of the standards or customs in other countries; nor will it be easy to obtain the relevant information.

In practice many countries apply the rule to all compound ingredients present at a level of less than 25%, and not just those for which there is a compositional standard.

Extensive world trade in foods, and developments in processing and technology increase these problems.

As many processed foods, non-traditional ingredients, imported foods with a non-traditional composition, and new and novel ingredients are unfamiliar to the consumers, it is essential that the labelling is sufficiently detailed.

The unsatisfactory declaration of compound ingredients concerns not only the rule per se, but also the way in which this Codex provision is interpreted in different countries.

This situation gives cause to raise the question as to whether the 25% rule is in fact still a valid one. A rule which in many parts of the world is not being implemented as was intended, and which is no longer in harmony with current practice, has perhaps outplayed its role.

4.2 Class names

The use of class names may conceal the presence of allergenic ingredients. This is an unsatisfactory situation for hypersensitive people, and may result in unexpected hypersensitivity reactions, or at least cause such consumers to avoid more foods than actually necessary.

4.3 Food additives and processing aids

Food additives carried over with raw materials/ingredients at levels which do not serve a technological function in the finished product, and processing aids, need not be declared.

As regards food additives and hypersensitivity, there is evidence that sulphites induce hypersensitivity reactions when present at levels exceeding 10 mg/kg, i.e. below the level for technological effect.

The significance of other potential intolerance-inducing food additives (e.g. benzoates, azo-colours, antioxidants, glutamate etc.) being present without declaration is less certain and needs further investigation. It is also a question as to how the carry over-principle and the term "technological effect" is interpreted and practised.

4.4 Conclusion

The General Labelling Standard is not satisfactory as regards ensuring that hypersensitive people receive adequate information to enable them to limit their selection of foods to those which they can tolerate, and help them avoid those which they cannot. Because of the extent and gravity of the problem, it seems proper that the consumers concerned should receive the information they need concerning the composition of foods, either through improved labelling regulations, or other appropriate means.

5. ALTERNATIVES TO LABEL DECLARATIONS

Detailed product information could be collated in data banks, product catalogues, etc. However, there will always be uncertainty as to whether such information is up-to-date.

As reliance on wrong or incomplete information may have considerable adverse health implications, such systems may in fact aggravate the situation for the consumers concerned, unless they function properly. This type of information is unlikely to cover the whole range of products, it is unlikely to reach out to all consumers, and it is unlikely that the products included in catalogues are always available to all consumers.

Product catalogues, databases etc would be useful supplements to label information, but could not replace detailed labelling.

Nor is it possible to develop symbols or the like to adequately replace detailed and correct labelling. This idea must be treated with great caution. People suffering from hypersensitivity may react to several food components, the combinations of specific allergies/intolerances varying from person to person. A product which is suitable for one patient may be life-threatening for another.

6. IMPROVEMENT OF LABELLING REQUIREMENTS IN RELATION TO HYPERSENSITIVITY

The only satisfactory solution with regard to ensuring that consumers suffering from hypersensitivity conditions are given adequate information, is to improve labelling requirements.

Incomplete labelling may result in the ingestion of food which may cause considerable discomfort, and at worst serious illness and even death.

The key principle with regard to labelling provisions in relation to allergy and intolerance should be that ingredients which may induce hypersensitivity should, as far as possible, be specifically mentioned in the list of ingredients. Particular emphasis must be given to substances of which even small amounts may trigger off severe reactions, such that ingredients which give severe, debilitating or life-threatening symptoms are <u>always</u> declared.

6.1 Amendment of the 25%-rule

As regards the 25% rule, an appropriate solution would seem to be to reduce the lower limit above which declaration of the components of a compound ingredient is required. Based on an assessment of what is feasible, this lower limit could be set at 5%. Such a limit would necessitate full declaration of the ingredients in a compound ingredient in very many cases. However, even this lower limit will not ensure the declaration of potent allergens capable of

inducing severe hypersensitivity reactions in small amounts. Should compound ingredients contain such components, measures should be taken to make sure that these are always declared.

6.2 Amendment of the provisions concerning class names

Although the ideal solution (from the point of view of hypersensitivity) would be to revoke the provisions allowing declaration of ingredients by class names, this seems to be unrealistic, at least in the short term. However, it should be required that at least ingredients containing the most potent substances be always declared specifically, and not just by class names.

6.3 Amendment to the rules for the declaration of carried-over food additives

Food additives which are carried over with raw materials and compound ingredients, and which can induce hypersensitivity reactions in amounts present in the product, should always be declared regardless of whether they have technological effect or not. This has been documented for sulphites, and the corresponding situation for other additives and processing aids should be investigated.

6.4 Declaration of potent hypersensitivity-inducing substances

Provisions in the General Labelling Standard concerning the declaration of compound ingredients, class names, and the declaration of food additives carried over with raw materials/ingredients, should be amended so as to always require the specific declaration of ingredients which may cause severe allergic or hypersensitivity reactions. A list of ingredients which should always be declared by specific name should be elaborated. The list should be open-ended and be supplemented as needed, in the light of new information.

7. RECOMMENDATIONS

7.1 Amendment of the Codex General Labelling Standard

In light of the considerations presented in this document, it is recommended that that the Committee (CCFL) discuss the following proposed amendments to the Codex General Labelling Standard (text to be deleted in brackets) <u>text to be added underlined</u>:

Section 4.2.1.3:

Where an ingredient is itself the product of two or more ingredients, such a compound ingredient may be declared, as such, in the list of ingredients, provided that it is immediately accompanied by a list in brackets of its ingredients in descending order of proportion (m/m). Where a compound ingredient (for which a name has been established in a Codex standard or in national legislation) constitutes less than (25%) <u>5%</u> of the food, the ingredients other than food additives which serve a technological function in the finished product <u>and ingredients known to cause allergic or intolerance reactions,</u> need not be declared.

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

<u>Barley, oats, wheat, rye, triticale , and products of these (gluten and starch included)</u>

<u>Crustaceans, shellfish, and products of these</u>

Eggs and egg products

Fish and fish products

Legumes: peas, peanuts, soybeans and products of these

Milk and milk products (lactose included)

Sulphite in concentrations of 10 mg/kg or more

Tree nuts, poppy seeds, sesame seeds and products of these

Section 4.2.2.1:

Except for ingredients known to cause reactions of allergy or intolerance such as those listed in Section 4.2.1.3, the following class names may be used.....etc. (rest of section as is).

Section 4.2.3.2:

A food additive carried over into foods at a level less than that required to achieve a technological function, and processing aids, are exempted from declaration in the list of ingredients. The exemption does not apply to food additives and processing aids known to cause reactions of food allergy or intolerance, such as those listed in in Section 4.2.1.3.

7.2 Further consideration of the issues.

Carried-over food additives and processing aids.

In addition to the above recomendations, it is proposed that the Codex Committee on Food Additives and Contaminants (CCFAC) is requested to assist in assessing labelling requirements for carried-over food additives and processing aids.

CCFAC should be asked to report on what hypersensitivity-inducing food additives and processing aids are likely to be present in a product in amounts which may induce a hypersensitivity response, without, under current requirements, having to be declared. As regards carried-over food additives, the relationship between levels which have a technological function and levels which are required to elicit a reaction will be important. It is also of importance to define precisely how the term "technological function" is to be understood and interpreted in practice, and to consider whether declaration of intolerance-inducing food additives should be required above a certain level rather than being tied to the concept of technological effect.

Other ingredients

Recommendations concerning other ingredients such as rice, corn (maize), oils, fruits, vegetables, spices, hydrolized proteins etc. require further investigation.

Annex

LABELLING OF FOODS THAT MAY CAUSE HYPERSENSITIVITY.

Background document
Annex to the working document "Labelling of potential allergens"
Prepared by Norway (Ragnhild Kjelkevik) in cooperation with Finland, Iceland and Sweden.

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- 5.4 Declaration of potent hypersensitivity-inducing substances

6. RECOMMENDATIONS

6.1 Amendment of the Codex General Labelling Standard

6.2 Further consideration of the issues.

7. LIST OF REFERENCES

1. BACKGROUND

The Codex General Labelling Standard provides the basis for national food labelling regulations in many countries throughout the world. In light of the widespread occurrence of hypersensitivity problems, and of their not infrequent serious nature, and of the consequent critical significance of food labelling for people with allergies, there seems to be good reason to re-examine the Standard with the needs of this group of consumers in mind.

Various forms of food hypersensitiviuty affect many people, either directly, or indirectly (for example when responsible for preparing food for family members with allergies). Hypersensitivity in general is becoming more common (1,2). Lacking valid data for prevalence, it is not known whether the occurrence of hypersensitivity to food in general is increasing. The frequency of allergy to pollen is, however, rising, which could mean that the prevalence of pollen-related reactions to foods like nuts, apples etc is also increasing.

The food components causing the hypersensitivity varies with the individual.

Hypersensitivty reactions also vary considerably both as to type and degree of severity, from mild discomfort to life-threatening symptoms. However, generally speaking, hypersensitivity gives rise to problems, sometimes serious, in the daily life of many consumers. The only effective countermeasure is to avoid the substances which connot be tolerated.

Problems are mostly due to commonly used foodstuffs and ingredients, foodstuffs which are desirable in the diet of normal healthy people. It is not feasible to protect hypersensitive consumers by forbidding or limiting the use of such foodstuffs. The regulation of food additives in this connection would only have a marginal effect, and would have to be limited to apply to certain types of foods, for example staple foods.

Labelling constitutes the most important aid in enabling the consumer to avoid products likely to induce hypersensitivity reactions. It is therefore essential that potentially hypersensitivity-inducing ingredients are properly declared.

The current trend is towards the production of more and more processed compound foods, using new and non-traditional ingredients. The horizontal approach to food law has resulted in a move away from commodity standards towards general regulations with emphasis on informative labelling. Foods with a standardised composition are becoming less common.

The removal of trade barriers and the freer movement of foods in international trade, also gives rise to a situation where consumers are faced with new and unfamiliar products. This adds importance to the international harmonisation and uniform application of labelling regulations.

Consumers have less insight into the composition of the variety of food products on the market, and are therefore dependent upon adequate information in order to know what they are buying.

2. HYPERSENSITIVITY REACTIONS

Hypersensitivity reactions are classified somewhat differently in different parts of the world. The most important distinction is between allergy, and what can be termed intolerance/pseudo-allergy.

In this document hypersensitivity is used as a collective term to denote both allergy and intolerance.

2.1 Allergy

Allergy is a condition in which the immune response is altered. The response is specific and can be induced by very small amounts of the substance in question, the allergen.

Well documented common allergens are proteins from milk, eggs, fish, nuts, legumes, and cereals. For some people, minute amounts of these allergens can give rise to life-threatening symptoms.

Allergies to proteins in fruits and vegetables are common in patients suffering from pollen allergy (hay fever). These are probably caused by sensitisation to pollen via the respiratory tract. IgE antibodies cross-react with epitopes in pollen and in the fruit or vegetables in question (3).

The possibility of certain contact allergens such as nickel being able to induce reactions on ingestion has also been suggested (4).

2.2 Intolerance/pseudo-allergy

It is sometimes impossible to determine an immunological cause of hypersensitivity reactions. In such cases, the condition is often termed intolerance or pseudo-allergy.

Hypersensitivity is also associated with metabolic disorders, for example lactose intolerance. Other reactions are of unknown etiology. Coeliacic diseases involves the immunesystem but is not an allergic disease. The mechanism is not fully known.

The symptoms of intolerance may be the same as observed in food allergy.

Proteins may also cause allergy-like symptoms without any role of the immune system being identified.

Certain food additives have been stated to cause intolerance.

2.3 Symptoms

Symptoms of allergy manifest themselves not only in the alimentary tract but also in the skin, respiratory tract, or as general systematic signs:

Gastro-intestinal tract	Itching and swelling of the mouth, nausea, vomiting, colic, diarrhoea
Skin	Urticaria, eczema
Respiratory tract	Rhinitis, asthma
Systematic	Anaphylactic shock

2.4 Occurrence

With regard to children, studies carried out in Finland (5) and USA (6) have revealed that approx. 8% of children under, respectively, three and four years of age showed confirmed hypersensitivity reactions.

Some authors estimate the incidence of food allergies in children to be 1-3%, with a figure perhaps as high as 30% in some groups, for example, children with atopic dermatitis (7), while others consider that approx. 20% of all children react (8).

The frequency of many typical child allergies falls with increasing age. Other types of hypersensitive response, however, arise later on, especially the food allergies which are associated with pollen allergy. Approx. 50% of patients with birch pollen allergy react to food, especially nuts, and fruits and vegetables (8). This type of allergy is probably on the increase as respiratory tract allergies are becoming more common.

Because it is difficult to perform satisfactory epidemiological studies of the prevalence of hypersensitivity to foods in adults, few such studies have been carried out.

A Swedish study indicates that about 15% of people between 25-30 years old have some form of food hypersensitivity (8). Others refer to estimates in the area of 10-15% (9,10).

A Swedish official report mentions that the prevalence data to be found in the literature varies considerably, from a few percent up to 43%, but concludes that food hypersensitivity occurs in about 20% of children up to three years old, 8% among six-year olds, about 15% among young adults, and is probably just as common in older people (8).

Hypersensitivity to food additives is uncommon in people who are otherwise not affected by allergic conditions. Investigations in England showed that though about 7% of the population considered themselves to be hypersensitive to food additives, this could only be confirmed in 0.2% at the most (11).

Studies in Denmark revealed a prevalence in schoolchildren of approx.1-2%. The children reacted to food additives such as artificial colours and preservatives. All the children who reacted to food additives had some form of concurrent allergic condition (12).

A controlled challenge of asthma patients who stated that they did not tolerate red wine showed that 5% reacted to sulphite in the red wine (13). In another investigation (14) of asthmatics, it was shown that about 5% of the patients reacted to sulphite (15), tartrazine and other food additives. Patients suffering from urticaria may react to tartrazin and other azo-colours (15b).

As regards specific diseases, it should be mentioned that coeliac disease is considered to affect at least one European in a thousand. However, there is considerable inter-country variation. In certain European countries, the frequency seems to be increasing, being as high as one in 300 in Sweden (16). Frequency of one in 496, and one in 585, have been reported in Austria (17) and Israel (18), respectively.

Lactose intolerance is very common on a world basis, prevalence being very high among certain population groups in some countries. For example, figures of up to 87-89% of people with lactose intolerance have been reported from several Asiatic and African countries. In other countries, for example among the dark-skinned population in North America, India, and Israel, prevalence can be about 50%, compared with the corresponding figure of 3% in Denmark (19).

Data and estimates concerning frequency of food hypersensitivity in general show considerable variation, from a few percent to about 40% of the population. However, even the most conservative figures imply that a large number of consumers are affected by hypersensitivity in one form or another. If only 2% were actually to suffer from such reactions, which is probably an underestimation, this would mean millions of affected consumers in Europe alone.

A reasonable estimate for the overall incidence of food hypersensitivity would seem to be about 10%.

2.5 Foods which most commonly give rise to hypersensitivity

A number of commmon foods cause symptoms in many people in many parts of the world, which may be unpleasant and reduce the quality of life. Other allergies and intolerances are not so common, but nevertheless very serious for those concerned. Normal foods can induce reactions of a crippling, even life-threatening, nature.

A brief account is given in the following of the foodstuffs and ingredients which most often induce reactions. Many of these foods, even in small amounts, may trigger off anaphylactic shock in susceptible people.

The list is not complete or exhaustive, both because hypersensitivity reactions are very individual, and because hypersensitivity reactions are related to patterns of consumption and dietary habits, especially in childhood. For instance, allergy to rice in Japan and to corn (maize) and peanuts in USA is more common in these countries than in Scandinavia. This means that there will be differences between population groups and countries as regards the foods most commonly giving rise to allergy and intolerance.

Nuts, almonds, and the like: People allergic to nuts may react to very small amounts, reactions such as anaphylactic shock not being unusual. People who are allergic to pollen from deciduous trees often suffer from allergy to nuts.

Fish: Fish allergy is not among the most common forms of allergy, but often give rise to dramatic symptoms, - for some people minute amounts of fish is enough to cause an attack. All species of fish may be involved. People with egg allergy sometimes also have fish allergy.

Shellfish and crustacea: It is not uncommon for such foods to give rise to pure allergic reactions and to other forms of hypersensitivity.

Eggs: Egg allergy is most frequently seen in children. Most of the allergenic substances are present in the egg white.

Milk: Cows-milk allergy with acute symptoms may occur in infancy, perhaps immediately after weaning. The allergy may be transient, most three to four-year olds tolerating milk. Another type of milk allergy is the so-called slow form, which often affects somewhat older children.

Milk may also induce intolerance reactions. Many people in the world lack lactase, the enzyme breaking down lactose.

Legumes: Proteins in soy beans, peas, peanuts, and other legumes, often cause allergic reactions. Such allergies may be life-threatening, for example, soy, peanut and pea allergies.

Protein residues in, for example, starch and fibre products from these sources may be enough to give cause manifest symptoms of hypersensitivity.

Cereals: Cereals may give rise to several types of hypersensitivity. Wheat, rye, barley, and oats, contain the protein gluten, which damages the intestinal mucosa in some people (coeliac disease). Very small amounts of gluten are sufficient to cause illness in people suffering this condition.

Cereals may also cause allergy.

Fruit and vegetables: This members of this large and heterogenous group of foods contain substances which may cause reactions. The substances giving rise to symptoms are often heat-labile. As mentioned previously, many of the foods in this group give cross-reactions with pollen. Reactions may be severe.

Food additives: In spite of the widespread view that many food additives can cause hypersensitivity reactions, this has been actually confirmed for only a very few substances. These are colours (mainly azo-colours), the preservatives benzoic acid/benzoates and sulphites, and the antioxidants butylhydroxyanisol (BHA) and butylhydroxytoluene (BHT) (20,21).

As mentioned above, hypersensitivity to food additives is very unusual in people not already suffering from an allergic condition. Symptoms in some cases may be grave; this is especially the case with regard to reactions against sulphite in people suffering from asthma, amounts of sulphite as low as 10 ppm giving symptoms (22).

It is otherwise difficult to find unequivocal data in the literature regarding the amounts of various food additives which can give rise to reactions. However, it seems that in some cases small amounts may be involved, 50 mg og benzoate having, for example, been shown to cause reactions (23). The same is true for BHA/BHT (24) and azo-colours (25).

Although glutamate has been described as a cause of asthma, it seems mainly to have other modes action (26).

As regards food additives, reference is also made to a background document elaborated for the 1985 meeting of the (then) Codex Committee on Food Additives (27).

> **The foods and ingredients which have been well-documented and generally accepted to give rise to hypersensitivity reactions in people are: cereals; eggs; fish; legumes; milk; nuts, almonds etc.; shellfish/crustacea.**
>
> **These foods may cause manifest symptoms in a large number of people, and may be life-threatening in small amounts in susceptible people. Several types of fruit and vegetable give rise to symptoms in people with pollen allergies. Aspects such as amount, severity, effects of processing etc., have, however, not been fully elucidated.**
>
> **As regards food additives, it has been documented that sulphites at levels down to 10 ppm may cause severe reactions in susceptible individuals. It is also known that colours, especially azo-colours, preservatives such as benzoates, and antioxidants such as BHA and BHT, give rise to hypersensitivity. The effects of these and other substances, especially concerning the amounts necessary to trigger off reactions, appear not to have been fully clarified.**

3. PROBLEMS ASSOCIATED WITH LABELLING REGULATIONS

The essential requirements which hypersensitive consumers have as regards food labelling are:

a) that the declaration of ingredients must be sufficiently precise so as to enable the avoidance of food components which are not tolerated, and

b) that the labelling designations used must be familiar, unequivocal, and not subject to misunderstanding.

The main rule for the declaration of ingredients in the Codex General Standard on Labelling is contained in Section 4.2.1.2:

> "All ingredients shall be listed in descending order of ingoing weight(m/m) at the time of the manufacture of the food."

In other words, the main rule is that there shall be a complete and detailed declaration.

However, less specific declaration of ingredients is permissible in certain cases. It is these exemptions i.e. the so-called 25% rule, and declaration by class names, which cause problems for hypersensitive consumers, and which therefore must be examined with regard to possible amendment to alleviate the situation.

3.1 Compound ingredients - the 25% rule.

Section 4.2.1.3 of the General Standard reads:

> "Where an ingredient is itself the product of two or more ingredients, such a compound ingredient may be declared, as such, in the list of ingredients provided that it is immediately accompanied by a list in brackets of its ingredients in descending order of proportion (m/m). Where a compound ingredient for which a name has been established in a Codex standard or in national legislation constitutes less than 25% of the food, the ingredients other than food additives which serve a technological function in the finished product need not be declared."

This provision leads to the paradoxical situation that a substance added to a food in small amounts as an ingredient must be declared, whereas the same substance can be present in much larger amounts in another product, as a component of a compound ingredient, without being declared.

3.1.1 Prerequisites for the application of the 25% rule

According to the General Standard, the rule shall only be applied to products for which there is a Codex standard, or which are defined in the national legislation of the country in which the food is sold. This must mean that the compound ingredients which are not declared in full as to their component ingredients, must have a composition which is the same at all times in all products. This also presumes that the composition of the ingredient is familiar to the consumer, or that the necessary information is readily available.

There is every reason to question whether these presumptions are fulfilled for foods on the market today. Moreover, commodity standards do not always regulate all ingredients in a food product, which means that ingredients can be present which are not specified in the standard.

The most important consideration, nevertheless, is that both in Codex and at the national level, work on detailed recipe standards is being played down in favour of general, horizontal rules, with stress on, among other things, informative labelling.

The current trend in legislative policy implies that more and more food products and ingredients are appearing on the market which do not have the standardised composition on which the 25% rule is based. In theory, the rule should then not be applied.

3.1.2 Implementation of the 25% rule

In many countries the 25% rule is also being applied to products which are produced according to custom or tradition, without the composition necessarily being specified in a standard. In practice, this often mean most or all composite ingredients present in amounts less than 25%.

Increasing international trade and greater efforts to achieve international harmonisation of food regulations, has resulted in a tendency for countries to accept products which are in accordance with other countries' standards or traditions. If these are included as compound ingredients in another product, there is every likelihood that the declaration of the component ingredients in the compound ingredient will not be required.

Consumers will usually not be aware of the standards or customs in other countries; nor will it be easy to obtain the relevant information.

There thus seems to be trend that the rule is applied to all compound ingredients present in the product at a level of less then 25%.

3.1.3 Evaluation of the 25%-rule

The 25%-rule creates difficulties for people who for health reasons must avoid eating a number of commonly used food ingredients.

Extensive world trade in foods and developments in processing and technology increase these problems.

As many processed foods, non-traditional ingredients, imported foods with a non-traditional composition, and new and novel ingredients are un-familiar to the consumers it is essential that the labelling is sufficiently detailed.

For instance, fat substitutes made from egg and milk protein have been shown to induce symptoms in people allergic to eggs and milk (28). It is essential that ingredients like these are specified on the label.

It can be claimed that the basis for the 25%-rule has been considerably undermined by the fall in the number of standardised products, the increasing volume of international trade in food, and the fact that foods and ingredients with different compositions are being marketed under similar names.

This unsatisfactory declaration of compound ingredients concerns not only the rule per se, but also the way in which this Codex provision is interpreted in different countries.

This situation gives cause to raise the question as to whether the 25%-rule is in fact workable in practice. A rule which in many parts of the world is not practised as intended, and which is difficult to adapt to the current situation, has outplayed its role.

3.2 Ingredient designations

There is no doubt that the most important aspect of labelling as regards hypersensitivity is to ensure adequate specification of the list of ingredients. However, it must be emphasised that it is also very important that ingredient designations are unequivocal and not open to misunderstanding.

Increasing international trade will aggravate the problem in that designations might well be used that are understandable in the exporting country but which do not provide enough information to consumers in the importing country.

It is also important that the ingredient declaration is sufficiently specific.

3.3 Class names

Section 4.4.2.1 of the General Standard provides for the declaration of certain ingredients by class name instead of specific name. Several of these classes include ingredients which may induce reactions in hypersensitive people.

For example, peanut oil is in some countries associated with allergic reactions, but need not be declared specifically, only by the class name "vegetable oil". The same may be the case for other fats and oils.

Starchs from various sources can be declared as "starch" without specification of source. There is a possibility that pea starch may contain sufficient amounts of pea protein to trigger off an allergic reaction in pea-hypersensitive people. The label declaration in this case will give no indication that the product contains pea components. Apparently some kinds of wheat starch may contain gluten in amounts large enough to affect consumers with coeliac disease.

As regards spices, the situation is unclear. There are some indications of sensitive people reacting to nutmeg in amounts less than 2%, when only the class name "spice" is required.

Consumers who are aware that they do not tolerate certain ingredients within a class will often "play safe" and simply not buy a product, when the label does not give a specific indication of the ingredients.

> **In light of the above considerations, the use of class names provided for in the General Standard is not satisfactory for hypersensitive people. The declaration of allergy-inducing ingredients by general class names may either result in unforeseen hypersensitivity reactions, or in the consumers in question having to refrain from buying food products more often than actually necessary.**

3.4. Declaration of carried-over food additives and processing aids

The 25 %-rule clearly states that food additives in the compound ingredient which have a technological function in the finished product shall be declared even though the remaining ingredients in the compound ingredient need not be declared. This is also provided for in Section 4.2.3 of the General Standard, which states:

> "4.2.3.1 A food additive carried over into a food in a significant quantity or in an amount sufficient to perform a technological function in that food as a result of the use of raw materials or other ingredients in which the additive was used shall be included in the list of ingredients.

4.2.3.2 A food additive carried over into foods at a level less than that required to achieve a technological function, and processing aids, are exempted from declaration in the list of ingredients.

In other words, food additives with no technological function in the finished product will not appear in the list of ingredients, the same being true for processing aids.

Some food additives may trigger off hypersensitivity reactions at levels below that required to exert a technological function, e.g. sulphites.

Others, e.g. benzoic acid, seem to have a technological function at levels inducing reactions, and shall therefore be declared according to the carry-over principle. However, it is a question as to how this provision is interpreted. The amount of benzoic acid in, for example a fruit preparation used as an ingredient in ice cream may be large enough to exert a preservative effect in theory but not have this effect in practice. Whether or not benzoic acid would be declared in such a case is uncertain.

Concerning other intolerance-inducing food additives like antioxidants, colours, glutamate etc. the relationship between amounts triggering off symptoms and levels considered to have technological effect is unclear.

It is also unclear whether certain processing aids, e.g. nickel and chromium used as catalysts in the hydrogenation of fats, or eggwhite and milk used as clarifying agents in the production of juice, nectar and wine, may give residues which are not tolerated by some consumers. Such substances are not declared on the label, making it difficult to find out whether these residues are of any significance.

Sulphites can induce hypersensitivity reactions at levels of 10 mg/kg, i.e. below the level necessary for technological function.

The significance of other potential intolerance-inducing food additives (e.g. benzoates, azo-colours, antioxidants, glutamate etc.) being present without declaration is less certain and needs further investigation. It is also a question as to how the carry over-principle and the term "technological function" is interpreted and practised.

3.5 Conclusion

In light of the above considerations, it seems quite clear that the General Labelling standard is not satisfactory as regards ensuring that sufficient information is provided to people suffering from food hypersensitivity to enable them to choose products they can tolerate and to avoid products they cannot.

Considering the extent and severity of the problem, it is obviously important that the consumers in question are given the information they need, either by improving labelling requirements or in other ways.

4. POSSIBLE ALTERNATIVES TO THE LABEL DECLARATION OF INGREDIENTS

The essential factor for hypersensitive people is that they are able to make an informed choice . The question could be asked whether the relevant information need always be given on the label, or whether it can be provided in other ways. There are several possibilties.

4.1 Product catalogues, data banks etc.

Product catalogues with detailed information on composition, or lists of products not containing certain ingredients, could be elaborated.

Data banks could be established with detailed product information, with consumers with hypersensitivity in mind. Such data banks already exist to a certain extent with lists of products not containing certain ingredients. Up-dated product catalogues with information from the data bank could be regularly issued.

Product information could also be made available in shops, by means of catalogues, signs, notices etc., or perhaps in the form of leaflets.

Such measures are of great benefit for consumers and not least for dieticians and other health personnel, as an aid in dietary planning.

However, there will always be uncertainty as to whether such information is up-to-date. Product composition may be changed without corresponding updating of the information material. This is likely to be especially a problem with imported products. The wide selection of products on the market further adds to the difficulty of ensuring that information is always correct.

Though data bases are somewhat more reliable in this respect, there is still a considerable risk of erroneous information. As reliance on wrong or incomplete information may have considerable adverse health implications, such systems may in fact aggravate the situation for the consumers concerned, unless it functions properly. This type of information is unlikely to cover the whole range of products, it is unlikely to reach out to all consumers, and it is unlikely that the products included in catalogues are always available to all consumers.

Data banks, product catalogues etc. are useful supplements to label information, but cannot replace detailed labelling.

4.2 Symbols and logos

The proposal has been made of developing logos or marks to identify products of a certain composition or which are suitable for people with certain kinds of allergy. This idea must be treated with great caution. People suffering from hypersensitivity may react to several food components, the combinations of allergies/intolerances arising varying from person to person. A product which is suitable for one patient may be life-threatening for another.

It would be a difficult, not to say impossible, task to develop symbols which could replace detailed and correct label declarations.

5. IMPROVEMENT OF LABELLING REQUIREMENTS

As stated above, it seems quite clear that the General Labelling Standard is unsatisfactory as regards the declaration of ingredients which can induce hypersensitivity, and that though alternative ways of providing product information may be very useful, they cannot replace detailed labelling. The labelling requirements especially in need of improvement are the 25%-rule and provisions concerning class names. The lacking obligation to declare certain food additives carried over with raw materials and ingredients may also cause some problems.

Incomplete labelling may result in the ingestion of food which may cause considerable discomfort, and at worst serious illness and even death.

The fundamental principle as regards labelling regulations in relation to allergy and intolerance should be that, as far as practically possible, ingredients which are likely to induce hypersensitivity should be declared in the list of ingredients. Special attention must be given to subtances of which small amounts can trigger off severe reactions.

Uncertainty as to whether labelling is correct also results in many people refraining from buying food which they in fact would have tolerated, because they don't know what the product contains, and dare not run the risk of mistakes . The choice of products available to allergic people becomes unnecessarily restricted, and sales of inadequately labelled foods thus reduced.

5.1 The 25%-rule

Ideally, the best solution would be to revoke the 25%-rule, so that section 4. 2. 1. 2 of the General Standard would apply without exception to compound ingredients. However, this might involve practical difficulties. If several compound ingredients are present in small amounts in a product, the ingredient list could well be very long and complex. The declaration would require a lot of space, would be difficult to read, and the information of interest for a person suffering from allergy perhaps difficult to pick out.

Therefore some limitation on the extent to which compound ingredients should be specified is probably necessary. Though this would not be a completely satisfactory for people with hypersensitivity, the increased though still limited degree to which compound ingredients would be specified, would be a step in the right direction. Many more ingredients would be declared, and many more consumers would benefit.

An alternative solution would be to introduce a provision which does not fix a numerical limit, but which lays down guidelines as to when components in a compound ingredient should be declared. For example, a provision stating that ingredients in a compound ingredient shall be declared to the extent necessary to give the consumer a satisfactory picture of the product, and that should a compound ingredient contain components which may represent a potential health problem, e.g. in connection with allergy or intolerance, such components must always be specifically declared.

Such a rule is, however, difficult to implement, as it implies knowledge and awareness on the part of the producer. This is true even if the rule is supplemented by a list of ingredients likely to give rise to health problems. It would also be open to different interpretation in different countries, and thus may give rise to trade barriers.

The most feasible solution would seem to be to reduce the lower limit for specification of compound ingredients as much as is practically possible. Based on an assessment of what is feasible, this lower limit could be set at 5%.

This would trigger off the requirement to specify the components of a compound ingredient in very many cases. However, such a lower limit would still not ensure the declaration of potent allergens which can induce hypersensitive reactions in small amounts. If compound ingredients contain such substances, they should always be declared.

5.2 Class names

As already mentioned, the use of class names may conceal the presence of allergenic ingredients. Class names also create uncertainty for people who for one reason or another must avoid certain kinds of foodstuffs. It would therefore seem best to revoke the possibility to declare ingredients by class name, and require specific declaration in all cases.

On the other hand, however, the use of class names permits a certain degree of freedom to change recipes according to availability of raw materials etc., without having to change the label. Moreover, spice and herb mixtures, for example, in a product are considered by producers to contribute to the special characteristics of the product, and constitute a production secret which they would be very reluctant to divulge. A proposal to revoke the provisions concerning the use of class names will therefore probably meet with vigorous opposition, and may delay the improvements allergic people sorely need. This should rather be a long-term objective. As the next best solution, the withdrawal of some classes should be considered.

Nevertheless, declaration of the most potent allergenic substances must be ensured.

> **As a minimum solution, a provision should be introduced in the rules governing the use of class names, that states that ingredients which may give rise to health problems in connection with allergy or intolerance may not be declared by class names . A list of ingredients for which specific name declaration is required should be elaborated.**

5.3 Declaration of carried-over food additives

The carry-over principle's rules providing for exemption from declaration (i.e. non-functional levels) should not apply to food additives which are known to trigger off hypersensitivity reactions in amounts lower than those giving technological effects. Based on current knowledge, this would only apply to sulphites.

As mentioned in paragraph 4.4, the situation regarding other food additives is less clear. The issue should therefore be examined further.

> **Food additives which are carried over with raw materials and compound ingredients, and which can induce hypersensitivity reactions in amounts present in the product, should always be declared regardless of whether or not they have technological effect.**

5.4 Ingredients which can give rise to hypersensitivity, and which should always be declared no matter the amount present.

As mentioned above, labelling requirements should ensure that ingredients which can induce grave or life-threatening symptoms are always declared, no matter the amounts in which they are present in the product. If all ingredients are not declared by specific name and all components of compound ingredients not specified, special provisions should be elaborated for the declaration of these particular substances. This will, as mentioned, also be necessary even if the the 25%-rule is changed to a 5%-rule.

These ingredients could be declared in association with the class name, or the compound ingredient, as the case may be. Such declarations as "margarine with milk" or "chocolate containing nuts" are obvious examples.

The rules concerning the declaration of compound ingredients and the use of class names must thus include a requirement that the designation of such ingredients shall include the name of the hypersensitivity-inducing substance contained in the ingredient.

It would seem more appropriate to include the name of the component in question in the list of ingredients, rather than as a separate declaration. A special rubric etc. might well give rise to unnecessary apprehension regarding hypersensitivity in consumers not affected by such conditions. The consumers who require special information would know what to look for, and where.

> **The following ingredients, listed in alphabetic order, can trigger-off reactions in a large number of consumers, and may give rise to serious illness. They should therefore always be declared by specific name in the list of ingredients. The list comprises foods documented to be common causes of allergy and intolerance (7,8,29,30):**
>
> **Barley, oats, wheat, rye, triticale , and products of these (gluten and starch included)**
> **Crustaceans, shellfish, and products of these**
> **Eggs and egg products**
> **Fish and fish products**
> **Legumes: peas, peanuts, soybeans and products of these**
> **Milk and milk products (lactose included)**
> **Sulphite in concentrations of 10 mg/kg or more**
> **Tree nuts, poppy seeds, sesame seeds and products of these**

6. RECOMMENDATIONS

6.1 Amendment of the Codex General Labelling standard

In light of the considerations presented in the document, it is recommended that the Committee (CCFL) discuss the following proposed amendments to the Codex General Labelling Standard (text to be deleted in brackets), text to be added underlined:

Section 4.2.1.3:

Where an ingredient is itself the product of two or more ingredients, such a compound ingredient may be declared, as such, in the list of ingredients, provided that it is immediately accompanied by a list in brackets of its ingredients in descending order of proportion (m/m). Where a compound ingredient (for which a name has been established in a Codex standard or in national legislation) constitutes less than (25%) 5% of the food, the ingredients other than food additives which serve a technological function in the finished product and ingredients known to cause allergic or intolerance reactions need not be declared.

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

Barley, oats, wheat, rye, triticale, and products of these (gluten and starch included)

Crustaceans, shellfish, and products of these

Eggs and egg products

Fish and fish products

Legumes: peas peanuts, soybeans and products of these

Milk and milk products (lactose included)

Sulphite in concentrations of 10 mg/kg or more

Tree nuts, poppy seeds, sesame seeds and products of these

Section 4.2.2.1:

Except for ingredients known to cause reactions of allergy or intolerance such as those listed in Section 4.2.1.3, the following class names may be used .....etc., rest of section as is.

Section 4.2.3.2:

A food additive carried over into foods at a level less than that required to achieve a technological function, and processing aids, are exempted from declaration in the list of ingredients. The exemption does not apply to food additives and processing aids known to cause reactions of food allergy or intolerance, such as those listed in in Section 4.2.1.3.

6.2 Further consideration of the issues.

Carried-over food additives and processing aids.

In addition to the above recomendations, it is proposed that the Codex Committee on Food Additives and Contaminants (CCFAC) is requested to assist in assessing labelling requirements for carried-over food additives and processing aids.

CCFAC should be asked to report on what hypersensitivity-inducing food additives and processing aids are likely to be present in a product in amounts which may induce a hypersensitivity response, without, under current requirements, having to be declared . As regards carried-over food additives, the relationship between levels which have a technological function and levels which are required to elicit a reaction will be important. It is also of importance to define precisely how the term "technological function" is to be understood and interpreted in practice and to consider whether declaration of intolerance-inducing food additives should be required above a certain level rather than being tied to the concept of technological function.

Other ingredients

Recommendations concerning other ingredients such as rice, corn(maize), oils, fruits, vegetables, spices, hydrolized proteins etc. require further investigation.

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APPENDIX V

PROPOSED DRAFT GUIDELINES FOR THE PRODUCTION, PROCESSING, LABELLING AND MARKETING OF ORGANICALLY PRODUCED FOODS
(At Step 5 of the Procedure)

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

FOREWORD

Background

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

2. Organic agriculture is essentially a system based on low external inputs which replace artificial fertilisers and pesticides with an environment that has a high diversity of species and high biological activity. In themselves, organic practices will not ensure that products are completely free of residues of agricultural and veterinary chemicals, and contaminants. It is accepted that pollution from the air, soil, water and other sources is sometimes beyond the control of the operator.

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

4. The term "organic" has generally become well understood by those associated with this form of agriculture although in some parts of the world its suitability has been questioned. Other terms have also been introduced such as "biological" and "ecological" in an effort to describe the organic system more clearly. Nevertheless, the term "organic" appears to be the term most widely accepted by the general community.

5. For the practical application of organic production methods, more detailed standards are needed to assist the operator in achieving optimal systems which are socially, ecologically and economically sustainable. With the increased interest in organic production, a system of farm evaluation has developed to ensure that products labelled and sold as "organic" actually originate from farms that follow organic production methods. In this way, the consumer is assured of the efficacy of the product and the integrity of the operator is protected.

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

7. The concept of close contact between the consumer and the producer was common in the early days of organic agriculture. It has, however, given way to the introduction of external control and certification procedures stimulated by greater market demand, the increasing economic interests in production, and the increasing distance between producer and consumer.

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

9. Apart from a small portion of agricultural commodities marketed directly from the farm to consumers, most products find their way to consumers via established trade channels. Unfortunately, these are not always free from deceptive practices and transparency of the market is necessary for an audit of the trade and processing enterprises.

10. The regulation of a process, rather than a final product, demands responsible action by all involved parties. Generally, it is not possible to fully police the process with inspection staff. Although organic products should be subject to the same testing requirements and standards for safety as conventional products, it is the organic designation which signifies the method of production. To remain credible, the organic industry must be willing to self regulate on an international scale in accordance with internationally adopted guidelines.

11. In some countries a number of organic farmer organizations exist. There may be minor differences between their production standards, ideology and regional or personal affiliations although in most cases their aims align very closely. The formation of national "umbrella" organisations enables the whole organic industry to coordinate its activities and to heighten its impact on both the public and the government.

12. More recently, some governments have moved to authorise the inspection and certification programs created and operated by inspection bodies. This facilitates government-to-government export certification when required by trading partners and enables competent authorities to verify product.

13. These guidelines have been prepared for the purpose of providing an agreed approach to the requirements which underpin production of, and the labelling and claims for, organically produced foods. They take into account the system already introduced in the European Economic Community (EEC), other country developments and the work of the International Federation of Organic Agriculture Movements (IFOAM).

14. The aims of these guidelines are:

- to protect consumers against deception and fraud in the market place and unsubstantiated product claims;
- to protect producers of organic produce against misrepresentation of other agricultural produce as being organic;
- to ensure that all stages of production, processing and marketing are subject to inspection and comply with these guidelines;
- to harmonise provisions for the production, certification, identification and labelling of organically grown produce;
- to provide international guidelines for organic food control systems in order to facilitate recognition of national systems as equivalent for the purposes of imports.

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

16. Import requirements should be based on the principles of equivalency and transparency as set out in the draft GATT decisions on sanitary and phytosanitary measures. In accepting imports of organic

products, countries would usually assess the inspection and certification procedures and the standards applied in the exporting country.

17. As organic production systems continue to evolve, these guidelines are subject to review and amendment. In particular, the lists of permitted substances for the production of organic foods (Annex 2) are open ones subject to additions and deletions on an ongoing basis. The Codex Committee on Food Labelling (CCFL) will therefore regularly review these lists.

Procedures for revision of these guidelines

18. Member governments and international organisations are invited to make proposals to CCFL regarding amendments and/or additions to these guidelines. Specific provisions for the inclusion of materials in Annex 2 are set out in Section 5 of these guidelines. Proposals should be directed in the first instance to the Chief, Joint FAO/WHO Food Standards Programme, FAO, 00100 Rome, ITALY, (Facsimile No (39) 6 5797 3152) with a copy to the Chairperson, Codex Committee on Food Labelling, Consumer Products Branch, Consumer and Corporate Affairs, 50 Victoria Street, Hull, Quebec KIA OC9, Canada (Facsimile No (1) 819 953 2311).

1. SCOPE

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

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

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

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

- the terms "organic", "biological", "ecological", "bio-dynamic" or words of similar intent.

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

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

2. DESCRIPTION AND DEFINITIONS

2.1 Description

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

2.2 Definitions

For the purpose of these guidelines:

(a) "agricultural product" means any product or commodity, raw or processed, that is marketed for human consumption.

(b) "certified organic farm", or, portion of a farm, or site where agricultural products or livestock are produced, means that such land is certified by a nationally recognised inspection body as utilising a system of organic farming as described in these guidelines;

(c) "competent authority" means the official government agency having jurisdiction;

(d) "ingredients" means the substances, including additives, used in the preparation of the products specified in Section 1.1(b) that are still present, albeit in the modified form, in the final product";

(e) "inspection body" means a body which is responsible for verifying that a product sold or labelled as "organic" is produced, processed, [prepared] and handled according to these guidelines;

(f) "labelling" means any words, particulars, trademarks, brand names, pictorial matter or symbols, appearing on any packaging, document, notice, label, board or collar accompanying or referring to a product specified in Section 1.1;

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

(h) "marketing" means holding <u>for sale</u> or displaying for sale, offering for sale, selling, delivering or placing on the market in any other form;

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

(j) "preparation" means cooking, baking, heating, drying, mixing, grinding, churning, separating, extracting, cutting, fermenting eviscerating, preserving, dehydrating, freezing or otherwise manufacturing, and includes packaging, canning, jarring or otherwise enclosing food in a container; *or*:

["preparation" means the operations of processing, preserving and packaging of agricultural products];

(k) "production" means the operations involved in producing agricultural products in the state in which they are normally produced on the farm.

(l) ["veterinary drug" means ....]

3. LABELLING

3.1 Organic products should be labelled in accordance with the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985).

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

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

(b) the product was produced in accordance with the requirements of Section 4 or imported under the requirements laid down in Section 8;

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

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

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

(b) all the ingredients of agricultural origin of the product are, or are derived from, products obtained in accordance with the requirements of Section 4, or imported under the arrangements laid down in Section 8;

(c) the product contains only those ingredients of non-agricultural origin as set out in Annex 2, Table 4A;

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

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

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

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

- providing that such ingredients are of agricultural origin and are not produced in the country or in sufficient quantity in the country in accordance with the requirements of Section 4 of these guidelines.

3.5 Information on non-retail containers should be given either on the container or in accompanying documents, except that the name of the product, lot identification, and the name and address of the manufacturer or packer should appear on the container. Lot identification, and the name and address of the manufacturer or packer may be replaced by an identification mark provided that such a mark is clearly identifiable with the accompanying documents.

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

(a) at least [50%] of the ingredients of agricultural origin satisfy the production requirements of paragraph 3.3(b);

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

(c) the indications referring to organic production methods–

- [appear only in the list of ingredients],

- clearly refer to only those ingredients obtained in accordance with the requirements of Section 4 of these guidelines;

(d) the ingredients, and the relative levels of the ingredients of agricultural origin, appear in descending order (mass/mass) in the list of ingredients;

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

4. RULES OF PRODUCTION

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

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

(b) only products composed of substances [or incorporating substances such as those] listed in Annex 2, Tables 1, 2 and 3 may be used as plant protection products, fertilizers, soil conditioners, foliar sprays, animal feedstuffs, or animal protection products insofar as the corresponding use is authorised in general agriculture in the country concerned in accordance with the relevant national provisions.

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

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

(b) only products composed of substances or incorporating substances such as those listed in Annex 2, Tables 4A and 4B may be used as ingredients of non-agricultural origin or processing aids insofar as the corresponding use is authorised in the relevant national requirements concerning the preparation of food products and according to good manufacturing practice.

5. REQUIREMENTS FOR INCLUSION OF SUBSTANCES IN ANNEX 2

5.1 Countries should develop a list of substances which satisfy the requirements of these guidelines. The following criteria should be used for the purposes of amending these lists of substances not authorized for the purposes indicated in Section 4:

(a) if they are used for the purpose of plant pest or disease control–

- they are essential for the control of a harmful organism or a particular disease for which other biological, cultural, physical or plant breeding alternatives are not available,

- the conditions for their use [preclude any direct contact with the seed, the crop or crop products; however, in the case of perennial crops, direct contact may take place, but only outside the growing season of the edible parts (fruits) provided that such application] does not indirectly result in the presence of residues of the product in the edible parts,

- their use does not result in, or contribute to, unacceptable effects on, or contamination of, the environment [or have an irreversible influence on local eco-systems];

(b) if they are used for fertilisation or soil-conditioning purposes–

- they are essential for specific nutrition requirements of crops, or specific soil-conditioning and rotation purposes which cannot be satisfied by the practices mentioned in Annex 1,

- their use does not result in, or contribute to, unacceptable effects on, or contamination of, the environment, [or have an irreversible influence on local eco-systems];

(c) if they are used for the purpose of animal health or to ensure livestock product quality--

- they are essential for animal health in the advent of a disease outbreak and provided that such animals not be marketed as organic until such time as the residues of the materials have disappeared, provided that other biological, cultural, or physical treatments are not available,

- they do not include growth hormones,

- they are essential for ensuring product quality and preservation and other biological, cultural, or physical treatments are not available;

(d) if they are used in the production of food--

- they are indispensable for ensuring the safety of the food,

- they are essential to produce or preserve such foods.

- they are preferably nature identical and it is impossible to produce or preserve such food products without having recourse to such ingredients.

5.2 Member countries should provide the following for any substance proposed for inclusion in Annex 2:

(a) a detailed description of the product;

(b) the conditions of its use and compositional and/or solubility requirements, with regard in particular to the need to insure for these products a minimal presence of residues on edible parts of the crop and on edible crop products or animal products as well as a minimum effect on the environment;

5.3 Proposals for amendments to Annex 2, concerning either inclusion or deletion of permitted substances, should be directed in the first instance to the Chief, Joint FAO/WHO Food Standards Programme. Further details for the submission of proposals are provided in the foreword (paragraph 18).

6. INSPECTION AND CERTIFICATION SYSTEMS

6.1 Any operator who produces, prepares or imports products as specified in paragraph 1.1 for the purpose of marketing them should:

(a) give notification of this activity to the competent authority; such notification should include--

(i) the name and address of the operator,

(ii) the location of the premises and, where appropriate, parcels (land register data) where operations are carried out,

(iii) the nature of the operation and the products concerned,

(iv) an undertaking by the operator to carry out the operations in accordance with these guidelines,

(v) in the case of an agricultural holding, the date on which the producer ceased to apply products not compatible with the production requirements of these guidelines on the parcels concerned,

(vi) the name of the approved inspection body providing the inspection system;

(b) submit an undertaking to an inspection system as outlined in this Section.

6.2 A competent authority should designate an authority or body for the reception of notifications.

6.3 The competent authority should ensure that an updated list containing the names and addresses of operators subject to the inspection system is made available to interested parties.

6.4 A country authority should establish an inspection system operated by one or more designated inspection authorities and/or approved private bodies to which the operators producing or preparing products as referred to in paragraph 1.1 should be subject.

6.5 A country authority should adopt the measures necessary to ensure that an operator, who complies with the provisions of these guidelines and pays the contribution to inspection expenses, has access to the inspection system.

6.6 The inspection system should comprise at least the application of the inspection measures and other precautions set out in Annex 3.

6.7 For the application of the inspection system operated by private bodies, countries should designate an authority responsible for the approval and supervision of such bodies. The designated authority may delegate this function to its agent.

6.8 For the approval of a private inspection body, the following should be taken into account:

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

(b) the penalties which the body intends to apply where irregularities are found;

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

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

6.9 After an inspection body has been approved, the competent authority should:

(a) ensure that the inspections carried out by the inspection body are objective;

(b) verify the effectiveness of its inspections;

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

(d) withdraw approval of the inspection body where it fails to satisfy the requirements referred to in (a) and (b) or, no longer fulfills the criteria indicated in paragraph 6.6 or, fails to satisfy the requirements laid down in paragraphs 6.10 to 6.12.

6.10 The inspection authority and the approved inspection bodies referred to in paragraph 6.4 should:

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

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

6.11 Approved inspection bodies should :

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

(b) send to the competent authority of the country [by 31 January] each year a list of operators subject to their inspection [on 31 December of the previous year] and present to the said authority a concise annual report.

6.12 The inspection authority and inspection bodies referred to in paragraph 6.1 should:

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

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

7. IMPORTS

7.1 Without prejudice to Section 3, products as specified in paragraph 1.1 which are imported may be marketed only where the competent authority or body in the exporting country has issued a certificate of inspection stating that the lot designated in the certificate was obtained within a system of production and inspection applying rules equivalent to those laid down in these guidelines.

7.2 The certificate referred to in paragraph 8.1 above should accompany the goods, in the original copy, to the premises of the first consignee; thereafter the importer should keep the certificate at the disposal of the [inspection authorities/competent authority/inspection body] for not less than two years.

7.3 An importing country may:

(a) require detailed information, including reports established by independent experts, on the measures applied in the exporting country to enable it to make judgements on equivalency;

(b) conduct on-the-spot examinations of the rules of production and the inspection measures applied in the exporting country.

ANNEX 1

PRINCIPLES OF ORGANIC PRODUCTION

Plants and plant products

1. The principles set out in this Annex should normally have been applied on the parcels during a conversion period of at least two years before sowing, or in the case of perennial crops other than grassland, at least [two/three] years before [the first harvest/the start of the production cycle] of products as referred to in paragraph 1.1(a) of these guidelines. The inspection body may, with the approval of the competent authority, decide, in certain cases, to extend or reduce that period [but not less than 12 months] having regard to previous parcel use.

2. [Conversion from conventional to organic production should be effected using permitted techniques as defined in these guidelines, and in accordance with a progressive production plan designed to convert an area of land large enough to permit organic production to be developed and sustained.]

3. In cases where a whole farm is not converted at the one time, it may be done progressively, whereby these guidelines are applied from the start of conversion on the relevant fields.

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

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

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

(c) appropriate micro-organisms or plant-based preparations (biodynamic preparations) may be used.

Organic or mineral fertilisers, as specified in Annex 2, Table 1 may be applied only to the extent that adequate nutrition of the crop or soil conditioning are not possible by the methods set out in 4(a) and (b) above.

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

- choice of appropriate species and varieties;
- appropriate rotation programs;
- mechanical cultivation;
- protection of natural enemies of pests through provision of favourable habitat, such as hedges and nesting sites;
- flame weeding;
- biological control [release of predators];

- specific bio-dynamic measures;

- mulching and mowing;

- grazing of livestock;

- [diversified ecosystems. This will vary between geographical locations. For example, in the tropics ecological balancing zones should be established which retain the original vegetations to house pest predators, counteract erosion, etc];

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

- [steam sterilization].

6. Only in cases of [immediate] threat to the crop may recourse be had to products referred to in Annex 2.

7. Seeds and plant propagation material should be from organic production. However, by way of derogation from paragraph 4.1(b), seeds treated with substances not included in Annex 2 but authorised in general agriculture in the country may be used insofar as users of such seed can show to the satisfaction of the inspection body that they were unable to obtain on the market non-treated seed of an appropriate variety of the species in question.

Livestock Production

8. Where livestock are maintained, they should be an integral part of the organic farm unit and should be raised and held according to these guidelines.

9. Animal products must not be sold as organic unless the animal has been raised according to these guidelines for a period of at least one year.

10. Up to 10% of adult animals of a herd or flock may be brought-in annually from non-organic sources for expansion or replacement purposes.

11. All brought-in animals from non-organic sources must be produced according to these guidelines for a period of a minimum of one year before their products may be sold under an organic label. Exceptions may be allowed for:

(a) calves up to 14 (or 7?) days which have received colostrum and do not come from livestock markets;

(b) dairy animals provided that milk is kept separate for a period of 12 (or 4?) weeks;

(c) day old poultry; and

(d) laying hens, provided that eggs are kept separate for a period of 30 days.

12. All livestock systems should be planned to provide the optimum level of 100% of the diet of feedstuffs produced to the requirements of these guidelines;

- however, by way of derogation, at least [80%/85%] of fodder inputs, calculated on a dry matter basis, should be from organic sources produced in compliance with these guidelines. Exceptions may be granted in cases of extreme climatic or other extenuating circumstances.

13. Stocking rates for livestock should be appropriate for the region in question and as regulated by the inspection body for the region.

14. [Maintenance of livestock should be guided by an attitude of care, responsibility and respect for living creatures. Pain inflicted by treatments such as castrating, marking and mulesing should be kept to a minimum. Stress should be minimised. Living conditions should consider the natural needs of the animal for free movement, food, water, shelter and shade. Consideration should be given to their specific natural behavioural patterns.]

15. [Breeding methods should be in compliance with the principles of organic farming taking into account breeds and strains suitable for raising under local conditions and under an organic system. Own sires should be held. Artificial insemination is not recommended. Embryo transfer techniques are not permitted in the organic farming system.]

16. Vaccination of livestock is permitted in cases where a known problem exists or is required by national regulations.

17. Vitamins (synthetic), in the absence of natural source vitamins, pure amino acids and trace element supplements are permitted in cases where the need can be demonstrated

18. The use of veterinary drugs on livestock in the absence of illness is prohibited. Therapeutic use of veterinary drugs is permitted provided the withholding period is [equal to / double / triple] that required by national legislation for the veterinary drug concerned.

19. Growth promotants are prohibited.

[Processing, Storage and Transport]

20. The processing of organic food product should meet the requirements of Codex standards and codes of hygienic practice for food production.

21. Organic produce may neither be mixed nor substituted with conventional produce.

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

23. Products derived from conventional and organic methods should not be stored together, except when packed and handled.

24. Bulk stores for organic product should be set aside and clearly labelled to that effect.

25. Contamination from any possible non-approved pesticide treatments before using the storage areas shall be excluded.

26. Storage areas shall be thoroughly cleaned with methods appropriate to the product.

27. Permitted specific storage conditions may include controlled atmosphere (only CO_2, 0_2, N_2).

28. Pests should be avoided by GMP. Pest control treatment within storage areas may include physical barriers, sound, ultra-sound, light and UV-light; permitted treatments may include:

- traps (including pheromone traps and static bait traps);
- temperature control;
- controlled atmosphere;
- diatomaceous earth.

29. All materials used for packaging must conform to food grade packaging materials as established by national regulations.

30. In addition, packaging material used for organic products should not contain fungicides, preservatives, or other chemical additives.

31. Any food grade packaging material which has previously been in contact with any substance that could compromise the organic quality of the product should not be used.

ANNEX 2

PERMITTED SUBSTANCES FOR THE PRODUCTION OF ORGANIC FOODS

Precautions

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

2. 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.

3. The lists of ingredients and processing aids of non-agricultural origin included in Table 4 take into account the expectations of consumers that processed products from organic production systems should be composed essentially of ingredients as they occur in nature.

TABLE 1: SUBSTANCES FOR USE IN SOIL FERTILIZING AND CONDITIONING

Substance	Description; compositional requirements; conditions of use
Farmyard and poultry manure	—
Slurry or urine	—
Straw	—
Peat	—
Composts from spent mushroom and vermiculture substrates	—
Composts from organic household refuse	—
Composts from plant residues	—
Processed animal products from slaughterhouses and fish industries	—
Organic by-products of foodstuffs and textile industries	—
Seaweeds and seaweed products	—
Sawdust, bark and wood waste	—
Wood ash	—
Natural phosphate rock	—
Calcinated aluminium phosphate rock	—
Basic slag	—
Rock potash	—
Sulphate of potash	**Need recognised by control body**
Limestone	—
Chalk	—
Magnesium rock	—
Calcareous magnesium rock	—
Epsom salt (magnesium-sulphate)	—
Gypsum (calcium sulphate)	—
Trace elements (boron, copper, iron, manganese, molybdenum, zinc)	**Need recognised by control body**
Sulphur	**Need recognised by control body**
Stone meal	—
Clay (bentonite, perlite)	—
Homeopathic preparations	
Naturally occurring biological organisms (eg worms)	
Vermiculite	
Peat in seed, potting and module composts only	
Humus from earthworms	
Zeolites	
Wood charcoal	

TABLE 2: SUBSTANCES FOR PLANT PEST AND DISEASE CONTROL

Substance	Description; compositional requirements; conditions of use
Preparations on basis of pyrethrins extracted from *Chrysanthemum cinerariaefolium*, containing possibly a synergist	
Preparations from *Derris elliptica*	
Preparations from *Quassia amara*	
Preparations from *Ryania speciosa*	
Propolis	
Diatomaceous earth	
Stone meal	
Preparations on basis of metaldehyde containing a repellent to higher animal species and as far as applied within traps	
Sulphur	
Bordeaux mixture	
Burgundy mixture	
Sodium silicate	
Sodium bicarbonate	
Potassium soap (soft soap)	
Pheromone preparations	
Bacillus thuringiensis preparations	
Granulose virus preparations	
Plant and animal oils	
Paraffin oil	
Seaweed, seaweed meal, seaweed extracts, sea salts and salty water	
Homeopathic preparations	
Neem oil and extracts	
Natural plant extracts, excluding tobacco	
Potassium permanganate	
Carbon dioxide and nitrogen gas	
Vinegar	
Mineral powders	
Herbal and bio-dynamic preparations	

TABLE 3: SUBSTANCES FOR ANIMAL PEST AND DISEASE CONTROL

Substance	Description; compositional requirements; conditions for use
Pyrethrum extracted from *Chrysanthemum cinerariaefolium*,	
Rotenone extracted from *Derris elliptica*	
Quassia extracted from *Quassia amara*	
Neem oil and extracts	
Garlic oil, garlic extract or crushed garlic	
Seaweed, seaweed meal, seaweed extracts, sea salts and salty water	
Sulphur	
Potassium permanganate	
Homeopathic preparations	
Natural plant extracts obtained by infusion, excluding tobacco	
Essential oils	
Methylated spirits	
Tallow	
Cidar vinegar (certified organic)	
Nettle	
Diatomaceous earth (non heat-treated form)	
Selenium and other trace elements	
Zinc sulphate	
Copper sulphate	
Vaccines	

TABLE 4A: INGREDIENTS OF NON-AGRICULTURAL ORIGIN REFERRED TO IN SECTION 3 OF THESE GUIDELINES

A1. Food additives, including carriers

INS	Name	Specific conditions
170	Calcium carbonates	----
270	Lactic acid	----
290	Carbon dioxide	----
296	Malic acid	----
300	Ascorbic acid	----
322	Lecithin	----
330	Citric acid	----
334	Tartaric acid	----
335	Sodium tartrate	----
336	Potassium tartrate	----
400	Alginic acid	----
401	Sodium alginate	----
402	Potassium alginate	----
406	Agar	----
410	Locust bean gum	----
412	Guar gum	----
413	Tragacanth gum	----
414	Arabic gum	----
416	Karaga gum	----
440	Pectins (unmodified)	----
500	Sodium carbonates	----
501	Potassium carbonates	----
503	Ammonium carbonates	----
504	Magnesium carbonates	----
516	Calcium sulphate	Carrier
938	Argon	----
941	Nitrogen	----
948	Oxygen	----

A2. Flavourings

Substances and products labelled as natural flavouring substances or natural flavouring preparations as defined in CAC/Vol XIV - Ed 1. Supplement 1.

A3. Water and salts

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

A4. Preparations of Microorganisms

(a) Any preparations of microorganisms normally used in food processing, with the exception of microorganisms genetically modified;

(b) Microorganisms genetically modified if they have been included according to the decision procedure of Section 5 of these guidelines.

A5. Minerals (including trace elements) and vitamins

Only approved in so far as their use is legally required in the food products in which they are incorporated.

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

Name	Specific conditions
Water	----
Calcium chloride	coagulation agent
Calcium carbonate	----
Calcium hydroxide	----
Calcium sulphate	coagulation agent
Magnesium chloride (or nigari)	coagulation agent
Potassium carbonate	drying of raisins
Carbon dioxide	----
Nitrogen	----
Ethanol	solvent
Tannic acid	filtration aid
Egg white albumin	----
Casein	----
Gelatin	----
Isinglass	----
Vegetable oils	greasing or releasing agent
Silicon dioxide (gel) or colloidal solution	----
Activated carbon	----
Talc	----
Bentonite	----
Kaolin	----
Diatomaceous earth	----
Perlite	----
Hazelnut shells	----
Beeswax	releasing agent
Carnauba wax	releasing agent

Preparations of microorganisms and enzymes:

(a) Any preparations of microorganisms and enzymes normally used as processing aids in food processing, with the exception of genetically modified organisms and enzymes;

(b) Microorganisms genetically modified if they have been included hereunder according to the decision procedure of Section 5 of these guidelines.

ANNEX 3

MINIMUM INSPECTION REQUIREMENTS AND PRECAUTIONARY MEASURES UNDER THE INSPECTION SYSTEM

A. *Production at farm level*

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

2. When the inspection arrangements are first implemented, the operator and inspection body should draw up:

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

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

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

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

- an undertaking by the operator to carry out operations in accordance with Sections 3, 4 and 8 and to accept, in event of infringements, implementation of the measures as referred to in paragraph 6.12 of these guidelines.

3. Each year, before the date indicated by the inspection body, the operator should notify the body of its schedule of production of crop products [and livestock], giving a breakdown by land parcel [/herd].

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

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

6. Apart from unannounced inspection visits, the inspection body should make a full physical inspection, at least once a year, of the unit. Samples for testing of products not authorised [listed]

in these guidelines may be taken. Such samples should be taken where the use of unauthorised products is suspected. An inspection report should be drawn up after each visit and countersigned by the person responsible for the unit.

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

8. Products referred to in Section 1 of these guidelines which are not in their packaging for the end consumer should be transported in a manner which would prevent substitution of the content and provided with a label stating, without prejudice to any other indications required by law:

- the name and address of the person responsible for the production or preparation of the product;
- the name of the product;
- that the product is covered by an inspection arrangement equivalent to those set out in these guidelines.

9. Where an operator runs several production units in the same area, units in the area producing crop, crop products [or livestock] not covered by Section 1 should also be subject to the inspection arrangements as regards the dash points of paragraph 2 and paragraphs 3 and 4 above. Plants [and animals] of the same type as those produced at the unit referred to in paragraph 1 above should not be produced at these units.

B. ***Processing and packaging units***

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

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

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

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

In addition, the report should include an undertaking by the operator to perform the operations in such a way as to comply with Section 4 of these guidelines and to accept, in the event of infringements, the implementation of measures as referred to in paragraph 6.12 of these guidelines.

2. Written accounts should be kept enabling the inspection body to trace:

- the origin, nature and quantities of agricultural products as referred to in Section 1 of these guidelines which have been delivered to the unit;

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

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

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

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

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

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

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

4. Apart from unannounced inspection visits, the inspection body should make a full physical inspection, at least once a year, of the unit. Samples for testing of products not authorized under these guidelines may be taken. However, they should be taken where the use of unauthorized products is suspected. An inspection report must be drawn up after each visit countersigned by the person responsible for the unit inspected.

5. The operator should give the [inspection body], for inspection purposes, access to the unit and to written accounts and relevant supporting documents. The operator should also provide the [inspection body] with any information necessary for the purposes of inspection.

6. The requirements in respect to the transport as laid down in paragraph A.8 of this Annex are applicable.
