

SUMMARY AND CONCLUSIONS

The 21st Session of the Codex Committee on food Additives and Contaminants reached the following conclusions during its deliberations:

- Reviewed and adopted a text on the use of food additives in food, which, after adoption by the Commission, the member governments would be free to use as an official statement from the Commission (Para 21, Appendix II).
- Agreed to take the following action on the paper by Dr. Denner on "Proposals for General Provisions for the Use of Food Additives in Standardized and Non-Standardized Foods (CX/FAC 89/16):
 - (i) seek the views of the Commission on Recommendations 1, 2, 3 and 7;
 - (ii) seek the views of FAO and WHO on Recommendation 4;
 - (iii) endorse Recommendations 6 and 9 and ask the JECFA Secretariat to take action where necessary;
 - (iv) seek the views of member countries and interested international organizations on the paper, and in particular on Recommendations 5, 8 and 10 by means of a circular letter (para 26).
(The recommendations are reproduced in Appendix III)
- Reviewed the Joint FAO/WHO proposals for radionuclide contamination of food in international trade as contained in CX/FAC 89/17-Revised and agreed to forward the revised paper to the Commission (Para 37).
- Agreed to consider some more specific aspects, like dilution factors and the question of how to treat minor dietary components at a future date.
- Agreed that a circular letter should be sent out to governments requesting additional information on the intake of intense sweeteners (Para 41).
- Agreed to continue collecting information on the intakes of mercury, cadmium and lead including, where possible, the identification of the sources of contamination, whether environmental or technological (Para 48).
- Advanced the Guidelines for Simple Evaluation of Food Additive Intake to Step 5 and recommended to the Commission adoption at step 8 with the omission of steps 6 and 7 (Para 50).
- Agreed to endorse several food additive and contaminant provisions in commodity standards with the exception of some flour treatment agents in the standard for wheat flour, which will now be referred to the Executive Committee and the Commission for final decision (Paras 54-64, 67-69).
- Agreed to request the relevant commodity committees to review the provisions on erythrosine in the standards elaborated by them and to seek substitutes for erythrosine (para 66).
- Agreed that the International Numbering System (INS) should include all food additives approved for use in individual member countries and that it had no toxicological significance since it extended well beyond those

additives cleared by JECFA. The list would have to be an open one and provisions would need to be made for it to be updated on an ongoing basis (Para 71).

- Agreed to bring to the attention of the Commission, the progress the Committee had made in developing the INS. Columns 1 and 2 of the System (Appendix VI) were final and Column 3 which referred to the technical function of the food additives was still subject to review. Prepare a foreward to the system which would also contain definitions for functional classes (Para 85) and seek comments by means of a CL.
- Agreed that the current inventory on processing aids (Appendix VIII) should be submitted to the Commission for adoption as a Codex advisory text, bearing in mind that additions to the inventory would always be possible (Para 91) and that it should not be considered as a positive list of permitted processing aids to be used for example by reference in Codex Standards.
- Agreed that an inventory of boiler water treatment agents used for the production of culinary steam should be established for inclusion in the main inventory of processing aids (Para 92).
- Discussed whether the question of water treatment agents used for water for food preparation would be within the terms of reference of CAC and decided to seek the opinion of the Executive Committee on this (Para 94).
- Agreed to identify categories of substances from the inventory which might leave residues in foods which were present in sufficient quantities that an evaluation by JECFA would be warranted (Para 97) by means of a CL.
- Agreed to collect more information on the distribution of aflatoxin(s) in consignments with a view to develop statistical sampling plans (Para 118).
- Concluded that the listing of processing aids in Codex Standards was not subject to endorsement.
- Decided to elaborate procedures whereby JECFA specifications can be rapidly adopted as Codex Advisory Specifications and published in final form with minimum delay (Para 106).
- Agreed that Codex Advisory Specifications should also be adopted under the following conditions (Para 108):
 - if there is no full JECFA ADI except where JECFA had withdrawn the ADI
 - if it is not listed in any Codex Standard, and
 - if it has been designated a food or food ingredient by JECFA
- Agreed to accept for immediate guidance, the simple and practical concept described by J. Waibel and by T.B. Whitaker. The slightly preferred concept of Waibel was worked out in a "Proposed Draft Inspection Scheme for Shelled Peanuts with Regard to Aflatoxins on which Government Comments are being Sought" (Para 120) by means of a CL.

- Proposed guideline levels for aflatoxins B₁ in peanuts (Para 123 Appendix IX) and for cadmium and lead in foods (Para 127-131, Appendix IX) and agreed to seek, by means of a CL, government comments at Step 3.
- Advanced guideline levels for methyl mercury in fish (Para 134, Appendix X) to Step 5.
- Advanced guideline levels for vinylchloride monomer and acrylonitrile in foods and packaging materials (Para 138, Appendix X) to Step 5 and seek information by means of a CL on sampling plans as well as alternate methodology for estimation of migrants.
- Agreed to prepare a paper on national strategies for control of dioxins in food and food contact material (Para 142).
- Established priorities for future consideration of contaminants (Para 145).
- Selected a number of food additives and contaminants for priority review by JECFA (para 152).
- Decided not to change the current Codex definition of food additives (Para 154).
- Discussed the issue of new food and other products of biotechnological origin and decided to inform the Commission about its deliberations on this item but agreed to await the consideration by the Commission of "Implications of Biotechnology in International Food Standards and Codes of Practice" before inviting governments' comments on "Approaches for the evaluation of novel foods" (Para 159).

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INTRODUCTION (Agenda item 1)

1. The Codex Committee on Food Additives and Contaminants held its twenty-first Session in The Hague, The Netherlands, from 13-18 March, 1989, through the courtesy of the Government of The Netherlands. Mr. A. Feberwee (The Netherlands) acted as Chairman. Mr. R. Top (The Netherlands) acted as vice chairman. The Session was attended by 193 participants, representing 35 member countries, 2 observer countries and 32 international organizations (See Appendix I for the List of Participants, including the Secretariat).

EXTRACT OF THE OPENING SPEECH BY Mr. C.C.J.M. VAN DER MEIJS, ON BEHALF OF Mr. J.P. VAN ZUTPHEN, DIRECTOR GENERAL OF THE MINISTRY OF AGRICULTURE AND FISHERIES OF THE NETHERLANDS

2. The Director General started by reminding the Committee that a global trend is emerging towards "horizontal" food regulations such as on food additives and less standardization product by product.

3. He stated that the activities of the Codex Alimentarius reflect this change. The activities of the so-called Commodity Committees have decreased substantially – several of them having been adjourned indefinitely. However, up till now the activities of the CCFAC have not been brought in line with this development. Endorsements of food additives by this Committee are still, with only a few exceptions, limited to the Commodity Standards. However, a very substantial proportion of the food containing additives moving in international trade is not standardized and this proportion will grow in the future. A change in the working methods of the CCFAC therefore is urgently needed, if not already slightly overdue. He was gratified to see that this trend was reflected in the CCFAC agenda, for example in the item "Proposals for General Provisions for the Use of Food Additives in Standardized and Non-Standardized Foods".

4. The Director-General welcomed the Joint FAO/WHO proposals on radionuclide contamination of food and expressed hope that they might form the basis for international agreement. The Netherlands Government had, since "Chernobyl", always stressed the need for such an agreement.

5. He also stated that environmental pollution posed a severe and ever-growing problem worldwide, which no one would deny. Therefore, much work would have to be done about these contaminants in food and that it was essential to make the right choices. He referred to the agenda item: "Priorities for Future Consideration- of Contaminants by CCFAC" and stated that it was most suitable in this respect.

6. The Director-General explained that many consumers were worried about the safety aspects and intolerance to food additives. These worries very seldom had a realistic basis. On the other hand, speaking about intolerance, he stated that one has to take consumers and their concerns seriously. Future activities of the Codex Alimentarius, therefore, would be justified in this field.

7. The Director-General emphasized the importance of Codex Standards for GATT and welcomed the efforts of both organizations to strengthen their collaboration and cooperation.

8. The Director-General stated that from the beginning, The Netherlands had always strongly supported the work of the Codex Alimentarius - its work being essential to free trade in safe food products. The Netherlands therefore is prepared and pleased to continue its efforts to convene and promote the activities of the Committee on Food

Additives and Contaminants and the Committee on Pesticide Residues.

9. The Director-General ended by wishing the Committee a good and productive meeting.

ADOPTION OF THE AGENDA (Agenda item 2)

10. The Committee adopted the provisional agenda (CX/FAC 89/1) including all changes listed in the list of documents {CX/FAC 89/1- Add. 1): Agenda Item 5 document CX/FAC/17-Add. 1 was not issued; Agenda Item 12(e) "Guideline Levels also in view for Methyl Mercury in Fish", Conference Room Document 10 was introduced; Agenda Item 13(b) should read "Report of the Working Group on Methods of Analysis", Agenda Item 16 should read "Consideration of new foods and other products of biotechnological origin".

APPOINTMENT OF RAPPORTEURS (Agenda Item 3)

11. Mr. Ronk (USA) was appointed as rapporteur. The Committee agreed with the proposal of the Chairman not to appoint a French and Spanish rapporteur due to the fact that qualified expertise from FAO was present at this session.

CONSIDERATION OF THE REPORT OF THE THIRTY-THIRD MEETING OF THE JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES (Agenda item 4)

12. The thirty-third report of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) was introduced by the Joint Secretariat of JECFA, Dr. J.L. Herrman (WHO) and Dr. J. Weatherwax (FAO). The report has been published by WHO as Technical Report Series 776. A summary report had been published immediately after the meeting, that outlined the general conclusions of the Committee.

13. Thirteen food additives and seven contaminants were on the agenda for toxicological evaluation. The relatively large number of contaminants is a reflection of the increasing emphasis placed on contaminants by CCFAC. The method for setting priorities for the safety review of food flavouring ingredients that had been endorsed by the Twentieth Session of CCFAC was also evaluated from a scientific point of view by the Committee, which endorsed the method. The method is now being used for placing food flavouring agents on the agenda of future meetings of JECFA.

14. The only substances that were evaluated for the first time were sucralose, which was evaluated under the name "trichlorogalactosucrose", and iodine. A temporary ADI of 0-3.5 mg/kg body weight was established for trichlorogalactosucrose and a provisional maximum tolerable daily intake of 0.017 mg/kg body weight was established for iodine. Temporary ADIs were maintained for d-1-carvone, and mineral oils currently in use as releasing agents and lubricants. The temporary ADIs for trans-anethole and erythrosine were maintained but at lower levels. The tolerable intakes that had earlier been established for inorganic arsenic, cadmium, methylmercury, and tin were maintained, although for arsenic and tin they were changed from provisional maximum tolerable daily intakes to provisional weekly intakes. The Committee also investigated the acute toxic effects of tin exposure, and concluded that a numerical threshold for this effect could not be set. The Committee recommended that efforts be made to keep tin levels in canned foods as low as practical, consistent with the application of good manufacturing practice.

15. The Committee discussed three important principles which arose from specific considerations, but which apply to existing or future specifications.

1. In considering mineral oil, the Committee found insufficient information on chemical composition. The Committee therefore restated the importance

of detailed composition data for complex substances (such as mineral oil) in order to make a full evaluation and prepare proper specifications.

2. In considering the substance called "sucralose" the Committee found the name did not derive from any governmental or international body or from common usage. For this and future naming difficulties, the Committee developed guidelines for titles of specification monographs.
 3. The Committee noted the continuing need to revise the methods section of the Guide to Specifications. The last such revision was in 1983. The Committee further discussed the need for analytical performance data for new method to be included.
16. The delegation of Sweden requested clarification of the JECFA evaluation of mineral oils with regard to whether the restriction on their use as releasing agents and lubricants was based upon lack of data or upon adverse data. The WHO representative stated that a problem in evaluating the studies that were submitted on mineral oil was that it was difficult to relate the substance tested to the substance in commerce. Even though some effects were noted in the study, their significance could not be fully assessed until more was known about the nature of the substance tested. Thus, the restrictive ADI was primarily based upon a lack of information.

17. The delegation of Egypt emphasized the need for restricting exposure to mineral oils when it is used as a releasing agent. In response to a question from the delegation of Australia about whether the generation of safety data on aluminium should be encouraged, the WHO representative pointed out that the evaluations of all the contaminants at the thirty-third meeting resulted in provisional decisions and that JECFA would reevaluate them whenever new significant data could be made available.

Matters Arising from Codex Sessions

18. The Committee had before it document CX/FA 89/4 containing Matters of Interest arising from Codex Sessions. The Committee noted that there were a number of matters of interest in the document which would be discussed under other agenda items and agreed to defer discussion on them until the particular agenda item was presented.

Misleading Information concerning the use of Food Additives in Food

19. The Committee recalled the discussions at its 19th Session, at which it concluded that the issue of statements counteracting misleading information concerning the use of food additives was not within its terms of reference as it was the responsibility of governments to take appropriate action. The Committee noted further that it adhered to the General Principles for the Use of Food Additives and that several FAO/WHO and Joint FAO/WHO Expert Committee documents provided information on the safe use of food additives which could be used by governments.

20. The Codex Alimentarius Commission (CAC) had continued discussion on this issue at its 17th Session and had also concluded that the dissemination of information counteracting erroneous publications was primarily the responsibility of governments and had asked the Coordinating Committee for Europe to consider a coordinated approach.

21. The Coordinating Committee for Europe at its 16th Session had adopted a text on the subject. The CCFAC reviewed the text proposed by the Coordinating Committee for Europe and on the basis of this review the Secretariat prepared a revised statement which is attached as Appendix II to this report. The Committee noted that after adoption

of the statement by the Commission, the member governments would be free to use it as an official statement from the Commission.

PROPOSALS FOR GENERAL PROVISIONS FOR THE USE OF FOOD ADDITIVES IN STANDARDIZED AND NON-STANDARDIZED FOODS (Agenda Item 5)

22. The Committee had before it document CX/FAC 89/16, prepared by Dr Denner in the capacity of an independent consultant, in response to the request of the Committee at its last session (para 63, ALINORM 89/12). Dr Denner introduced the document and stressed that it addressed a number of difficult issues in a forthright way. It was his intention, however, to facilitate improvements in the effectiveness of Codex.

23. Many delegations stressed that they had only just received the document and it was difficult for them to commit themselves on such fundamental matters without time to reflect fully on the possible consequences. Nevertheless, in general, the document was welcomed by many delegates as an important stimulus to the debate. In this regard, several delegations supported the concept of horizontal standardization and commended the paper as a good basis on which to progress this in a difficult area of food additives.

24. The delegations of Fed. Rep. of Germany and India expressed concerns that a horizontal approach such as that proposed might liberalize the use of food additives. It was important to protect consumers from fraudulent practices such as using colours to mask inferior quality. Safety was not the only issue. Dr Denner replied that it was not his intention to undermine the General Principles for the Use of Food Additives, but he felt it was vital to recognise that the 'need' for an additive might vary from country to country. Provided the additive was used at 'safe' levels this variation should not result in barriers to trade.

25. Mr Fondu, as Chairman of the ad hoc Working Group on Food Additive Intake, agreed that there was a need to collect and assess data on additives from all foods, not just those subject to Codex Standards, in order to obtain a wider perspective.

26. After a full discussion, the Committee agreed:

- (i) that it would seek the views of the Commission on Recommendations 1,2,3 & 7
- (ii) that it would seek the views of FAO and WHO on Recommendation 4
- (iii) that it would endorse Recommendations 6 & 9 and ask the JECFA secretariat to take action where necessary
- (iv) that the views of member countries and interested international organisations should be sought on the paper and, in particular on Recommendations 5, 8 & 10 by means of a Circular Letter.

The Recommendations of the consultant's report are reproduced in Appendix III of this report.

CONSIDERATION OF JOINT FAO/WHO PROPOSED LEVELS FOR RADIONUCLIDE CONTAMINATION OF FOOD IN INTERNATIONAL TRADE (Agenda Item 6)

27. The Committee recalled that the Seventeenth Session of the Commission, had called for speedy action by FAO and WHO in arriving at joint proposals in relation to radionuclide contamination of foods moving in international trade. It had before it for consideration, document CX/FAC 89/17, which had been prepared on the basis of a joint FAO/WHO/IAEA inter-secretariat meeting held in March 1988, and amended to provide additional clarification of certain points following the 35th Session of the Executive

Committee, held in July 1988. The Committee also had before it government comments contained in CX/FAC 89/17-Add.1 (Canada, Germany F.R., Luxembourg, Norway, United Kingdom; and the Nuclear Energy Agency of the OECD), CK/FAC 89/17-Add.1b (Combined comments of Finland, Iceland, Norway and Sweden), CK/FAC 89/17-Add.1c (USA) and Conference Room Documents 6 (EEC), 7 (Switzerland) and 12 (Italy).

28. The representative of the EEC drew attention to Regulation No. 3954/87 of the EEC Council of Ministers, dated 22 December 1987, which specified maximum levels for the contamination of certain foods. Proposals to complete this Regulation by its extension to other foods were under study. The representative noted that the FAO/WHO proposals were very close to the levels used in the EEC, and outlined the principal differences. Several delegations spoke in support of the EEC approach.

29. The delegation of Malaysia supported by the delegations of Thailand, India and Republic of Korea, stated that the levels proposed by FAO/WHO were too high and that the basis of calculation should be 1 mSv per annum rather than 5 mSv. It was, however, pointed out by the representatives of FAO and WHO that the proposals were intended to apply in the case of accidental contamination of food, and that in such cases the basic intervention level of 5 mSv was appropriate. It was agreed to reflect this in the title of the revised document. In accordance with the recommendations of the International Commission on Radiological Protection this level was intended only for short-term application for one year after a nuclear accident.

30. The delegation of Argentina stated that levels similar to those proposed by FAO and WHO had been adopted for use in that country. The delegation stressed the importance of continuing the examination of laying down of more uniform criteria with a view to harmonize international trade practices in terms of minor dietary nutrients. This application to minor dietary components was also stressed by other delegations.

31. The delegation of Sweden drew attention to the comments contained in CX/FAC 89/17-Add.1(b), and to the need to control the dose in an accidental situation at a level not exceeding 5 mSv per annum. The delegation of Switzerland drew attention to the need to specify the radionuclides which needed to be controlled so that natural gamma-emitters, such as ^{40}K would be excluded.

32. Several delegations drew attention to the need to provide guidance on uniform procedures for sampling and analysis, especially analysis for alpha- and beta-emitters. The delegation of The Netherlands drew attention to the extensive certification which was required for the export of food commodities, and stated that the need for this certification was no longer justified. On the basis of this discussion, the Committee asked the representatives of WHO and the Secretariat to revise the paper for its further evaluation during this session of the Committee.

33. The revised paper contained separate recommendations for foods for the general population and for infant foods. The Committee, noting a divergence of opinion on the application of dilution factors and the difficulty of treating minor dietary components, agreed not to discuss these issues but to recommend that they be considered at a future date. The Committee also agreed that questions related to the techniques of sampling and analysis, especially in regard to the alpha-emitters, required further consideration and harmonization by the organizations having competence in this area.

34. The Committee following a lengthy debate, agreed with the proposals of several delegations to treat Iodine 131 as a special case. Due to the difference between the dose conversion factors for iodine in children as compared to adults, the Committee

included Iodine 131 in infant foods and milk in the grouping of radionuclides with a dose conversion factor of 10^{-7} . In this case the level would be 100 Bq/kg, to be considered together with Strontium 90.

35. The Committee confirmed that the levels proposed applied only to a nuclear accident situation that had been declared under the notification Conventions of IAEA. The Committee agreed that the levels should not apply to naturally occurring radionuclides. The delegation of Egypt expressed disappointment that levels were not being elaborated for trade during non-accidental situations.

36. The delegation of Malaysia questioned whether the additivity of the various classes of radionuclides had been taken into account. The representative of WHO stated that as the proposed FAO/WHO levels had extensive conservative assumptions built in, there was no need to add contribution between these groups and each of the groups should be treated independently.

37. The Committee agreed to forward the revised proposals to the Commission. It was agreed that the document should be distributed well in advance of the Commission meeting so as to allow governments to study the final draft proposals and provide written comments. The complete revised document will be issued as ALINORM 89/11.

38. The Committee expressed its sincere appreciation for the work of the Secretariat and Dr. Peter Waight (WHO) in preparing the document and assisting the Committee in arriving at a resolution of this difficult matter.

CONSIDERATION OF INTAKE OF FOOD ADDITIVES AND CONTAMINANTS (Agenda Item 7)

39. The Committee had before it the report of the ad-hoc Working Group on Intake of Food Additives and Contaminants (CX/FAC 89/5-Add. 3) which was introduced by the Chairman of the WG Mr M. Fondu (Belgium). The WG reviewed the following documents: Intake of Food Additives (CX/FAC 89/5), Dietary Intake of Mercury, Cadmium and Lead (CX/FAC 89/5 Add. 1) Guidelines for Simple Evaluation of Food Additive Intake (CX/FAC 89/5-Add. 3) and Government comments on these Guidelines (CX/FAC 89/5 Add. 2). The report of the WG also contained the discussion on the possible implications of the document CX/FAC 89/16 on its future activities.

Intense Sweeteners

40. Intake of intense sweeteners was studied by the WG since the ADI for some of these sweeteners was low and authorized usage was increasing. The Netherlands provided intake estimates of intense sweeteners using limits proposed for inclusion in a national draft regulation. The approach used by The Netherlands was essentially the same approach described in the Guidelines and the WG considered it to be of sufficient value for inclusion as an additional example of intake estimates in the Guidelines. The Committee noted that where such estimates approach the ADI, more detailed intake studies should be carried out by countries. Japan provided information on intake of sodium saccharin based on actual analysis of the additive in the diet using three different approaches: analysis of individual foods, duplicate portion and market basket studies. These approaches provide intake estimates closer to the actual intake, however they require extensive resources and would be difficult to implement in most countries.

41. Advantages of continuing this exercise are obvious in that it encourages countries to carry out such intake estimates to ensure that with increasing authorized usage, the ADI is not exceeded by the population. The Committee agreed that a Circular

letter should be sent out to Governments requesting additional information on the intake of intense sweeteners.

Annatto and Amaranth

42. Information on the intake of annatto and amaranth was provided by Canada, Japan and the UK. In view of the fact that the intakes were well below the ADI, and the authorized usage of these compounds do not seem to be on the increase, the Committee agreed that there was no further need to continue this work.

BHA and BHT

43. Information on the intake of BHA and BHT, and amounts contributed by different foods was provided by Belgium, Canada and Japan. Estimates of intake of BHA and BHT using permitted levels in national regulations were below the respective ADIs. Cereals and cereal products, potatoes and confectionery products, contributed most to the intake. Dried fish and shellfish also contributed to the intake in Japan. Information provided by the USA indicated that about 1% of the BHT present in chewing gum would be extracted by the saliva. The Committee agreed that there was no further need to continue this work.

44. The Chairman of the WG brought to the attention of the Committee to the excellent document prepared by Japan on the intake of food additives which is available from Japan Food Additives Association (1989).

Dietary Intake of Cadmium, Mercury and Lead

45. Information on the intake of these contaminants was provided by Canada, Denmark, Finland, Italy, The Netherlands, Sweden, Thailand, UK and USA. All intakes reported for mercury were below the provisional tolerable weekly intake (PTWI) for both organic and total mercury. The contribution of fish to the total intake of mercury varied from 20 to 80% depending on the country. The Committee was also informed that studies carried out in the Republic of Korea showed that the intake of mercury was well below the PTWI.

46. Intakes of cadmium were all well below the PTWI, with cereals and potatoes contributing most to the intake. In the case of lead, intakes for adults reported by Italy and Thailand exceeded or approached the PTWI. The delegation of Italy pointed out that the lead intake studies referred to were carried out during 1981-1982. In 1983, canning processes were modified and a substantial decrease in intake was noted. For infants and children, Canada reported an intake of about 70% of the PTWI for that population group; the intake exceeded the PTWI where lead-soldered cans were used for infant formula. Because of the limited data available, it was difficult to identify the particular food responsible for the major part of the intake. Data collected from the Joint FAO/WHO Food Contamination Monitoring Programme indicated that canned foods contributed most to this intake.

47. Denmark noted that lead contamination of wines does occur. From 1979-1984, a considerable decrease in lead content of cereals, fruit and vegetables was noted which could be attributed to the use of lead-free gasoline in automobiles. The representative of the International Federation on Wholesale Trade of Wines and Spirits (FIVS) brought the attention of the Committee to the significant contribution of sugars to the lead intake of populations.

48. The Committee agreed to continue collecting information on the intakes of mercury, cadmium and lead including where possible the identification of the sources of

contamination, whether environmental or technological. A circular letter will be sent out to governments.

Guidelines for Simple Evaluation of Food Additive Intake

49. This document was prepared by the WG in response to requests from Governments for simple and inexpensive methods for estimating intakes of food additives. Comments were received on the draft document from Canada, Denmark, Ireland, The Netherlands, Thailand and the USA. The WG reviewed the draft document taking into account the various comments received and presented the final version of the document to the Committee.

50. The Committee noted that it did not follow the Codex Step Procedure while elaborating the guidelines. The guidelines had been sent to governments twice. The Committee advanced the guidelines to step 5 and recommended to the Commission, adoption at step 8 with the omission of steps 6 and 7.

51. The guidelines for Simple Evaluation of Food Additive Intake are attached as Appendix V to this report.

Implication of CX/FAC 89/16 on the activities of the Working Group on Food Additive Intake

52. The Chairman of the WG stated that the WG had so far carried out evaluation of some food additive intakes for comparison with ADIs, based on Codex Standards and national regulations. Such exercises had increased the awareness of member countries of the Codex to the importance of intake studies in protecting consumers. The WG also established "The Guidelines for Simple Evaluation of Food Additive Intake" for carrying out intake studies. If the Committee undertakes work in the area of food additive provisions in non-standardized foods, the activities of the WG could assume more importance.

Establishment of an ad-hoc Working Group on Food Additive Intake

53. The Committee provisionally reinstated the Working Group with Belgium as Chairman with the provision that it would only meet before the next session if there was sufficient work. The following countries and organizations indicated their interest to participate in the Group: Australia, Belgium, Canada, Denmark, Finland, Federal Republic of Germany, France, Italy, The Netherlands, Norway, Spain, Sweden, Switzerland, Thailand, UK, USA, EEC, ASPEC, CIAA, MARINALG, IDF, International Food Additives Council, FAO and WHO.

ENDORSEMENT OF MAXIMUM LEVELS FOR FOOD ADDITIVES AND CONTAMINANTS IN CODEX COMMODITY STANDARDS AND REVISIONS OF PREVIOUS ENDORSEMENTS (Agenda Item 8)

Endorsement of Food Additive Provisions

54. The decisions of the Committee concerning the endorsement or postponement of the endorsement of food additive provisions are indicated in this report (Appendix V, Part I).

Codex Committee on Cereals, Pulses and Legumes (CCCPL)

Food Additive Provisions in Wheat Flour .

55. The Committee had before it document CK/FAC 89/10 Part I prepared by the Secretariat. The Committee noted that it should consider for endorsement in the Codex standard for wheat flour, provisions for chlorine, chlorine dioxide, monocalciumphosphate, benzoyl peroxide, azodicarbonamide, potassium bromate, fungal amylase from *Aspergillus oryzae* and proteolytic enzyme from *Aspergillus oryzae*. The Committee was advised that the technological basis for consideration of endorsement of the food additives in wheat flour was contained in document CX/FAC 88/10-Part II, which was presented at the last session of the Committee.

56. The CCCPL at its 6th Session had endorsed the statement of technological justification contained in CX/FAC 88/10-Part II and requested that this statement be submitted to CCFAC. Noting that the additives in question had been evaluated and cleared by JECFA, the CCCPL saw no impediment to the endorsement of these provisions by CCFAC, provided that the standard clearly indicated that there would be certain restrictions on their use and countries would be able to indicate specified deviations from the standard.

57. The recommendations of the Secretariat for endorsement of the food additive provisions were placed before the Committee for discussion.

58. The delegation of the Fed.Rep. of Germany expressed the view that oxidizing agents should not be permitted in bread as their use would impair the vitamin content of bread, which is a staple food for many. The delegation also objected to the inclusion of potassium bromate which had been evaluated by the Scientific Committee for Food of the European Community and had been classified as a genotoxic carcinogenic compound. The Secretariat informed the Committee that according to JECFA, potassium bromate is highly toxic but that no detectable residues are left in baked products.

59. Many delegations expressed their reservations with reference to the use of chlorine, chlorine dioxide, benzoylperoxide, azodicarbonamide and potassium bromate. Some delegations expressed a reservation on the whole list. The Committee agreed to the proposal of the Chairman to endorse the provisions for fungal amylase, proteolytic enzyme and monocalciumphosphate. The Committee noted that the food additive provisions in wheat flour which were not endorsed will be referred to the Executive Committee and the CAC for a final decision.

Codex Committee on Fish and Fishery Products

Draft Standard for Quick Frozen Blocks of Fish Fillet, Minced Fish Flesh and Mixtures of Fillet and Minced Fish Flesh (Alinorm 89/18, Appendix II)

60. The Committee endorsed all the food additive provisions and agreed to the Secretariat's proposal that the maximum levels of phosphates should be expressed as 10 g/kg in the final product, to account for the level of phosphates naturally present.

Draft Standard for Quick Frozen Fish Sticks (Fish Fingers) and Fish Portions - Breaded or in Batter (Alinorm 89/18, Appendix III)

61. The Committee endorsed the provisions for food additives proposed by the CCFPP.

Draft standard for Dried Salted Fish (Alinorm 89/18, Appendix IV)'

62. The Committee endorsed the provisions for the food additives.

62A. The delegations of Fed.Rep. of Germany, France, Italy, Poland and Switzerland expressed their reservations for the provision of phosphates in all fish product standards. The delegation of Brazil expressed reservation for all the food additives in fish products except phosphates. The delegation of Argentina expressed reservations for the use of methylethylcellulose, hydroxy propyl methyl cellulose and food colours for all fish product standards.

Coordinating Committee for Europe

Draft European Regional Standard for Mayonnaise (Alinorm 89/19, Appendix III)

63. The Committee endorsed all the food additive provisions, except lutein, which was not toxicologically cleared by JECFA for use in food. The Committee agreed with the proposals made by the representative of CIMSCEE. These changes are reflected in the Appendix V, Part I of the report.

64. The delegation of Denmark expressed reservations with reference to the use of BHT. The delegation of the Federal Republic of Germany expressed the view that the list of food additives in the standard was too long.

Action needed by CCFAC resulting from change in ADI Status of Food Additives

65. The Committee had before it document CX/FAC 89/10, Part II, prepared by the Secretariat. The document presented the action needed to be taken by CCFAC resulting from changes by JECFA in the ADI status of food additives. The decisions of the Committee are tabulated in Appendix V, Part II to this report.

66. At its 33rd Meeting, JECFA allocated a full ADI (0-0.5) to BHA and lowered the ADI allocated to Erythrosine from 0-1.25 (Temp.) to 0-0.05 (Temp.). In view of these changes the Committee decided to endorse fully the provisions for BHA in all Codex Standards for fats and oils. The Committee confirmed its decision of the 20th Session requesting a review by the Codex Commodity Committees of the provisions for Erythrosine in Codex Standards for fruits and vegetables, fish and fishery products, meat and poultry products and milk and milk products. It expressed the opinion that in view of the very low ADI allocated to Erythrosine the Commodity Committees should be asked to seek substitutes for this colour.

Endorsement of Food Contaminant Provisions in Codex Commodity Standards

67. The Committee had before it document CX/FAC 89/10-Part III and Room Document No. 1.

Codex Committee on Cereals, Pulses and Legumes

Draft Standards for Certain Pulses (Alinorm 89/29, Appendix II), Sorghum Grains (Alinorm 89/29, Appendix III), Sorghum Flour (Alinorm 89/29, Appendix IV)

68. The Committee reworded the provision for contaminants in the draft standards for Certain pulses, for Sorghum grains and for Sorghum flour to read as "The Commodity shall not contain heavy metals in amounts which may represent a hazard to health". The Committee temporarily endorsed the redrafted provision for contaminants.

Codex Committee on Vegetable Proteins

Draft Standards for Vegetable Protein Products (Alinorm 89/30, Appendix III) and Soy Protein Products (Alinorm 89/30, Appendix IV)."

69. The Committee took the same action on the provision for contaminants as that for draft standards for certain pulses, sorghum grains and sorghum flour (See Para 68). The decisions of the Committee concerning endorsement of contaminants are indicated in Appendix V, Part III.

CONSIDERATION OF CLASS NAMES AND INTERNATIONAL NUMBERING SYSTEM (INS) (Agenda Item 9)

70. The Committee had before it the report of the ad hoc Working Group on Class Names and the International Numbering System (INS) which was introduced by the Chairman of the Working Group, Mr L.J. Erwin (Australia). The WG considered document CX/FAC 89/9 which contained the responses of member governments to CL 1988/52 and additional written responses provided by Thailand, the EEC and ECSS.

71. The Committee was reminded that the purpose of the INS was to provide internationally agreed numbers that could be used on food labels to identify food additives in compliance with the Codex General Standard for Labelling of Prepackaged foods (Codex Stan 1-1985). The Committee agreed that the system should include all food additives approved for use in individual member countries and that it had no toxicological significance since it extended well beyond those additives cleared by JECFA. The list would have to be an open one and provisions would need to be made for it to be updated on an ongoing basis.

72. The Committee agreed that there is a need for preparing a detailed foreword to the INS that should include the purpose or intent for which the system was developed. The foreword should also include simple definitions for the functional classes included in the system. It was also agreed that draft definitions for the functional classes should be prepared well in advance of the next session and the definitions and foreword circulated to member governments by means of a Circular Letter for comments. The foreword and the definitions could be finalized at the next session of the Committee. The Committee noted that at its earlier sessions an effort had been made to group additives with similar functions together. However, as the list has to be an open one and most spaces for three digit numbers had already been allocated, the Committee agreed that this approach would not be possible in the future. Consequently, the positioning of food additives in the list should not be taken as an indication of their function. The Committee agreed that this should be explained in the foreword.

The International Numbering System

73. The Committee agreed that the numbers allotted to the food additives were final and that any changes to these numbers that had already been established would cause difficulties for both industry and consumers. It also agreed that in some instances an alphabetical subscript would be necessary to enable adequate identification for consumers. Consequently, the caramels 150a to 150d; carotenoids 160a to 160f and 161a to 161g; and the fatty acid esters of glycerol 472a to 472g should be included in the left column for labelling purposes. The further identification of food additives in the center column would more appropriately be numerical subscripts, for example curcumins- (i) curcumin, (ii) turmeric.

74. The Committee included a number of additional food additives in the INS as listed below:

152	- Carbon black (hydrocarbon-sources)
163(iii)	- Blackcurrant extract
242	- Dimethyl dicarbonate
331(ii)	- Disodium monohydrogen citrate
410	- Gellan gum
570	- Fatty acids
910	- Wax esters
945	- Isobutane
959	- Neohesperidine dihydrochalcone
1505	- Triethyl citrate

and changed no. 965 to read maltitol and maltitol syrup in accordance with the recent JECFA decision.

75. In order to improve the lay-out of the INS the Committee made the following changes:

- ethyl cellulose was included as number 462 and deleted from 1525
- sodium calcium polyphosphate was included as 452(iii) and deleted from 543
- calcium polyphosphates was included as 452(iv) and deleted from 544
- ammonium polyphosphates was included as 452 (v) and deleted from 545
- dicalcium diphosphate was included as 450(vi) and deleted from 540
- dimagnesium diphosphate was included as 450(viii) and deleted from 546

76. As proposed by The Netherlands, the technological functions "yeast food", "nutrient" and "salt substitute" were deleted from the third column (Technical functions) of the INS. The references to "taste modifier" were amended to read as "flavour modifier". As proposed by CCPMPP, "water retention agent" was included as a function of the phosphates (339, 340, 341 and 450).

77. The Committee agreed to delete numbers 1411, 1423 and 1443 which referred to distarch glycerol, acetylated distarch glycerol and hydroxy propyl distarch glycerol, since the additives were no longer used in food. The committee also agreed that sodium caseinate (469) was a food and not a food additive and therefore deleted it from the system. The Committee also agreed to delete (241) wood smoke. The delegate of India drew the attention of the Committee to the fact that some of the substances included in the system had also functions as food. It was agreed that the Committee should also maintain an internal list of those food additives either removed from the list (e.g. wood smoke) or not included in the list, together with an explanation of why it was not in the list.

78. The Committee accepted to include "emulsifier" as a function of sorbitol and "anticaking agent" as a function of mannitol and isomalt. The delegation of Federal Republic of Germany expressed its reservation. The Committee also agreed that when polyols were used as food additives, they should be declared on the label along with their appropriate functional class, e.g. humectants. The Committee deferred consideration of the situations where polyols constituted the main component of foods such as confectionery.

Enzymes which function as food additives

79. The Committee agreed that enzymes should be identified in the list of ingredients under the appropriate functional class and that numbers should be allocated to those enzymes which functioned as food additives rather than as processing aids. Although it was considered that the enzymes should be incorporated into the INS in positions near other food additives with comparable functions (e.g. "flour treatment agents"), it was found that this was not possible since there were no spare numbers available near the presently listed "flour treatment agents". It was therefore agreed that the enzymes should be incorporated as an 1100 series as follows:

- | | |
|------------------------|---|
| - 1100 Amylase | Flour treatment agent |
| - 1101 Proteases | Flour treatment agent, flavour enhancer, stabilizer, tenderizer |
| (i) protease | |
| (ii) papain | |
| (iii) bromelain | |
| (iv) ficin | |
| - 1102 Glucose oxidase | Antioxidant |
| - 1103 Invertase | Stabilizer |
| - 1104 Lipase | Flavour enhancer |
| - 1105 Lysozyme | Preservative |

80. The Committee noted that there remained some difficulty in clearly differentiating enzymes that acted as food additives or as processing aids and agreed that further consideration should be given to the list proposed above. Additional comments will be requested by Circular Letter along with proposals for any other enzymes which should be appropriately listed as food additives. Proposals for inclusion of i) Cellulase (Finland), ii) Glucose isomerase and iii) Pectinase (Thailand) will also be considered at the session. A list of food additives, proposed by member countries for inclusion in the INS and for which numbers had yet to be allotted are given in Appendix VI Annex 1 to this report. These will be allotted numbers by the Committee at its next session.

81. The amended INS is attached as Appendix VI to this report. The Committee agreed to send out a Circular Letter to member governments requesting proposals for additional food additives for inclusion in the INS.

Table of functional Classes

82. Although some delegations considered that "gelling agent" was only a sub-class of "thickener", the Committee noted that there was support for its retention as a functional class on the basis that the function was different from that of thickening. There was also support for the retention of "emulsifying salt" as a functional class on the basis that it had now been used for many years and was understood by consumers. "Melding salt" and "sequestrant" were added as technological functions. The functional class "colour stabilizer" was changed to "colour retention agent". Two additional functional classes were proposed, and it was agreed that the following should be included in square brackets and further comments requested by means of a Circular Letter:

22. [Acidifier/acid/food acid]
23. [Firming agent]

83. The delegation of Australia expressed the view that the functional class "sweetener" did not adequately distinguish between food additive sweeteners and sweet

foods such as sugar and honey. He proposed that the term "artificial sweetener", as presently required by the Codex Labelling Standard and the EEC Labelling Directive, should be retained. The Committee recalled the discussions at its last session which supported the descriptive term "sweetener" and took no action. Australia reserved its position on this matter.

84. The Committee agreed with the proposal of New Zealand that a footnote should be included in the table of functional classes drawing attention to the requirements in the Codex General Standard for Labelling regarding the declaration of flavours and modified starches. The Table of Functional Classes is attached as Appendix VI Annex 2 to the Report. The Committee agreed that it should be referred to the forth coming meeting of CCFL for its views which could then be reviewed at the next meeting of CCFAC.

Status of the International Numbering System

85. The Committee agreed to bring to the attention of the CAC the progress the Committee had made in developing the INS. Columns 1 and 2 of the System (Appendix VI) were final and column 3 which referred to the technical functions of the food additives was still subject to review. The list will be an open one and proposals for inclusion of further food additives into the system will be considered. A foreword to the system which would also contain definitions for functional classes will be prepared.

Establishment of an ad-hoc Working Group on International Numbering System and class Names

86. The Committee reappointed Australia as Chairman of the Working Group. The following countries and organizations indicated their interest to participate in the Working Group: Australia, Belgium, Canada, Denmark, Finland, Federal Republic of Germany, The Netherlands, New Zealand, Portugal, Spain, Sweden, Switzerland, Thailand, UK, USA, AMFEP, ASPEC, CIAA, EEC, ECSS and IFG.

Revisions to Codex List B

87. The Committee had before it document CX/FAC 89/2 containing proposals for revisions of Codex List B. The purpose of this paper was to bring Codex List B up-to-date in the light of decisions of the 30th, 31st and 33rd meetings of JECFA. The revisions to Codex List B are included in Appendix VII to this report.

88. The Committee noted that the full text of Codex List B which was available in the report of its 18th Session (ALINORM 87/12) was not updated after that session. The Committee was informed that the full text of the revised Codex List B would not be appended to the present report. Member governments were requested to incorporate the present revisions to Codex List B in the full text of Codex List B found in ALINORM 87/12, Appendix V.

89. The Committee expressed the view that Codex List B, which contained those food additives in which the member governments and national and international organizations had shown interest from a technological point of view and the evaluation of which by the JECFA was pending, was serving a useful purpose. The Committee agreed that Codex List B should be maintained.

CONSIDERATION OF PROCESSING AIDS (Agenda Item 10)

An inventory of Processing Aids

90. The Committee had before it documents CX/FAC 89/12 and Add. 1, which summarized government comments on the inventory of processing aids. Dr. Ronk (USA), Chairman of the ad hoc Working Group on Processing Aids presented the report of the WG (CX/FAC 89/12-Add. 3). The report confirmed that many food additives were also used as processing aids within the meaning of the definitions. However, the objective of establishing an Inventory was to identify substances used as processing aids to determine whether or not they would require full evaluation by JECFA. It was further pointed out that substances known to be used as food additives were identified as such in Appendix A to the Inventory. The WG did not recommend revision of the definitions for food additives and processing aids as it was felt that these definitions were adequate for that purpose.

91. The Committee agreed that the current Inventory, as revised at the present session, should be submitted to the CAC for adoption as a Codex Advisory text, bearing in mind that additions to the Inventory would always be possible. The revised Inventory is contained in Appendix VIII to the present report.

92. The Committee agreed with the recommendation of the WG that an inventory of boiler-water treatment agents used for the production of culinary steam should be established for inclusion in the main Inventory of Processing Aids. The same procedures would be used as were used for the preparation of the main inventory, and a Circular Letter requesting information will be sent to governments.

93. The Italian delegation raised the question of the inclusion in the Inventory of water-treatment agents used for drinking water for food preparation purposes.

94. Several delegations (Italy, Switzerland, United Kingdom) were in favour of sending out a Circular Letter to member governments requesting comments on the use of substances for the treatment of water used in food processing. It was pointed out by the Secretariat that consideration of water-treatment agents could be outside the terms of reference of the CAC, and that the circulation of a Circular Letter could itself be considered a decision on which the prior opinion of the Executive Committee should have been sought. The Committee therefore decided to seek first the opinion of the Executive Committee.

Government Comments on Washing and Peeling Agents (CX/FAC 89/12-Add. 2)

95. The Chairman of the WG informed the Committee of the conclusion of the WG that in this category of processing aids the maximum potential intake for any of the substances used was 0.02 mg/person/day and that none of the data found warranted further evaluation by JECFA. The Committee agreed with this conclusion.

Future work

96. The Committee agreed with the WG that the first objective of its work in respect to processing aids had been achieved; that is a comprehensive inventory had been prepared and substances had been classified according to their uses as processing aids. At the same time those substances also used as food additives had been identified. The inventory on processing aids is attached as Appendix VIII to this report. The Committee confirmed that the Inventory should not be considered as a complete and final list, and that new substances could be added when required. Similarly, it drew attention to the status of the Inventory and emphasized that it was not intended to be

considered as a positive list of permitted processing aids to be used, for example, by reference in Codex Standards.

97. The Committee agreed to proceed with the next stage in its approach to processing aids; that is, to identify categories of substances from the Inventory which might leave residues in foods which were present in sufficient quantities that an evaluation by JECFA would be warranted. It agreed that a Circular Letter should be sent to governments requesting comments on which categories of processing aids should be selected for attention and requesting also an indication of residue levels that might be found in foods.

Consideration of the Technological Justification for the Use of Processing Aids in the Production of Primary Protein Products and Discussion of the Use of Certain Additives in Secondary Vegetable Protein Products (Room documents 5 and 9?)

98. The Secretariat informed the Committee that a list of processing aids for use in the production of primary vegetable proteins had been submitted by the Committee on Vegetable Protein Products to this Committee for information. Considerable discussion took place as to whether or not these substances were food additives or processing aids. Several delegations (Finland, Switzerland, United Kingdom, United States) expressed the view that many substances on the list were in fact food additives for which endorsement of this Committee would be required and that the CCVP should be informed of this. As stated above, reference to the Inventory of Processing Aids in the Codex Standard could be misleading, as the object of the Inventory was not to provide a positive list of approved processing aids.

99. The Committee concluded that the listing of processing aids in Codex Standards was not subject to endorsement, and that individual processing aids in the list provided by the Committee on Vegetable Protein Products would be considered for inclusion in the Inventory.

Nitrates in Processed Meat Products

100. The Committee had been requested by the Codex Committee on Processed Meat and Poultry Products to advise on the presence of nitrate in meat products from the authorized use of nitrite salts. The Committee agreed that break-down or metabolic products were considered as a normal consequence of the use of an approved food additive; for example, as in the case of antioxidants. The presence of a small amount of nitrate present as a result of the oxidation of nitrites when used in accordance with Codex Standards, would therefore not need to be listed in the Standards, either as a contaminant or, in the labelling.

Reinstatement of the Working Group

101. The Committee expressed its appreciation for the work of the WG and reinstated it under the Chairmanship of Dr. R.J. Ronk (USA) with the same membership: Belgium, Denmark, France, Finland, Italy, Fed.Rep. of Germany, Malaysia, The Netherlands, New Zealand, Spain, Sweden, Thailand, Switzerland, UK, USA, AMFEP, ASPEC, CIAA, IFG, MARINALG, and WHO.

CONSIDERATION OF SPECIFICATIONS FOR THE IDENTITY AND PURITY OF FOOD ADDITIVES (Agenda Item 11)

102. The Committee had before it documents, CX/FAC 89/7 (Status of Codex Specifications and their Implementation), CX/FAC 89/7-Add. 1 (Information document on JECFA Specifications) and CX/FAC 89/7-Add. 2 (Report of the Working Group on Specifications). The WG was chaired by Mr. D. Dodgen (USA). In introducing the WG report, Mr. Dodgen stated that no specifications were reviewed, but that this WG instead addressed two areas of concern relating to specifications.

103. During the last Session of the CCFAC the Secretariat was requested to prepare an information document containing a listing of JECFA specifications which had been adopted as Codex Advisory Specifications. This was document CX/FAC 89/7-Add. 1 before this Committee. In this paper the Secretariat detailed the procedure first adopted in 1971 and revised in 1983 by the CAC for the elaboration of Codex Advisory Specifications. It was indicated that about 70% of JECFA specifications adopted as Codex Advisory Specifications have been so adopted without modification. It was then suggested in the paper that the CCFAC may wish to consider JECFA specifications as Codex Advisory Specifications essentially without change. The WG rejected this and concluded that there was a need for member governments to review a draft of JECFA specifications and that there should be a single compendium of published specifications with both JECFA and Codex endorsement.

104. The WG then proposed that an approach to accomplish a joint JECFA/Codex publication could be:

1. Preparation of draft specifications by a JECFA meeting,
2. Editorial correction of the draft by respective JECFA experts,
3. Circulation of the corrected drafts to Codex Contact Points with requests for comments,
4. Consideration of government comments by CCFAC and/or a subsequent JECFA, and
5. Publication of the Joint JECFA/Codex Specifications in a looseleaf format.

105. The JECFA Secretariat pointed out that there was a need for a "fast track" system to permit early publication of those specifications for which there are no government comments. The Committee generally agreed that there was a need for member governments' review, and several delegations expressed the opinion that all results of the request for government comments should be referred to the Committee for final decision before publication.

106. After further discussion the Committee requested the Secretariat to prepare a paper for the next meeting of the CCFAC, and to propose procedures whereby JECFA specifications can be rapidly adopted as Codex Advisory Specifications and published in final form with minimum delay.

107. Following the last CCFAC meeting a Circular Letter was sent asking for comments whether Codex Advisory Specifications should be adopted for a substance if:

1. there is no full JECFA ADI,
 - (a) there is a temporary ADI,
 - (b) it has been reviewed by JECFA but no ADI established,

- (c) it has not been reviewed by JECFA,
 - (d) JECFA had withdrawn the ADI,
2. it is not listed in any Codex Standard, and
 3. it has been designated a food or food ingredient by JECFA.

The results of this survey were presented in document CX/FAC 89/7 and included replies from five member governments and the European Community representing 12 countries.

108. The WG noted that the consensus of replies to all of the questions indicated that Codex Advisory Specifications should be adopted under all of the conditions noted, except 1(d) where JECFA had withdrawn a previous ADI. The WG agreed with this conclusion with the provision that the ADI withdrawal was for safety reasons. A withdrawal of an ADI for other, no-safety related reasons would not necessarily preclude adoption as a Codex Advisory Specification. The Committee endorsed the conclusions of the WG including the single publication of the Joint JECFA/Codex specifications in loose leaf format.

109. The Committee expressed its appreciation for the work of the WG and reinstated it under the Chairmanship of Dr. P. Schwartz (USA) with the same membership: Denmark, Fed.Rep. of Germany, Finland, France, Switzerland, UK, EEC, IFG, ISO, MARINALG, and FAO. The WG Chairman expressed the appreciation of the group to the former Chairman, Dr. John Modderman (USA), who served as special advisor to this WG at this meeting. The Committee also expressed its general appreciation.

Aflatoxins in Foods

110. The Committee decided to treat all the agenda items related to the different aspects of aflatoxins in foods together.

METHODS OF ANALYSIS (Agenda Item 13)

111. The Committee had before it the report of its ad hoc Working Group on Methods of Analysis, CX/FAC 89/18-Add. 2, which was introduced by the Chairman of the WG, Dr. B.L. Huston (Canada). The WG considered the documents CX/FAC 89/18-Add. 1, Methods of Analysis of Aflatoxin in Food and Feed including aflatoxins M1 in milk prepared by the Secretariat and CX/FAC 88/18-Add. 1 Methods for determination of Aflatoxin M1 in milk and milk products.

112. The Committee noted that the WG had mainly dealt with three topics:

- the determination of aflatoxin M1 in milk and milk products
- a proposal by The Netherlands delegation to analyse for only aflatoxin B1 in food
- the list of methods of analysis of food additives.

Determination of aflatoxin M1 in milk and milk products

113. The Committee was informed that several methods were available for the determination of aflatoxin M1 in milk, but that many of these methods had not yet been subjected to collaborative studies. The Committee noted that the task of the WG to recommend a method to the Committee was also complicated because the Committee had not yet decided upon a guideline level for aflatoxin M1 in milk.

114. The Committee noted that the IDF was elaborating a method in this respect and therefore decided not to take action in this regard, but await the proposals from IDF.

Determination of aflatoxins in food

115. The Committee was informed of an investigation of The Netherlands, which showed that there was a good correlation between the level of aflatoxin B1 in peanuts and peanut butter and the levels of the other aflatoxins (B2, G1 and G2) in these products. The Committee discussed the suggestion that because of these relationships, an analysis of aflatoxin B1 only might be sufficient and have the advantage of being analytically easier and less time consuming than an analysis for total aflatoxins. However, the Committee also noted, that analysis for aflatoxin B1 alone could result in an underestimation of the total aflatoxin content of the products.

116. The Committee also noted that no decision about using only the B1 metabolite in the analysis for aflatoxin could be taken without consideration of the sampling plan for aflatoxin. The Committee decided to circulate a CL on this matter. The Chairmen of the WG on Methods of Analysis and Sampling in conjunction with the Secretariat were requested to draft the CL.

Methods of analysis for food additives

117. The Committee welcomed the information that Canada was continuing the preparation of the necessary documentation, for those methods of analysis which had been fully studied collaboratively and which would be submitted to CCMAS. The representative from CEFIC emphasized the importance of this work and expressed the wish that it be given more consideration by national authorities.

METHODS OF SAMPLING FOR AFLATOXIN(S) (Agenda Item 12)

118. In introducing the report of the WG, the Chairman of the WG, Mr. W.J. de Koe (The Netherlands) informed the Committee that it had considered a document prepared by the USA as well as a second document which had been prepared by *The Netherlands* and reviewed by the CCCPL. The Committee noted that more information is needed on the distribution of aflatoxin(s) in consignments for the development of statistical sampling plans. The Committee decided to request more information on this subject through a Circular Letter.

119. The Committee also welcomed the action taken by CCCPL on this matter and decided to continue its own work for food commodities other than cereals, pulses and legumes.

120. The Committee agreed to accept for immediate guidance, the simple and practical sampling concept described by J. Waibel¹ and T.B. Whitaker². The Committee noted that sampling plans for aflatoxin should be able to determine aflatoxin at low levels in order to assure a low probability of acceptance of lots which contain aflatoxins that exceed whatever tolerance is established.

¹ A distribution suggested by J. Waibel in "Stichproben-grosse für die Bestimmung von Aflatoxin in Erdnüsse", *Deutsche Lebensmittel-Rundschau*, vol. 73, nr. 11, November 1977, pp. 353-357.

² The negative binomial distribution by Whitaker, T.B and J.W. Dickens, *Journal of American Oil Chemists Society*, 49, pp. 590-593, 1972.

121. The Committee had no adequate information on correlation between levels of aflatoxin B1 and total aflatoxins in foods (except peanuts) and agreed to request comments from governments as regards establishing guideline levels for aflatoxin B1 alone or for total aflatoxins.

Guideline Levels for Aflatoxins in Food

122. The Committee had before it documents CX/FAC 89/18 and Conference Room Documents 3, 8 and 13 containing government comments on the guideline levels for aflatoxins in food and feed, that it had proposed at its last session. An analysis of the replies showed that there was no agreement among governments to the guideline levels proposed. Most of the governments supported the establishment of a higher guideline level than that proposed for nuts, oilseeds, cereals and their products.

123. The Committee noted that it had sufficient information provided by The Netherlands on aflatoxin B1 in Peanuts and Peanut butter which enabled it to propose a guideline level for peanuts only. The Committee did not have information on other foods. The Committee agreed to seek government comments on a proposed guideline level of 5 ug/kg for aflatoxin B1 for peanuts for human consumption at Step 3 (Appendix IX).

Establishment of a Working Group on Mycotoxins

124. Taking into account the interrelationship of the different aspects of guideline levels, methods of analysis and sampling, the Committee decided to install a Working Group on Mycotoxins, which could deal with all the related subjects. Mr. de Koe of The Netherlands will be Chairman of the WG. The membership is: Australia, Belgium, Brazil, Canada, Denmark, Federal Republic of Germany, Finland, France, Japan, Malaysia, The Netherlands, New Zealand, Norway, Portugal, Spain, Switzerland, Sweden, Thailand, UK, USA, EEC, AOAC and IDF. The previous ad hoc Working Groups on Methods of Analysis and sampling were discontinued.

Report of the Joint UNEP/FAO/WHO Food Contamination Monitoring Programme (gems/food)

125. At present, 37 countries participate in the Programme. GEMS/Food is open to any country wishing to participate in the Programme and participation of developing countries is particularly encouraged. Countries participating in GEMS/Food submit data on the concentrations of agreed contaminants in individual foods and in total diets. Contaminants covered by GEMS/Food include selected organochlorine and organophosphorus pesticides, PCBs, lead, cadmium, mercury, tin and aflatoxins. A major objective of GEMS/Food is to compile these food contamination monitoring data from the different countries for a global presentation, synthesis and evaluation. The most recent assessment report covers the period 1971-1985 and draws upon GEMS/Food data as well as data available in the open literature. These data indicate that in the industrialized countries, the current levels of contaminants in foods are generally well within established health guidelines and the trend in contamination is generally downward while data relating to the developing countries are much less complete, there are indications that the levels - particularly organochlorine pesticide, aflatoxins and lead - can in many places be quite high and in excess of health guidelines.

126. Guidelines for Predicting Dietary Intake of Pesticide Residues have been prepared by GEMS/Food in collaboration with the Codex Committee on Pesticide Residues. A global and several regional diets are being developed for use in intake predictions of varying degree of precision. These diets are based on the most recent FAO Food Balance Sheets which provide information on food consumption in over 150 countries.

Guideline Levels for Cadmium and Lead in Food

127. The Committee had before it document CX/FAC 89/18-Add. 5 which was a compilation of government maximum or guideline levels prepared by the delegation of Sweden on the basis of replies to Circular Letter 1988/16-FAC. On the basis of these data and the data contained in a former survey conducted on behalf of the Committee (CX/FA 85/18), the Secretariat had prepared Conference Room Document 14, which was also before the Committee. The paper had collated the information into a relatively restricted number of food categories. The most common levels used by countries as levels for control were tabulated and further adjusted on the basis of data received from the Joint FAO/WHO/UNEP Food Contamination Monitoring Programme. The Committee discussed draft guideline levels for cadmium and lead proposed by the Secretariat.

128. The delegations of Australia and Brazil drew attention to the need to discuss the levels in relation to data actually observed in monitoring programmes. In particular, the delegations stressed that if these proposed guideline levels would be adopted and used as mandatory levels they could create difficulties in trade. The delegation of Denmark supported by Brazil stated that the comprehensive surveys conducted in their country indicated that a more detailed description of food commodities might be required. The delegation of The Netherlands stated also for their Country, extensive surveyance data were available, which could provide further information.

129. The Committee also noted that the proposed draft guideline levels applied to food products "as consumed" as dehydrated or concentrated products had been excluded from the Secretariat's analysis of the data.

130. The delegation of India informed the Committee that national regulations in his country specified a single level of cadmium in all foods at 1.5 mg/kg and a wide range of levels for lead in different commodities. The delegation of the Republic of Korea noted that in his country a single level of 3 mg/kg was set for total heavy metals, this does not apply to infant foods and special foods in liquid form.

Status on the proposed Guideline Levels for Cadmium and Lead

131. The Committee agreed to send the proposed draft guideline levels, as contained in Appendix IX to this report, to governments for comment at Step 3, At the same time, it requested governments to provide survey data which could be used by the Committee's ad hoc Working Group on Intake to support the of guideline levels elaborated.

Guideline levels for Methyl mercury in Fish

132. The Committee had before it Conference Room Document 10 prepared by the Secretariat. The Committee recalled the earlier work that it had undertaken to establish guideline levels for mercury. It had recommended at its 19th Session guideline levels of 0.5 mg/kg total mercury for fish in general and 1.0 mg/kg for predatory fish. It had also agreed to submit these levels to governments for comments at Step 3.

133. The subject was discussed by the 17th Session of the CAC and the 35th Session of the Executive Committee. The Executive Committee noted the recommendations of the 33rd JECFA that efforts should continue to minimize human exposure to methyl mercury and agreed that guideline levels for methyl mercury, rather than for total mercury in fish, should be elaborated.

134. The Committee noted that most of the mercury in fish was present in the organic form and proposed the same guideline levels that it had proposed at its 19th Session i.e. 0.5 mg/kg methyl mercury for fish in general and 1.0 mg/kg methyl mercury predatory

fish and advanced the guideline to Step 5 of the Codex procedure (Appendix X).

GUIDELINE LEVELS FOR VINYLCHLORIDE MONOMER (VCM) AND ACRYLONITRILE (ACN) IN FOODS AND PACKAGING MATERIALS (Agenda Item 14)

135. The Committee had before it CX/FAC 89/11 and Conference Room Document 4 containing comments from governments on the guideline levels that the Committee had proposed for VCM and ACN in Packaging Material and in Food.

136. The Committee noted that the guideline levels for VCM and ACN were supported by a number of delegations. The delegation of the USA informed the Committee that it would not be in a position to accept the guideline levels without suitable sampling plans and validated methods of analysis. Because of the extreme toxicity of these substances, the delegation of Switzerland would consider the GL proposed for VCM in foods (0.02 mg/kg) as highly provisional and propose its submission to regular review or assessment by this Committee.

137. The Committee noted that methods for estimation of VCM in packaging material and in food and accepted by the European Economic Community, were available in the EEC Directives, 80/767/EEC and 81/432/EEC. Also the method accepted by Sweden for estimation of ACN was available in Analyst, 1979, vol. 104, pp. 106-110.

138. The Committee advanced the guideline levels to Step 5 and agreed to send out a Circular Letter asking for information on sampling plans as well as alternate methodology for the estimation of the migrants (Appendix X).

PRIORITIES FOR FUTURE CONSIDERATION OF CONTAMINANTS BY CCFAC (Agenda Item 15)

139. The Committee had before it the document CX/FAC 89/20, containing the comments from governments received in response to CL 1988/23. The CL presented the contaminants identified by the Committee for future consideration by JECFA under the headings, A (contaminants which have been evaluated by JECFA) and B (contaminants pending consideration by JECFA and others).

140. The Chairman had in cooperation with the Secretariat reviewed the comments and proposed the following contaminants as priorities for future consideration by the Committee:

- PCBs
- Diethylhexylphtalate
- Ethylcarbamate (urethane)
- Hydrogen cyanide
- Benz(a)pyrene
- Dioxins

The Committee noted that it had referred Aflatoxin M1 to the Milk Committee and therefore no further action was needed.

141. The Committee was informed that the CCPR had decided that it would not undertake further work on PCBs or dioxins and referred these substances to CCFAC for action.

142. The Committee noted that the analytical methodology available for dioxin was very complicated and that it would therefore be very difficult for the Committee to make any progress on this matter. The Secretariat in conjunction with the USA will prepare a

paper on national strategies for control of dioxins in food and food contact materials. The paper will include information on methods of analysis and sampling plans. This paper will be available as a working paper before the next session of this Committee.

143. The Committee learned that it would take considerable time before adequate data could be made available for JECFA evaluation of ethylcarbamate (urethane).

144. The Committee also noted that limits for hydrogen cyanide were included in the Codex regional standard for manioc and gari and that it was therefore useful to include these substances in the list for future priority action.

145. The Committee decided also to include ochratoxins in the list, since it was informed that there was new information available which deserved further attention. The Committee decided to refer the matter of ochratoxins to the WG on Mycotoxins and to include them on the priority list for JECFA evaluation. The Committee agreed on the need for priority consideration of contaminants included in para 140.

Proposals for the Priority Evaluation of Food Additives and Contaminants by JECFA

146. There was no document available for this agenda item and comments were invited from the plenary.

147. From the priority list of the 20th Meeting of this Committee, a number of substances had not yet been evaluated by JECFA. These were nitrites, nitrates and nitrosamines.

148. The Committee was informed that The Netherlands is collecting new information on nitrates, nitrites and nitrosamines and that it could make this information available at the appropriate time.

149. The Secretariat informed the Committee that the CCPMPP at its 14th Session proposed the reevaluation of Isoascorbic acid by JECFA.

150. The delegation of Finland proposed solanine for evaluation. The delegation of The Netherlands requested the inclusion of benz(a)pyrene but informed the Committee that ingestion studies of benz(a)pyrene and of solanine were underway in The Netherlands and that the results of these studies could be made available to the Secretariat in due course for evaluation by JECFA. The Netherlands proposed gellan gum for inclusion in the priority list.

151. The delegation of the USA requested the inclusion of dimethyldicarbamate, dioctylsodium sulfosuccinate and chymosin A from the source organism Modified E. Coli K12. The Netherlands also proposed chymosin B from the source organism Modified Kluyveromyces Lactis. The Committee also included glycoyanides in the JECFA priority list.

152. The food additives and contaminants proposed by the Committee for priority evaluation by JECFA are given in Appendix XI.

Interpretation of Codex Definition of Food Additives

153. The Committee had before it document CX/FAC 89/21, prepared by the Secretariat. At its 20th Session, the Committee had expressed the view that the present Codex definition for "food additive" made it difficult to identify all those substances which should be considered as food additives for inclusion in the International Numbering System (INS) and that a number of substances included in the INS, could be more appropriately regarded as foods. The Committee had experienced difficulties in the correct interpretation of the definition of "food additive" and asked the Secretariat to

prepare a paper listing past decisions of the Committee on the subject and indicating trends (ALINORM 89/12, Para 82 and 183). Comments on this paper were contained in CX/FAC 89/21-Add.1 and Conference Room Document 2 and 11.

154. The Committee agreed with the conclusion of the paper that the current Codex definition of food additive did not need revision. It also agreed that separating a food into different components by concentration or extraction, did not necessarily change the character of a food. The Committee concluded that no a priori decisions could be made in regard to those substances which might be treated either as a food or as a food additive, and that such decisions would have to be taken on a case-by-case basis.

CONSIDERATION OF NEW FOODS AND OTHER PRODUCTS OF BIOTECHNOLOGICAL ORIGIN (Agenda Item 16)

155. The delegation of The Netherlands presented document CX/FAC 89/19 entitled "Novel Food Constituents in Relation to the Codex Definitions of Food and Food Additives". The paper drew attention to the need to define novel foods, described approaches to their safety assessment, and their conditions of use and labelling aspects. The paper proposed that the CAC should be invited to study the advisability of applying a uniform procedure by one and the same Committee for the safety evaluation of novel foods, food additives and other food constituents.

156. The delegation of the UK, USA, Fed. Rep. of Germany and Belgium, expressed the view that a new approach would be needed if the CAC decided to undertake work in this area. In particular, it was stressed that the safety assessment of novel foods would require different procedures from those used for the evaluation of additives, and that the present system of evaluation had not been designed to cope with these.

157. It was also pointed out that a definition of novel foods would require careful evaluation and would need to exclude foods, food additives and ingredients which were derived by traditional processes. The delegation of France drew attention to the problems of labelling and to the nutritional and toxicological evaluations that might be required.

158. The delegation of Denmark supported the general conclusion of the paper CX/FAC 89/19, that new food ingredients should be examined within the present system, and that FAO and WHO should consider extending the terms of reference of JECFA if required and stressed that in its opinion, defining of a new category between foods and food additives would only create new problems.

159. The Committee noted that the CAC has an agenda item entitled Implications of Biotechnology in International Food Standards and Codes of Practice (ALINORM 89/39) that will be discussed at its next session. Therefore, the Committee agreed that the Chairman will inform the CAC of this Committee's deliberations and seek the advice of the CAC on how to proceed in this area. If the CAC agrees then a Circular Letter prepared by the Secretariat and The Netherlands outlining the situation will be sent to governments inviting to prepare information on approaches for the evaluation of novel foods.

FUTURE WORK (Agenda Item 17)

160. There was no document before the Committee for consideration and items relating to future work are contained elsewhere in the report.

OTHER BUSINESS (Agenda Item 18)

161. There was no other business brought before the Committee for consideration.

DATE AND PLACE OF NEXT SESSION (Agenda Item 19)

162. The Committee noted that its next session would be held in The Hague in The Netherlands, Congressgebouw, from March 19-24, 1990. The Working Group Meetings would be held from March 15-17, 1990.

SUMMARY STATUS OF WORK

Subject Matter	Step	For Action by:	Document Reference
Consideration of JECFA Reports	-	22nd CCFAC	Continuing activity
Matters arising from Codex Sessions	-	22nd CCFAC	Continuing activity
Proposals for General Provisions for the Use of Food Additives in Standardized and Non-Standardized Foods	-	a) Governments b) 22nd CCFAC	ALINORM 89/12A (Paras 22-26)
Intake of Food Additives and Contaminants	-	a) Governments b) 22nd CCFAC	ALINORM 89/12A (Paras 39-53)
Endorsement of Provisions for Food Additives and Contaminants in Codex Commodity Standards	-	22nd CCFAC	Continuing activity
Action needed by CCFAC resulting from change in ADI status of Food Additives	-	22nd CCFAC	Continuing activity
Consideration of Class Names	-	a) 20th CCFL b) 22nd CCFAC	ALINORM 89/12A (Paras 82-84)
Consideration of International Numbering System	-	a) 18th CAC b) Governments c) 22nd CCFAC	ALINORM 89/12A (Paras 70-81)
Revisions to Codex List B	-	a) Governments b) 22nd CCFAC	ALINORM 89/12A (Paras 87-89)
Inventory of Processing Aids	-	a) 18th CAC b) Governments c) 22nd CCFAC	ALINORM 89/12A (Paras 90-101)
Consideration of Specifications for the Identity and Purity of Food Additives	-	a) Governments b) 22nd CCFAC	Continuing activity
Sampling Plans for Aflatoxin(s) in Food	-	a) Governments b) 22nd CCFAC c) 7th CCCPL	ALINORM 89/12A (Paras 118-121)
Methods of Analysis for Determination of Aflatoxin in Food	-	a) Governments b) 22nd CCFAC	ALINORM 89/12A (Paras 115-116)
Guideline Levels for Aflatoxin in Peanuts	3	a) Governments b) 22nd CCFAC	ALINORM 89/12A (Paras 122-124)
Report of the Joint FAO/WHO Food Contamination Monitoring Programme	-	22nd CCFAC	Continuing activity
Guideline Levels for Cadmium and Lead in Food	3	a) Governments b) 22nd CCFAC	ALINORM 89/12A (Paras 127-131)
Guideline Levels for Methyl	5	a) 18th CAC	ALINORM 89/12A

Mercury in Fish		b) 22nd CCFAC	(Paras 132-134)
Guideline Levels for VCM and ACN in food and Packaging Materials	5	a) 18th CAC b) Governments c) 22nd CCFAC	ALINORM 89/12A (Paras 135-138)
National Strategies for Control of dioxins in Food and Food contact Materials	-	a) Codex Secretariat and USA b) 22nd CCFAC	ALINORM 89/12A) (Paras 142)
Methods of Analysis for Food Additives	-	a) CCMAS b) 24th CCFAC	ALINORM 89/12A (Para 117)
Food Additives for Priority Evaluation by JECFA	-	a) Governments b) 22nd CCFAC	Continuing activity
Consideration of New Foods of Biotechnological Origin	-	a) 18th CAC b) Governments c) 22nd CCFAC	ALINORM 89/12A (Para 159)

**ALINORM 89/12A
APPENDIX I**

**LIST OF PARTICIPANTS *
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Les Chefs de délégations figurent en tête et les suppléants, conseillers et consultants sont énumérés par ordre alphabétique.

Figuran en primer lugar los Jefes de las delegaciones, los Supletes, Asesores y Consultores aparecen por orden alfabético.

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Appendix II

INFORMATION ON THE USE OF FOOD ADDITIVES IN FOODS

Widespread use of food additives has generated a great deal of controversy in recent years and their safety and necessity have been questioned. Food additives serve the interests of both the consumer and the producer of foodstuffs since they inhibit the spoilage of food, thus reducing the losses and enabling greater production at a lower cost. They also increase the variability of the diet and make the preparation of food more convenient. The development of the vast array of reasonably priced, stable quality modern food products presently found on the market would have been impossible without the use of food additives.

The Codex Alimentarius Commission

The Codex Alimentarius Commission is an FAO/WHO subsidiary body. It was established in 1963 to implement the Joint FAO/WHO Food Standards Programme, the purpose of which is, particularly:

- To protect the health of the consumer;
- To ensure fair practices in the international trade;
- To promote coordination of all food standards work undertaken by international, governmental and non-governmental organizations;
- To determine priorities and initiate and guide the preparation of appropriate standards.

These standards comprise the Codex Alimentarius, which aims at guiding and promoting the preparation, implementation and harmonization of definitions and requirements on food products, thereby facilitating international trade.

The Codex Alimentarius consists of a set of international standards applying to the major food products for delivery to consumers. All the standards include provisions on the hygienic and nutritional quality of food, food additives, contaminants, labelling and presentation, and methods of analysis and sampling.

One of the Committees set up by the Codex Alimentarius Commission is the Codex Committee on Food Additives and Contaminants (CCFAC). The terms of reference of this Committee are to endorse maximum permissible levels of use of additives in specific foods. While endorsing the use of food additives in food the CCFAC takes into consideration:

- the toxicological clearance of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) for the use of the Food Additive in Food;
- the technological justifications for the use of food additives in the food;
and
- the potential daily intakes of additives and their relation to the acceptable daily intakes.

CCFAC helped to establish the General Principles for the use of Food Additives, adopted in 1972 by the 9th Session of the Codex Alimentarius Commission, the purpose of which is to ensure that all food additive provisions contained in the Codex Alimentarius Standards conform to these principles.

The CCFAC examines the technological need for the use of food additives in food based on information supplied by the Codex Commodity Committees. It further applies safety considerations based on the reports of the JECFA. These two sources are combined as CCFAC's contribution to Codex Alimentarius Standards. The discussions take place in an objective, scientific climate in which all opinions are given full consideration.

The job of the CCFAC is to ensure the consistency of Codex Activities in this domain, and to see that all Codex Committees observe the same strict safety measures.

It is essential for governments, control authorities and, above all, the public, to know that prior to listing as a substance for authorized use, a given additive has been evaluated by independent, respected experts who have voiced on this additive an unanimous opinion which can be accepted in full confidence.

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) is composed of a small group of experts of international renown in their special fields appointed jointly by FAO and WHO. The Committee was established after the Joint FAO/WHO Conference on Food Additives, held in 1955. The terms of reference of this Committee are to evaluate food additives and, where necessary, to establish "acceptable daily intakes" (ADI) and chemical specifications. Its recommendations are based on scientific and technical considerations on the safety of food additives. The JECFA is the principal advisor of the CCFAC in its work to establish a practical base for the determination of toxicological safety and the regulation of food additives in food.

The general principles governing the JECFA's toxicological evaluations have been described in several of its reports.

The objective of the toxicological analysis of any food additive is to define its safety-in-use. In most cases, this amounts to establishing the ADI for man. This dose was initially defined by the JECFA as representing the amount of a substance expressed in mg/kg of body weight which can be taken daily in the diet even over a lifetime, without appreciable risk, considering all known factors at the time of evaluation.

An ADI without an explicit indication of the upper limit of intake {"not limited"}, means that on the basis of the toxicological, biological, chemical, and clinical data available, the total daily intake of the substance present as a result of its use or uses in concentrations necessary to achieve the desired technical effect in food, represents no hazard to health. It is thus considered unnecessary to establish a numerical limit for the ADI of these substances. ADIs are calculated on the basis of experiments on animals and involve a sizeable safety margin taking into consideration all safety factors. The most frequent order of magnitude of the combined safety factors is 100 (10 x 10). Nevertheless, the daily intakes resulting from the use of a food additive seldom tends to exceed the ADI. The JECFA and the CCFAC treat all additives in the same way and make no distinction between those of "natural" and those of "not of natural" origin.

General Principles for the Use of Food Additives

These General Principles are adhered to when proposing use of food additives in food.

- a. All food additives whether actually in use or proposed for use should undergo the appropriate toxicological tests and evaluations. Such evaluation should take account of any cumulative, synergistic or potentiation effect of their use.

- b. Only those food additives should be used, which so far as can be judged on the evidence presently available, present no hazard to consumer health at the levels of use proposed.
- c. All food additives shall be subjected to continuous observation and re-evaluated whenever necessary, in the light of changing conditions of use and new scientific information.
- d. Food additives shall always conform to an approved specification, for example, the identity and purity specifications recommended by the Codex Alimentarius Commission.
- e. The use of food additives is justified only where they serve one or more of the purposes indicated from i) to iv) and only where these purposes cannot be achieved by other economically and practically feasible methods at no risk to consumer health;
 - i) To preserve the nutritional qualities of the food; an intentional reduction of the nutritional quality of the food would be justified in the circumstances set in sub-paragraph ii), and also in other cases where the food does not constitute a major item of a normal diet;
 - ii) to provide the ingredients or constituents necessary for food products manufactured for consumer groups with specific dietary needs;
 - iii) to enhance the keeping quality or stability of a food or to improve its organoleptic properties, provided that neither the nature nor the substance nor the quality of the food are thereby altered in such a way as to deceive the consumer;
 - iv) to aid in the manufacture, processing, preparation, treatment, packaging, transport or storage of food; provided that the additive is not used for the purpose of masking the effects of the use of defective raw materials or of undesirable (including unhygienic) methods or techniques during the course of any of these activities.
- f. The approval or provisional approval of the incorporation of a food additive to an advisory list or in a food standard should:
 - i) be limited as far as possible to specific foods for specific purposes and under specific conditions;
 - ii) be at the lowest level of use necessary to achieve the desired effect;
 - iii) as far as possible take into account any ADI or equivalent assessment established for the food additive and the probable daily intake of the additive from all sources. Where the food additive is to be used in foods consumed by special groups of consumers, the probable daily intake of this additive for this type of consumer should be taken into account.

Consumer Information

The Codex Committee on Food Labelling, which, like the CCFAC, is a subsidiary body of the Codex Alimentarius Commission, had developed a General Standard for the Labelling of Pre-Packaged Foods (Codex Stan 1-1985). This standard deals specifically with the declaration of food additives in food in such a way that the consumer is made aware of what additives are present in the food, their function (e.g. preservative), as well as their specific name (e.g. potassium sorbate), or the use of an internationally recognized code number.

The reports of the Joint FAO/WHO Expert Committee on Food Additives, detailed monographs on the toxicological data evaluated and specifications for the purity of food-grade additives as well as reports of the Codex Committee on Food Additives and Contaminants are freely available to governments and interested national and international organizations from FAO.

RECOMMENDATIONS IN REGARD TO THE ESTABLISHMENT AND REGULAR REVIEW OF PROVISIONS RELATING TO FOOD ADDITIVES IN CODEX STANDARD AND POSSIBLE MECHANISMS FOR THE ESTABLISHMENT OF GENERAL PROVISIONS FOR THE USE OF FOOD ADDITIVES IN NON-STANDARDIZED FOOD

RECOMMENDATION 1

FAO should arrange for the Commission at its next Session to consider the future of the Codex Food Standards Programme in respect of compositional food standards taking into account:

- (i) hanging attitudes towards compositional food standards
- (ii) hanging food technology
- (iii) hanging consumer expectations

It may be that a special conference should be convened to allow a more wide-ranging debate outside the constraints of a formal Commission Session.

RECOMMENDATION 2

All member nations should give comprehensive and constructive responses to requests for comments from FAO. Codex will serve member nations best if FAO is in a position to understand fully the various national positions. It is particularly important to identify changes in national food policies or shifts in government thinking so that FAO can plan ahead accordingly.

RECOMMENDATION 3

Member nations should agree to accept the safety evaluations of JECFA.

RECOMMENDATION 4

Negotiations with member nations should be initiated with a view to obtaining additional resources for a considerable expansion of the role of JECFA and a major acceleration in the rate of safety evaluations made by the Committee each year.

RECOMMENDATIONS 5

CCFAC should consider in the light of "principles for the safety assessment of food additives and contaminants in food" whether it has sufficient information from JECFA on how to translate ADIs into levels of use in food and drink. If so, then it should produce clear guidelines so that all member nations will understand what factors are, and are not, included in the overall safety factor to ensure, for example, that everyone takes account of special groups in the population (especially children) in the same way. If CCFAC requires further assistance from JECFA then a comprehensive list of clear direct questions should be prepared and forwarded to JECFA.

RECOMMENDATION 6

Continuing efforts should be made to ensure that JECFA reports and monographs are as helpful as possible to users of ADIs. JECFA monographs should continue to explain precisely how the ADI was derived from the toxicological data. It is particularly important to set out in each case the quantitative value of each individual factor contributing to the overall safety factor used to convert the "no effect level" to the ADI. When it is not possible to allocate an ADI to a particular additive, every effort should be made to

establish whether or not particular levels in particular foods can be at least provisionally endorsed.

RECOMMENDATION 7

In the interests of free trade there should be greater recognition of, and tolerance shown towards, the variability of technological need among different nations and also with time. There should be a corresponding decrease in government prohibitions on additives in individual foods and a greater reliance on informative labelling so that consumers can choose for themselves which type of product they wish to buy.

RECOMMENDATION 8

CCFAC can never properly carry out its function of endorsing food additive usage in individual foods unless it considers additive usage in all foods. CCFAC should formally take on this task to enable it to serve Codex more effectively. In consequence, the Codex Standard for Food Additives requires a major revision including a complete restructuring to accommodate provisions for non-standardized foods.

RECOMMENDATION 9

CCFAC needs to be absolutely certain of the implications of JECFA evaluations in order to translate these into levels of use in individual foods. Doubts exist in particular in relation to certain groups of closely related compounds which have been allocated the same numerical ADI but do not appear to have been formally assigned to a group ADI. In theory such compounds could, therefore, each be used in the same food up to the limit of the individual ADIs rather than to the limit of the collective ADI. The Secretariat should clarify, seeking advice as necessary from JECFA, so that CCFAC has an unequivocal database on which to base its work.

RECOMMENDATION 10

The CCFAC should adopt the following work plan:

- (i) Agree to prepare a new Codex Standard for Food Additives along the lines proposed (par. 39 - 40 and Appendix III of CX/FAC 89/16)
- (ii) Set up 3 working parties to deal with different classes of additives and to begin work, as a first priority, with additives with an ADI of 10 or less (par. 41 - 46 of CX/FAC 89/16)
- (iii) Collect usage and intake data for additives with an ADI of 10 or less and, where necessary, prepare a list of restrictions on use taking proper account of technological need and national "styles" of product (par. 46 - 51 & 55 of CX/FAC 89/16)
- (iv) Redraft the food additive provisions of existing commodity standards to cross refer to the new standard for food additives (par. 52 - 54 of CX/FAC 89/16).
- (v) As an interim measure, allow the "low priority" additives to be used subject only to GMP, except in those foods from which they would be totally excluded (par. 56 of CX/FAC 89/16)

GUIDELINES FOR SIMPLE EVALUATION OF FOOD ADDITIVE INTAKE

C O N T E N T S

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1. INTRODUCTION

The first step in the permitted use of food additives is the examination of toxicological studies by the Joint Expert Committee on Food Additives (JECFA), the establishment of an Acceptable Daily Intake (ADI), and the elaboration of identity and purity criteria.

In the second step, proposals for the permitted use of an additive in different foodstuffs are made by the responsible governmental agencies or by the Codex commodity committees to the Codex Committee on Food Additives and contaminants (CCFAC). The endorsement of the proposed use in a foodstuff is done in accordance with the General Principles for the Use of Food Additives (Codex Alimentarius Commission Procedural manual, 6th Ed. p. 144, 1986) which states that "Approval or temporary approval for the inclusion of a food additive in an advisory list or in a food standard should:...(iii) as far as possible take into account any Acceptable Daily Intake, or equivalent assessment, established for the food additive, and the probable daily intake of it from all sources. Where the food additive is to be used in foods eaten by special groups of consumers, account should be taken of the probable daily intake of the food additive by consumers in those groups."

Information regarding the probable daily intake is therefore needed, especially in the case of food additives with low ADI, high levels of an additive in a food of high consumption and/or the use of additives in food eaten by special population groups.

Different approaches exist as regards the estimation of the probable daily intake, some of these being very expensive and time consuming. Some countries have therefore difficulties in initiating studies on intake of food additives.

For this reason, CCFAC requested the Working Group on Intake of Food Additives and Contaminants to prepare guidelines for simple evaluation of food additive intake (ALINORM 87/12, para 46).

2. BACKGROUND

2.1 Acceptable Daily Intake

The Acceptable Daily Intake (ADI) is an estimate by JECFA of the amount of a food additive, expressed on a body weight basis, that can be ingested daily over a lifetime without appreciable health risk (standard man - 60 Kg) (WHO Environmental Health Criteria document N^o 70, Principles for the Safety Assessment of food Additives and Contaminants in Food, Geneva, 1987). The ADI is expressed in milligrams of the additive per kilogram of body weight.

For this purpose, "without appreciable risk" is taken to mean the practical certainty that injury will not result even after a life-time's exposure (Report of the 1975 JMPR, TRS 592, WHO, 1976).

The ADI is established over a lifetime. A body weight of 60 kg is usually taken to represent the average weight of the population (Report of the 1988 JECFA, TRS 776 sec. 2.2.3. WHO, 1989). However, in some countries, and especially in the developing ones, a 50 kg body weight would better represent the average body weight of the population.

2.2 Theoretical Maximum Daily Intake

The Theoretical Maximum Daily Intake (TMDI) is calculated by multiplying the average per capita daily food consumption for each foodstuff or food group by the legal maximum use level of the additive established by Codex standards or by national regulations and by summing up the figures.

The TMDI gives only a rough indication of the dietary intake of a food additive since it does not take into consideration the food habits of special populations groups, and it assumes that:

- (a) all foods in which an additive is permitted contain that additive;
- (b) the additive is always present at the maximum permitted level;
- (c) the foods in question containing the additive are consumed by people each day of their lives at the average per capita level;
- (d) the additive does not undergo a decrease in level as a result of cooking or processing techniques;
- (e) all foods permitted to contain the additive are ingested and nothing is discarded.

2.3 Estimated Daily Intake

The Estimated Daily Intake (EDI) of a food additive is the amount of an additive ingested by the average consumer of the food based on a) the actual use of the additive by industry, b) according to Good Manufacturing Practice (GMP), or c) an approximation as close as possible to the actual use level.

There is a wide variety of procedures for calculating intakes that closely approach actual intakes. These procedures are described in Sections 4 and 5.

3. ACCEPTABLE DAILY INTAKE AND INTAKE ESTIMATES

Before discussing different approaches used in estimating food additive intake, the methods of establishing an ADI need to be reviewed.

Groups of animals (e.g. rats) are given daily diets containing different levels of the additive under examination. For example, levels of the additives in the diet could be: 0.1%, 1%, 2%, 5%. If a toxic effect is found at the 2% level and a "no toxic effect" at 1% level, the 1% level (expressed in mg/kg body weight) will be the "no-observed-effect level", and it is from this level that the extrapolation to humans is done. In this case, the no-observed-effect level lies between the 1% and 2% levels, and if no toxicological evaluations are done at intermediary levels (1.25%, 1.50%, 1.75%) the choice of the 1% level as the no-observed-effect level introduces already a first safety factor.

The extrapolation from the no-observed-effect level to an ADI is often done by using a safety factor of 100 (10 x 10) which assumes that humans are 10 times more sensitive than experimental animals and that there is a 10-fold variation in sensitivity within the human population. This safety factor of 100 is based on the experience and common sense of toxicologists and therefore cannot be compared to a physical value such as the boiling point of a pure substance. More information regarding the no-observed-effect level and the use of safety factors can be found in "Principles for the Safety Assessment of Food Additives and contaminants in Food". (Environmental Health Criteria № 70, WHO, Geneva 1987, p. 77-79).

Estimations of intake may be sequentially calculated starting with the simplest TMDI and proceeding to more refined EDI if necessary. When precise data on

consumption of foodstuff exist, they should be used. When such precise data do not exist, approximations can be adequate to support a safe use. A hypothetical figure based upon extreme theoretical cases such as the TMDI can give adequate assurance of safety in use if such figure is lower than the ADI. However, if the ADI is exceeded, using this approach, before a decision is made a search would have to be made for data which approximate the actual intake (the TMDI can be improved by taking into account intake of special population groups).

4. DATA AVAILABLE

4.1 Food Consumption and Regulation of Use of food Additives

An excellent review of food consumption data has been presented in the "Guidelines for the Study of Deitary Intakes of Chemical Contaminants" WHO Offset publication N^o 87, 1985. In the case of a simple evaluation of food additive intake, the first step is to identify and collect all data available in the country and check if these data can provide sufficient information on the consumption of the food addtives under evaluation.

When examining existing food consumption data, the possible variation of food habits within groups of the population should not be forgotten. Some groups within the population will show patterns of food consumption that are widely different from those of the population as a whole and include, for example, ethnic and cultural minority groups within a community; people using some additives at home (glutamates, intense sweeteners); heavy eaters and drinkers; and the sick (e.g. diabetics).

The evaluation of the food consumption data existing in the country should be made taking into consideration the regulations in force concerning the additives.

The following three types of regulations will be considered:

- (a) The authorization to use the food additive is given according to the Principle of the Strict Positive List. That is, for each additive there is a list of foodstuffs in which the additive may be used with an indication of the maximum level of use. Here data on consumption of foodstuffs for which the additive is specifically authorized are only needed.
- (b) The additive is authorized in specified foodstuffs, but according to GMP. Here also, as in (a), consumption data are only needed for those specified foodstuffs. However, GMP has to be translated into figures. Contact with the food industry can solve the problem by providing figures for actual levels of use in different foodstuffs. A wide sampling of foodstuffs wherein the additives are authorized together with analytical evaluation of levels present in foodstuffs can also be done as long as the financial impact of this approach is not too heavy.
- (c) The additive is authorized according to GMP in all foodstuffs, prohibition of use being indicated for some of them. This legislative situation needs a close collaboration with the food industry and/or a rather complete sampling and analytical evaluation of the levels present in foodstuffs. The financial consequences of this approach will limit its applicability.

In some countries, incomplete regulations for the use of food additives can make the problem even more complicated, especially when the majority of processed food is imported.

The following information provided by the exporter may be of help:

- (i) Compliance of the imported food with the legislation of the exporting country;
- (ii) Regulation of the exporting country of food additives for the product under consideration.

4.2 Approaches for Determining Food consumption Data

There are two general approaches in order to obtain information on the dietary habits of a population or of individuals: (i) involving the collection of inferred data on the movement and disappearance of foodstuffs in a region or home; and (ii) involving the collection of direct personal data on the actual amounts of food consumed by an individual or household.

A summary of the methods that have been used generally is given in Table 1.

Table 1

Approaches for Determining Food consumption Data

<u>Assessment</u>	<u>Method</u>
Individual	Food diary, weighed intakes, Duplicate Portion Studies, Dietary Recall, Food frequency;
Population	Food diary, weighed intakes, Dietary recall, Food frequency, Food disappearance method - Household - National

These approaches are described in detail in WHO Offset publication N^o 87 referred to above.

As regards simple techniques, the national and household food disappearance methods and, to a lesser degree, the food frequency technique may be considered appropriate. The household food disappearance method can also be used to assess the food habits of special population groups (ethnic and cultural minority groups, adolescents, groups of heavy eaters or drinkers, people using some additives at home, etc.).

National Food disappearance Method

This method, when applied to processed foods (which are in general those containing the additives), can give a first approximation of the average consumption. It should, however, be complemented by information regarding average consumption by special population groups and use of the additives at home. Correction for wastage is normally not needed for processed food and, since the ADI is established over a lifetime, seasonal variations need not be considered. Food consumption data obtained by the national food disappearance method are calculated in the following way:

national food balance	-	food production
	+	food imported
	+	food taken from stocks
	-	food added to stocks
	-	food exported
generally not taken into account for processed food	-	food used for seed
	-	food used for non-edible purposes
	-	food loss from harvest to kitchen
	-	animal feed

Household Food Disappearance Method

Household food consumption data generally represent the amount of food that disappears from a home kitchen in a given time period divided by the number of persons in the home. The householder is asked to take an inventory of all the foods in the kitchen and to keep track of all food purchases made during a set time period (usually one week). Another kitchen inventory is taken at the end of that time. The food that has disappeared is assumed to reflect the food consumption of the family. The household food disappearance data are divided by the number of people in the family and the number of days of the time period to estimate the consumption per person per day.

To obtain more accurate estimate of food consumption using household data, the methodology may be modified to correct for: food fed to pets; food given away or received as gifts; food consumed away from home; and food consumed by guests.

Food Frequency

This method attempts to obtain a reflection of the usual patterns of consumption for individual types of food.

The food frequency form is a list of commonly consumed foods to be completed by the individual, indicating the number of times per day, week or month that each food is normally consumed. Each country or region may develop its own food frequency form to reflect the primary foods and food recipes in common use either nationally or regionally. Information regarding the quantity of food consumed is not usually requested on a food frequency form. Data on average serving sizes, obtained from previous diary or recall surveys, are used in connection with the frequency data to produce the desired information on food consumption.

5. SIMPLE APPROACH FOR THE EVALUATION OF FOOD ADDITIVE INTAKE

5.1 Additives for which an evaluation of intake would have to be done

The following priority list can be used to decide for which additives intake evaluation have first to be done:

1. additives authorized at high level in highly consumed foodstuffs,
2. additives authorized in highly consumed foodstuffs,
3. additives having received a low ADI (0-5 mg/kg of body weight)

A low priority can be given to additives which have a non specified ADI when they are used as additives according to good manufacturing practice.

5.2 Proposed Method for a Simple Evaluation of the Intake of an Additive

The following stepwise procedure is proposed:

A. Evaluation of the TMDI

- A.1 Elaboration of the list of foodstuffs in which the additive is permitted;
- A.2 Determination of the levels of use;
 - A.2.1 Maximum permitted levels according to the regulation;
 - A.2.2 Actual levels if authorization is given according to GMP (figures obtained from industry or from analysis);
- A.3 Determination of the average consumption of the foodstuffs in which the additive is permitted;
 - A.3.1 Collection of all available information regarding food habits in the country;
 - A.3.2 When little information is available, the national food disappearance method should be used as a first step;
 - A.3.3 Check if, for some foodstuffs, the average consumption of eaters is not much higher than the average consumption of the population. Consumption data for eaters should be used when the special food habits persist for a long period (additive taken daily in the diet during a lifetime: ADI definition);

- A.3.4 Obtain a better estimate of food consumption by replacing average values obtained from the national food disappearance method by average consumption for eater (see example in the Annexes).

If the TMDI < ADI and when there is no "use at home" of the additives, one can consider that the actual intake is lower than the ADI (overestimations in A.1 and A.2).

If the TMDI > ADI, the EDI approach would have to be followed.

B. Evaluation of the EDI

B.1 Checking the list of foodstuffs:

- Modify the food intake in such a way that only those foods are considered which may contain the additive. For example, if an additive is used only in fruit-flavoured soft drinks, use consumption value for this more precise category rather than consumption of all soft drinks.

B.2 Checking the actual levels of use:

- is the additive used at the maximum authorized level for all the foodstuffs, or only for some of them?

B.3 Introduction of these more accurate figures in the TMDI calculation.

If the EDI < ADI and when there is "no use at home" of the additive, one can consider that the actual intake is lower than the ADI. If the EDI > ADI, discussion should be started with the food industry to discuss levels of use.

C. Use at Home

Food consumption data obtained by the household food disappearance method or the food frequency technique may be used to estimate the intake of food additives used in the form of consumer-dispensed ingredients used in food preparation at the home or as condiments.

6. **SUMMARY**

This document describes a stepwise approach to ascertain that an ADI is not exceeded. Increasingly more accurate estimates of additive intake are made, using simple, inexpensive techniques.

Example of Calculation for Benzoic Acid and Salts

	ADI		0-5 mg/kg b.w.
For person weighing 50 kg:	5 x 50	=	250 rag/person
For person weighing 60 kg:	5 x 60	=	300 mg/person

	<u>Permitted Use</u>	<u>Maximum Level</u> <u>mg/kg Food</u>
1.	Meat products	
	1.1 Croquettes of meat, poultry, game	1500
2.	Fish Products	
	2.1 Caviar and other roe	8000
	2.2 Semi-preserves of fish and invertebrates	1500
	2.3 Shrimps	8000
	2.4 Smoked salmon	1000
	2.5 Croquettes of fish, shrimps	1500
3.	Liquid fruit syrup	250
4.	Vegetables	
	4.1 Gherkins	600
5.	Potato croquettes	250
6.	Drinks	
	6.1 Soft Drinks	100
	6.2 Cider	300
7.	Condiments	
	7.1 Mustard	250
	7.2 Emulsified sauces (from egg yolk)	1000
	Others	

TMDI Estimate

Average food consumption obtained by the national food disappearance method (and other sources)

		Daily Food Intake Consumption	Daily Intake of Additive mg/person
1.	Meat products		
1.1	Croquettes of meat, poultry, game	negligible	-
2.	Fish products		
2.1	Caviar and other roe	17 mg	negligible
2.2	Semi-preserves of fish and invertebrates	3.6 gr	5.4 mg
2.3	Shrimps	1.4 gr	11.2 mg
2.4	Smoked salmon	50 mg	negligible
2.5	Croquettes of fish, shrimps	negligible	-
3.	Liquid fruit syrup (used as concentrate for soft drinks to be included in total soft drinks intake)		
4.	Vegetables		
4.1	Gherkins	2.2 gr	1.3 mg
5.	Potato croquettes	negligible	-
6.	Drinks		
6.1	Soft Drinks	144 ml	14.4 mg
6.2	Cider	0.9 ml	negligible
7.	Condiments		
7.1	Mustard	0.9 g	0.2 mg
7.2	Emulsified sauces	3.4 g	3.4 mg
	TMDI Total		35.9 mg/person

Sources: National institute of Statistics
Federation of Fisheries
Federation of Soft Drinks

IMPROVED TMDI ESTIMATE

Average Intake of Users

Soft Drinks

Average intake of soft drink users: 600 ml
(instead of 144 ml, average intake of the population)

Emulsified Sauces

Average intake of users: 20 gr instead of 3.4 gr

Improved TMDI Estimate

	Daily Intake mg/person
- semi preserves of fish and invertebrates	5.4
- shrimps	11.2
- gherkins	1.3
- soft drinks	60.0
- mustard	0.2
- emulsified sauces	20.0
	<hr/>
Improved TMDI	<u>98.1</u> *

* Remarks: This level being below the ADI, it is considered that the actual intake will also be lower; a more accurate evaluation is therefore not needed.

APPENDIX IV ANNEX 2

EXAMPLE OF CALCULATION FOR SWEETENERS

Maximum Permitted Quantities of Sweeteners

Table 1 gives the maximum permitted quantities of sweeteners used in food and drinks as foreseen in the draft regulation of one country.

The preparation of this table was realized on the basis of a consumption estimate of the different sweeteners. This consumption estimate was carried out on the basis of a modification of the present Guidelines.

The modified model is based on the following starting-points:

- The consumption figures are calculated by the national Food Disappearance Method (production + import - export).
- The consumption of table top sweeteners is related to the consumption of cups of coffee and cups of tea, assuming that a cup of coffee is sweetened with one table-top sweetener corresponding to one sugar lump of 4 gram. The sweetening capacity relative to sucrose was considered to be as follows: saccharin 450; cyclamate 35; aspartame 200 and acesulfame 200.
- The model takes care of the consumption by heavy users of the sweetener.
- The assumption is made that the heavy user is only a heavy user of one product and has an average consumption of other products.
- For heavy users of a specific sweetener that particular product is selected which contributes most to the intake of the specific sweetener.
- A correction factor of 3 is used to estimate the heavy users consumption from the

average users consumption. This correction factor of 3 is based on information provided in the "Guidelines for the Study of Dietary intakes of Chemical Contaminants", WHO, 1985, which indicates that 95 percentile of the population eats less than 3 times the average consumption.

- A theoretical Maximum Daily Intake (TMDI) is calculated by adding the figure for heavy users to the average consumption figures of other foods and compared with the ADI.
- The Theoretical Maximum Daily Intake (TMDI) should not exceed the ADI.

As far as possible the consumption figures were checked with those obtained from dietary recall food consumption surveys. These data did, in general support the consumption estimates. Very few data were available on the consumption of sweeteners by children. The data are under review and checked with the results of a recently carried out nationwide dietary survey. This survey included 5898 persons constituting a representative sample of the population 1-75 years old.

For two product categories the quantites of saccharin and cyclamate, permitted in the final product were limited, in order not to exceed the ADI:

- In table-top sweeteners the maximum allowed quantity of cyclamate and saccharin is lowered to respectively 30 and 70% of the foreseen substitution of sucrose.
- In soft drinks the maximum allowed quantities of cyclamate and saccharin are respectively 400 and 125 mg/kg.

The results of this exercise are given in Table 2.

The consumption figures for the different sweeteners are then as follows:

Saccharin	:	135.7 mg
Cyclamate	:	659.4 mg
aspartame	:	669.6 mg
acesulfame	:	538.6 mg

These TMDIs being below the respective ADIs for a 60 kg person were considered acceptable.

TABLE 1
Maximum Permitted Quantities of Sweetener

Sweetener	Saccharin mg/kg	Cyclamate mg/kg	Aspartame mg/kg	Acesulfame mg/kg
Foodstuff or beverage				
soft drinks	125	400	750	600
syrops (ready to drink)	125	400	750	600
sugar confectionary	1000	4000	2500	2500
pudding powder	50	250	750	1000
Pickles	400	1100	0	0
pickled herring	50	0	140	200
flour confectionary	0	0	1500	500
Chocolate	300	900	5000	3000
Chocolate spread	300	900	0	3000
edible ice	150	1500	1000	1000
desserts	0	0	1000	0
special beer	60	0	0	0
chewing gum	2000	3000	5500	2000
liquid milk products:				
fruit yoghurt	150	250	300	0
others	50	250	750	200
fruit quark	150	250	300	0
salads	0	0	700	200
jam products:				
jams and jellies	300	1000	0	3000
sugar reduced jams	200	500	0	1500
fruit nectar	150	750	750	600
canned fruits	380	1500	0	1000
vitamin preparations	0	0	200	0

TABLE 2
Estimation of the possible consumption of some sweeteners (14.11.1988)

product	Consumption product in g per day	Saccharin		Cyclamate		Aspartame		Acesulfame	
		mg/kg	consumption sweetener via product mg	mg/kg	consumption sweetener via product mg	mg/kg	consumption sweetener via product mg	mg/kg	consumption sweetener via product mg
soft drinks	162	125	20.3	400	64.8	750	121.5	600	97.2
syrup concentrates *	5.1	625	3.2	2000	10.2	3750	19.1	3000	15.3
sugar confectionary ¹	13.5	1000	6.8	4000	27	2500	17	2500	17
pudding powder	1.5	50	0.1	250	0.4	750	1.1	1000	1.5
pickles	3.8	400	1.5	1100	4.2	-	-	-	-
pickled herring	2.2	50	0.1	-	-	140	0.3	20	0.4
flour confectionary	29.3	-	-	-	-	1500	43.9	500	14.6
chocolate	12.1	300	3.6	900	10.9	5000	60.5	3000	36.3
chocolate spread	1.2	300	0.4	900	1.1	-	-	3000	3.6
edible ice	8.8	150	1.3	1500	13.2	1000	8.8	1000	8.8
desserts	?	-	-	-	-	1000	-	-	-
special beer	?	60	-	-	-	-	-	-	-
chewing gum	1	2000	2	3000	3	5500	5.5	2000	2
liquid milk products:									
fruit yoghurt	1.0	150	0.1	250	0.2	300	0.3	-	-
others	24.4	50	1.2	250	6.1	750	18.3	200	4.9
fruit quark	1.7	150	0.2	250	0.4	300	0.5		
salads	4.9	-	-	-	-	700	3.4	200	1
jam products:									
jams and jellies	4	300	1.2	1000	4	-	-	3000	12
sugar reduced jams	0.3	200	0.1	500	0.2	-	-	1500	0.5
fruit nectar	5.8	150	0.9	750	4.4	750	4.4	600	3.5

canned fruits	3.6	380	1.4	1500	5.4	-	-	1000	3.6
coffee (cups)	4.3	²	26.7	³	147.4	-	86	-	86
tea (cups)	1.8	²	11.2	³	61.7		36	-	36
Subtotal			82.3		364.6		426.6		344.2
+ 2 x coffee consumption			53.4		294.8		-	-	
+ 2 x soft dring consumption			-		-		243.0		194.4
Total			135.7		659.4		669.6		538.6

* Assumes 5 : 1 dilution

¹ Consumption sweetener via product calculated with half the amount of sweetener

² Only 70% of the sweetness of a sweetener may be provided by saccharin.

³ Only 30% of the sweetness of a sweetener may be provided by cyclamate

**ENDORSEMENT OF MAXIMUM LEVELS FOR FOOD ADDITIVES
IN CODEX COMMODITY STANDARDS**

This Appendix summarizes all provisions which were considered by the Codex Committee on Food Additives and Contaminants at its 21st Session.

Abbreviations used

E	=	Endorsed
TE	=	Temporarily Endorsed
EP	=	Endorsement Postponed for reasons given in the footnotes
Limited by		
GMP	=	Limited by Good Manufacturing Practice
NE	=	Not Endorsed

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II	Fish and Fishery Products	18th	ALINORM 89/18
III	Coordinating Committee for Europe	18th	ALINORM 89/19
I	<u>CODEX COMMITTEE ON CEREALS, PULSES AND LEGUMES</u>		

Standard for Wheat Flour

<u>Food Additives</u>	<u>Maximum Level in the finished product</u>	<u>Paragraph</u>	<u>Status of Endorsement</u>
Chlorine	2500 mg/kg in high ratio cakes	55 - 59	NE
Chlorine Dioxide	30 mg/kg for yeast raised bakery products	55 - 59	NE
Mono Calcium Phosphate	2500 mg/kg	55 - 59	E
Benzoyl Peroxide	60 mg/kg	55 - 59	NE
Azodicarbonamide	A5 mg/kg for "leavened bread"	55 - 59	NE
Potassium Bromate	50 mg/kg	55 - 59	NE
Fungal Amylase from Asp. Oryzae	GMP	55 - 59	E
Proteolytic Enzyme from Asp. Oryzae	GMP	55 - 59	E

CODEX COMMITTEE ON FISH AND FISHERY PRODUCTS

DRAFT STANDARD FOR QUICK FROZEN BLOCKS OF FISH FILLET, MINCED FISH FLESH AND MIXTURES OF
FILLET AND MINCED FISH FLESH (ALINORM 89/18, APPENDIX II)

Food Additive	Maximum Level in the final product	Paragraph	Status of Endorsement
<u>Moisture/Water Retention Agents</u>			
Monophosphate, monosodium or monopotassium (Monosodium or Monopotassium Orthophosphate)			
Diphosphate, tetrasodium or tetrapotassium (Na or K pyrophosphate)	10 g/kg, expressed as P ₂ O ₅ , singly or in combination ¹		
Triphosphate, pentasodium or pentapotassium or calcium (Na, K or Ca tripolyphosphate)		60	E
Polyphosphate, sodium (Na hexametaphosphate)			
Sodium alginate	5 g/kg	60	E
<u>Antioxidants</u>			
Ascorbic acid or its sodium or potassium salts	1 g/kg, expressed as ascorbic acid, singly or in combination		
Ascorbyl palmitate		60	E
<u>In addition, for Minced Fish Flesh only:</u>			
Citric acid or its sodium or potassium salts	1 g/kg, expressed as citric acid, singly or in combination	60	E
<u>Thickeners</u>			
Guar gum			
Carob bean (locust bean) gum	5 g/kg singly	60	E

Pectins or in combination
 Sodium Carboxymethylcellulose
 Xanthan gum
 Carageenan
 Methyl Cellulose

¹ includes phosphates naturally present

DRAFT STANDARD FOR QUICK FROZEN FISH STICKS (FISH FINGERS) AND FISH PORTIONS - BREADED OR IN BATTER (ALINORM 89/18, APPENDIX III)

<u>Food Additives (for Fish Fillets and Minced Fish Flesh only)</u>	<u>Maximum Level in the final product</u>	<u>Paragraph</u>	<u>Status of Endorsement</u>
<u>Moisture/Water Retention Agents</u>			
Monophosphate, monosodium or monopotassium (Monosodium or monopotassium orthophosphates)	10 g/kg expressed as P ₂ O ₅ , singly or in combination ¹	61	E
Diphosphate, tetrasodium or tetrapotassium (Na or K pyrophosphate)			
Triphosphate, pentasodium or pentapotassium or calcium (Na, K or Ca tripolyphosphate)			
Polyphosphate, sodium (Na hexametaphosphate)			
Sodium alginate	5 g/kg	61	E
<u>Antioxidants</u>			
Ascorbic acid or its sodium or potassium salts	1 g/kg expressed as ascorbic acid, singly or in combination	61	E

Ascorbyl palmitate

In addition, for Minced Fish Flesh only:

Antioxidants

Citric acid or its sodium or potassium salts	1 g/kg singly or in combination	61	E
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Thickeners

Guar gum

Carob bean (locust bean) gum

Pectins

Sodium Carboxymethylcellulose

Xanthan gum

Carrageenan

Methyl cellulose

Food Additives for Breaded or Batter Coatings

Maximum level in breaded or batter coatings

Leavening Agents

Monocalcium phosphate

Dicalcium phosphate

Sodium aluminium phosphate

Sodium acid pyrophosphate

Sodium, potassium and ammonium carbonates

Sodium, potassium and ammonium bicarbonates

1 g/kg singly or in combination, expressed as P₂O₅

Limited by CMP

61

61

E

E

Flavour Enhancers

Monosodium glutamate

Monopotassium glutamate

Limited by CMP

61

E

Acidifying agents

Lactic acid

1 g/kg of the final

61

E

Citric acid or its sodium or potassium salts

product expressed as
lactic or citric
acid, as appropriate

Colours

Annatto	20 mg/kg expressed as bixin	61	E
Caramel (plain)	Limited by GMP	61	E
Beta-carotene	100 mg/kg singly or	61	E
Beta-apo-carotenal	in combination		
Paprika oleoresin	Limited by GMP	61	E

Thickeners

Guar Gum			
Carob bean (Locust bean) gum			
Carrageenan			
Xanthan gum			
Pectins	5 g/kg singly or in combination	61	E
Sodium alginate			
Hydroxypropyl cellulose			
Hydroxypropylmethyl cellulose			
Methylcellulose			
Sodium carboxymethylcellulose			
Methyl cellulose			

Emulsifiers

Lecithins	5 g/kg of the final product singly	61	E
Mono and diglycerides	or in combination	61	E

Modified Starches

- Acid treated starches (including white and yellow dextrins)		61	
- Alkali treated starches			

- Bleached or oxidized starches
- Distarch adipate, acetylated
- Distarch phosphate
- Distarch phosphate, acetylated
- Distarch phosphate, hydroxypropyl
- Distarch phosphate, phosphated
- Monostarch phosphate
- Starch acetate
- Starch, hydroxypropyl

Limited by GMP

E

¹ includes phosphates naturally present

DRAFT STANDARD FOR DRIED SALTED FISH (KLIPPFISH) OF THE GADIDAE FAMILY (ALINORM 89/18, APPENDIX IV)

<u>Food Additive</u>	<u>Maximum Level in the final product</u>	<u>Paragraph</u>	<u>Status of Endorsement</u>
Sorbic Acid or its Ca, Na or K salts	200 mg/kg singly or in combination, expressed as Sorbic acid	62	E

COORDINATING COMMITTEE FOR EUROPE

DRAFT EUROPEAN REGIONAL STANDARD FOR MAYONNAISE
(ALINORM 89/19, APPENDIX III)

<u>Food Additive</u>	<u>Maximum Level in the final product</u>	<u>Paragraph</u>	<u>Status of Endorsement</u>
<u>Antioxidants</u>			
Alpha Tocopherol and Mixed Concentrates of Tocopherol	240 mg/kg singly or in combination	63 - 64	E
Ascorbic Acid	500 mg/kg	63 - 64	E
Ascorbyl Palmitate	500 mg/kg	63 - 64	E
Butylated hydroxyanisole	140 mg/kg	63 - 64	E
Butylatedhydroxytoluene	60 mg/kg	63 - 64	TE
<u>Food Colours</u>			
Lutein	100 mg/kg singly or in combination	63 - 64	NE ¹⁾
Annatto Extracts	10 mg/kg calculated as Bixin	63 - 64	E
<u>Stabilizers</u>			
Pectins	1 g/kg singly		
Guar Gum	or in combination	63 - 64	E
Gum Acacia			
<u>Chemically Modified Starches</u>			
Acetylated distarch adipate	5 g/kg singly	63 - 64	E
Distarch, phosphate	or in combination		

Hydroxydistarch phosphate
Acetylated distarch phosphate

Flavour Enhancer

Monosodium glutaraate	5 g/kg in Mayonnaise with herbs	63 - 64	E
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¹⁾ NE, because the substance is not cleared by JECFA

CHANGE IN STATUS OF ENDORSEMENT OF FOOD ADDITIVES RESULTING FROM
CHANGE IN ADI STATUS

Codex Standards for Fats and Oils

	<u>Paragraph</u>	<u>Status of Endorsement</u>	
Butylatedhydroxyanisole	66	Old: TE	New: E

APPENDIX V - Part 3

ENDORSEMENT OF MAXIMUM LEVELS FOR CONTAMINANTS IN COMMODITY
STANDARDS

<u>Committee/Commodity</u>	<u>Session</u>	<u>Document</u>
I CEREALS, PULSES AND LEGUMES	6th	ALINORM 89/29
II VEGETABLE PROTEINS	5th	ALINORM 89/30

I COMMITTEE ON CEREALS, PULSES AND LEGUMES

Draft Standard for Certain Pulses (ALINORM 89/29, Appendix II)

Draft Standard for Sorghum Grains (ALINORM 89/29, Appendix III)

Draft Standard for Sorghum Flour (ALINORM 89/29, Appendix V)

<u>Contaminants</u>	<u>Paragraph</u>	<u>Status of Endorsemen</u>
The Commodity shall not contain heavy metals in amounts which may represent a hazard to health	68	TE ¹⁾

II COMMITTEE ON VEGETABLE PROTEINS

Draft Standard for Vegetable Protein Products (ALINORM 89/30, Appendix III)

Draft Standard for Soy Protein Products (ALINORM 89/30, Appendix V)

<u>Contaminants</u>	<u>Paragraph</u>	<u>Status of Endorsemen</u>
The Commodity shall not contain heavy metals in amounts which may represent a hazard to health	69	TE ¹⁾

1) TE, awaiting the setting of maximum or guideline levels for arsenic, mercury, cadmium and lead by the Commodity Committees

ALINORM 89/12A

APPENDIX VI

DRAFT INTERNATIONAL NUMBERING SYSTEM FOR FOOD ADDITIVES

LIST IN NUMERICAL ORDER

<u>NO.</u>	<u>NAME OF FOOD ADDITIVE</u>	<u>TECHNICAL FUNCTION(S)</u>
100	CURCUMINS (i)Curcumin (ii)Turmeric	Colour
101	RIBOFLAVINS (i)Riboflavin (ii)Riboflavin 5' - phosphate sodium	Colour
102	TARTRAZINE	Colour
103	ALKANET	Colour
104	QUINOLINE YELLOW	Colour
107	YELLOW 2G	Colour
110	SUNSET YELLOW FCF	Colour
120	CARMINES	Colour
121	CITRUS RED 2	Colour
122	AZORUBINE	Colour
123	AMARANTH	Colour
124	PONCEAU 4R	Colour
125	PONCEAU SX	Colour
127	ERYTHROSINE	Colour
128	RED 2G	Colour
129	ALLURA RED AC	Colour
131	PATENT BLUE V	Colour
132	INDIGOTINE	Colour
133	BRILLIANT BLUE FGF	Colour
140	CHLOROPHYLLS	Colour
141	COPPER CHLOROPHYLLS (i)Chlorophyll copper complex (ii)Chlorophyllin copper complex, sodium and potassium salts	Colour
142	GREEN S	Colour
143	FAST GREEN FCF	Colour
150a	Caramel I - plain	Colour
150b	Caramel II - caustic sulphite process	Colour
150c	Caramel III - Ammonia process	Colour
150d	Caramel IV - Ammonia-sulphite process	Colour
151	BRILLIANT BLACK PN	Colour
152	CARBON BLACK (hydrocarbon)	Colour

153	VEGETABLE CARBON	Colour
154	BROWN FK	Colour
155	BROWN HT	Colour
160a	Carotenes	Colour
	(i)Beta-carotene (synthetic)	"
	(ii)natural extracts	"
160b	Annatto extracts	"
160c	Paprika oleoresins	"
160d	Lycopene	"
160e	Beta-apo-carotenal	"
160f	Beta-apo-8'-carotenoic acid. methyl or ethyl ester	"
161a	Flavoxanthin	"
161b	Lutein	"
161c	Kryptoxanthin	"
161d	Rubixanthin	"
161e	Violoxanthin	"
161f	Rhodoxanthin	"
161g	Canthaxanthin	"
162	BEET RED	"
163	ANTHOCYANINS	"
	(i)Anthocyanins	"
	(ii)Grape skin extract	"
	(iii)Blackcurrant extract	"
166	SANDALWOOD	Colour
170	CALCIUM CARBONATES	Surface colourant, anticaking agent, stabilizer
	(i)Calcium carbonate	
	(ii)Calcium hydrogen carbonate	
171	TITANIUM DIOXIDE	Colour
172	IRON OXIDES	Colour
	(i)Iron oxide, black	
	(ii)Iron oxide, red	
	(iii)Iron oxide, yellow	
173	ALUMINIUM	Colour
174	SILVER	Colour
175	GOLD	Colour
180	LITHOL RUBINE BK	Colour
181	TANNINS, FOOD GRADE	Colour
182	ORCHIL	Colour
200	SORBIC ACID	Preservative
201	SODIUM SORBATE	Preservative
202	POTASSIUM SORBATE	Preservative
203	CALCIUM SORBATE	Preservative

209	HEPTYL p-HYDROXYBENZOATE	Preservative
210	BENZOIC ACID	Preservative
211	SODIUM BENZOATE	Preservative
212	POTASSIUM BENZOATE	Preservative
213	CALCIUM BENZOATE	Preservative
214	ETHYL p-HYDROXYBENZOATE	Preservative
215	SODIUM ETHYL P-HYDROXYBENZOATE	Preservative
216	PROPYL-p-HYDROXYBENZOATE	Preservative
217	SODIUM PROPYL p-HYDROXYBENZOATE	Preservative
218	METHYL p-HYDROXYBENZOATE	Preservative
219	SODIUM METHYL p-HYDROXYBENZOATE	Preservative
220	SULPHUR DIOXIDE	Preservative, antioxidant
221	SODIUM SULPHITE	Preservative, antioxidant
222	SODIUM HYDROGEN SULPHITE	Preservative, antioxidant
223	SODIUM METABISULPHITE	Preservative, bleaching agent, antioxidant
224	POTASSIUM METABISULPHITE	Preservative, antioxidant
225	POTASSIUM SULPHITE	Preservative, antioxidant
226	CALCIUM SULPHITE	Preservative, antioxidant
227	CALCIUM HYDROGEN SULPHITE	Preservative, antioxidant
228	POTASSIUM BISULPHITE	Preservative, antioxidant
230	DIPHENYL	Preservative
231	ORTHO-PHENYLPHENOL	Preservative
232	SODIUM O-PHENYLPHENOL	Preservative
233	THIABENDAZOLE	Preservative
234	NISIN	Preservative
235	PIMARICIN (NATAMYCIN)	Preservative
236	FORMIC ACID	Preservative
237	SODIUM FORMATE	Preservative
238	CALCIUM FORMATE	Preservative
239	HEXAMETHYLENE TETRAMINE	Preservative
240	FORMALDEHYDE	Preservative
242	DIMETHYL DICARBONATE	Preservative
249	POTASSIUM NITRITE	Preservative, colour fixative
250	SODIUM NITRITE	Preservative, colour fixative
251	SODIUM NITRATE	Preservative, colour fixative
252	POTASSIUM NITRATE	Preservative, colour fixative
260	ACETIC ACID GLACIAL	Preservative, acidity regulator
261	POTASSIUM ACETATES	Preservative, acidity regulator
262	SODIUM ACETATES (i)Sodium acetate	Preservative, acidity regulator, sequestrant

	(ii)Sodium diacetate	
263	CALCIUM ACETATE	Preservative, stabilizer, acidity regulator
264	AMMONIUM ACETATE	Acidity regulator
265	DEHYDROACETIC ACID	Preservative
266	SODIUM DEHYDROACETATE	Preservative
270	LACTIC ACID (L-, D- and DL-)	Acidity regulator
280	PROPIONIC ACID	Preservative
281	SODIUM PROPIONATE	Preservative
282	CALCIUM PROPIONATE	Preservative
283	POTASSIUM PROPIONATE	Preservative
290	CARBON DIOXIDE	Carbonating agent, packing gas
296	MALIC ACID (DL-)	Acidity regulator
297	FUMARIC ACID	Acidity regulator
300	ASCORBIC ACID (L-)	Antioxidant
301	SODIUM ASCORBATE	Antioxidant
302	CALCIUM ASCORBATE	Antioxidant
303	POTASSIUM ASCORBATE	Antioxidant
304	ASCORBYL PALMITATE	Antioxidant
304	ASCORBYL STEARATE	Antioxidant
306	MIXED TOCOPHEROLS CONCENTRATE	Antioxidant
307	ALPHA-TOCOPHEROL	Antioxidant
308	SYNTHETIC GAMMA-TOCOPHEROL	Antioxidant
309	SYNTHETIC DELTA-TOCOPHEROL	Antioxidant
310	PROPYL GALLATE	Antioxidant
311	OCTYL GALLATE	Antioxidant
312	DODECYL GALLATE	Antioxidant
313	ETHYL GALLATE	Antioxidant
314	GUAIAC RESIN	Antioxidant
315	ISOASCORBIC ACID	Antioxidant
316	SODIUM ISOASCORBATE	Antioxidant
317	POTASSIUM ISOASCORBATE	Antioxidant
318	CALCIUM ISOASCORBATE	Antioxidant
319	TERTIARY BUTYLHYDROQUINONE	Antioxidant
320	BUTYLATED HYDROXYANISOLE	Antioxidant
321	BUTYLATED HYDROXYTOLUENE	Antioxidant
322	LECITHINS	Antioxidant, emulsifier
323	ANOXOMER	Antioxidant
324	ETHOXYQUIN	Antioxidant
325	SODIUM LACTATE	Antioxidant synergist, humectant, bodying agent
326	POTASSIUM LACTATE	Antioxidant synergist, acidity regulator

327	CALCIUM LACTATE	Acidity regulator, flour treatment agent,
328	AMMONIUM LACTATE	Acidity regulator, flour treatment agent
329	MAGNESIUM LACTATE	Acidity regulator, flour treatment agent,
330	CITRIC ACID	Acidity regulator, antioxidant, sequestrant
331	SODIUM CITRATES (i)Sodium dihydrogen citrate (ii)Disodium monohydrogen citrate (iii)Trisodium citrate	Acidity regulator, sequestrant, Emulsifier, stabilizer
332	POTASSIUM CITRATES (i)Potassium dihydrogen citrate (ii)Tripotassium citrate	Acidity regulator, sequestrant, stabilizer
333	CALCIUM CITRATES	Acidity regulator, firming agent, sequestrant
334	TARTARIC ACID (L(+)-)	Acidity regulator, sequestrant, antioxidant synergist
¹ 335	SODIUM TARTRATE	Stabilizer, sequestrant
² 336	POTASSIUM TARTRATE	Stabilizer, sequestrant
337	POTASSIUM SODIUM TARTRATE	Stabilizer, sequestrant
338	ORTHOPHOSPHORIC ACID	Acidity regulator, antioxidant synergist
339	SODIUM PHOSPHATES (i)Monosodium orthophosphate (ii)Disodium orthophosphate (iii)Trisodium ofhophosphate	Acidity regulator, sequestrant, emulsifier, texturizer. stabilizer, water retention agent
340	POTASSIUM PHOSPHATES (i)Monopotassium orthophosphate (ii)Dipotassium orthophosphate (iii)fripotassium orthophosphate	Acidity regulator, sequestrant, Water retention agent
341	CALCIUM PHOSPHATES (i)Monocalcium orthophosphate (ii)Dicalciun orthophosphate (iii)Tricalcium orthophosphate	Acidity regulator, flour treatment agent, firming agent, texturizer, raising agent, anticaking agent
342	AMMONIUM PHOSPHATES (i)Monoammonium orthophosphate (ii)Diammonium orthophosphate	Acidity regulator, water retention agent flour treatment agent
343	MAGNESIUM PHOSPHATES (i)Monomagnesium orthophosphate (ii)Dimagnesium orthophosphate (iii)Trimagnesium orthophosphate	Acidity regulator, anticaking agent,
350	SODIUM MALATES (i)Sodium hydrogen malate (ii)Sodium malate	Acidity regulator, humectant

351	POTASSIUM MALATES (i)Potassium hydrogen malate (ii)Potassium malate	Acidity regulator
352	CALCIUM MALATES (i)Calcium hydrogen malate (ii)Calcium malate	Acidity regulator
353	METATARTARIC ACID	Acidity regulator
354	CALCIUM TARTRATE	Acidity regulator
355	ADIPIC ACID	Acidity regulator
356	SODIUM ADIPATES	Acidity regulator
357	POTASSIUM ADIPATES	Acidity regulator
359	AMMONIUM ADIPATES	Acidity regulator
363	SUCCINIC ACID	
365	SODIUM FUMARATES	Acidity regulator
366	POTASSIUM FUMARATES	Acidity regulator
367	CALCIUM FUMARATES	Acidity regulator
370	1, 4 - HEPTONOLACTONE	Acidity regulator, sequestrant
375	NICOTINIC ACID	Colour retention agent
380	AMMONIUM CITRATES	Acidity regulator
381	FERRIC AMMONIUM CITRATE	Anticaking agent
384	ISOPROPYL CITRATE MIXTURE	Antioxidant, preservative, sequestrant
385	CALCIUM DISODIUM ETHYLENE-DIAMINE-TETRA-ACETATE	Antioxidant, preservative, sequestrant
386	DISOOIUM ETHYLENE-DIAMINE-TETRA-ACETATE	Antioxidant, preservative, synergist, sequestrant
387	OXYSTEARIN	Antioxidant, sequestrant
388	THIODIPROPIONIC ACID	Antioxidant
389	OILLAURYL THIODIPROPIONATE	Antioxidant
390	DISTEARYL THIODIPROPIONATE	Antioxidant
400	ALGINIC ACID	Thickener, stabilizer
401	SODIUM ALGINATE	Thickener, stabilizer, gelling agent
402	POTASSIUM ALGINATE	Thickener, stabilizer
403	AMMONIUM ALGINATE	Thickener, stabilizer
404	CALCIUM ALGINATE	Thickener, stabilizer, gelling agent
405	PROPYLENE GLYCOL ALGINATE	Thickener, emulsifier, antifoaming agent
406	AGAR	Thickener, gelling agent, stabilizer
407	CARRAGEENAN (INCLUDES FURCELLARAN)	Thickener, gelling agent, stabilizer
410	CAROB BEAN GUM	Thickener, stabilizer
412	GUAR GUM	Thickener, stabilizer
413	TRAGACANTH GUM	Thickener, stabilizer, emulsifier
414	GUM ARABIC (ACACIA GUM)	Thickener, stabilizer
415	XANTHAN GUM	Thickener, stabilizer

416	KARAYA GUM	Thickener, stabilizer
417	TARA GUM	Thickener, stabilizer
418	GELLAN GUM	Thickener, stabilizer, gelling agent
420	SORBITOL AND SORBITOL SYRUP	Sweetener, humectant, sequestrant, texturizer, emulsifier
421	MANNITOL	Sweetener, anticaking agent
422	GLYCEROL	Humectant, bodying agent
430	POLYOXYETHYLENE (8) STEARATE	Emulsifier
431	POLYOXYETHYLENE (40) STEARATE	Emulsifier
432	POLYOXYETHYLENE (20) SORBITAN MONOLAUATE	Emulsifier, dispersing agent
433	POLYOXYETHYLENE (20) SORBITAN MONOOLEATE	Emulsifier, dispersing agent
434	POLYOXYETHYLENE (20) SORBITAN MONOPALMITATE	Emulsifier, dispersing agent
435	POLYOXYETHYLENE (20) SORBITAN MONOSTEARATE	Emulsifier, dispersing agent
436	POLYOXYETHYLENE (20) SORBITAN TRISTEARATE	Emulsifier, dispersing agent
440	PECIINS	Thickener, stabilizer, gelling agent
442	AMMONIUM SALTS OF PHOSPHATIDIC ACID	Emulsifier
443	BROMINATED VEGETABLE OIL	Emulsifier, stabilizer
444	SUCROSE ACETATE ISOBUTYRATE	Emulsifier, stabilizer
445	GLYCEROL ESTER OF WOOD ROSIN (i)glycerol abietate (ii)ester gum	Emulsifier, stabilizer
450	DIPHOSPHATES (i)Disodium diphosphate (ii)Trisodium diphosphate (iii)Tetrasodium diphosphate (iv)Dipotassium diphosphate (v)Tetrapotassium diphosphate (vi)Dicalcium diphosphate (vii)Calcium dihydrogen diphosphate (viii)Dimagnesium diphosphate	Emulsifier, stabilizer, acidity regulator, raising agent, sequestrant, water retention agent
451	TRIPHOSPHATES (i)Pentasodium triphosphate (ii)Pentapotassium triphosphate	Sequestrant, acidity regulator, texturizer
452	POLYPHOSPHATES (i)Sodium polyphosphate (ii)Potassium polyphosphate (iii)Sodium calcium polyphosphate (iv)Calcium polyphosphate	Emulsifier, stabilizer, sequestrant, texturizer, moisture retaining agent

	(v)Ammonium polyphosphate	
460	CELLULOSE	Emulsifier, anticaking agent
	(i)Microcrystalline cellulose	texturizer, dispersing agent
	(ii)Powdered cellulose	
461	METHYL CELLULOSE	Thickener, emulsifier, stabilizer
462	ETHYL CELLULOSE	Binder, filler
463	HYDROXYPKOPYL. CELLULOSE	Thickener, emulsifier, stabilizer
464	HYDROXYPROPYL METHYL CELLULOSE	Thickener, emulsifier, stabilizer
465	METHYL ETHYL CELLULOSE	Thickener, emulsifier, stabilizer, foaming agent
466	SODIUM CARBOXYMETHYL CELLULOSE	Thickener, stabilizer
467	ETHYL <u>HYDROXYETHYL</u> CELLULOSE	Emulsifier, stabilizer, thickener
470	SALTS OF FATTY ACIDS (with base Al, Ca, Na, Mg, K and NH4)	Emulsifier, stabilizer, anticaking agent
471	MONO- AND DI-GLYCERIDES OF FATTY ACIDS	Emulsifier, stabilizer
472a	Acetic and fatty acid esters of glycerol	Emulsifier, stabilizer, sequestrant
472b	Lactic and fatty acid esters of glycerol	"
472c	Citric and fatty acid esters of glycerol	"
472d	Tartaric acid esters of mono-and di- glycerides of fatty acids	"
472e	Diacetyltartaric and fatty acid esters of glycerol	"
472f	Mixed tartaric, acetic and fatty acid esters of glycerol	"
472g	Succinylated monoglycerides	"
473	SUCROSE ESTERS OF FATTY ACIDS	Emulsifier
474	SUCROGLYCERIDES	Emulsifier
475	POLYGLYCEROL ESTERS OF FATTY ACIDS	Emulsifier
476	POLYGGLYCEROL ESTERS OF INTERESTERIFIED RICINOLEIC ACID	Emulsifier
477	PROPYLENE GLYCOL ESTERS OF FATTY ACIDS	Emulsifier
478	LACTYLATED FATTY ACID ESTERS OF GLYCEROL AND PROPYLENE GLYCOL	Emulsifier
479	THERMALLY OXIDIZED SOYA BEAN OIL WITH MONO-AND DI- GLYCERIDES OF FATTY ACIDS	Emulsifier
480	DIOCTYL SODIUM SULPHOSUCCINATE	Emulsifier, wetting agent
481	SODIUM STEAROYL LACTYLATE	Emulsifier, stabilizer
482	CALCIUM STEAROYL LACTYLATE	Emulsifier, stabilizer

483	STEARYL TARTRATE	Flour treatment agent
484	STEARYL CITRATE	Emulsifier, sequestrant
485	SODIUM STEAROYL FUMARATE	Emulsifier
486	CALCIUM STEAROYL FUMARATE	Emulsifier
487	SODIUM LAURYL SULPHATE	Emulsifier
491	SORBITAN MONOSTEARATE	Emulsifier
492	SORBITAN TRISTEARATE	Emulsifier
493	SORBITAN MONOLAURATE	Emulsifier
494	SORBITAN MONOOLEATE	Emulsifier
495	SORBITAN MONOPALMITATE	Emulsifier
496	SORBITAN TRIOLEATE	Stabilizer, emulsifier
500	SODIUM CARBONATES	Acidity regulator, raising agent, anticaking agent
	(i) Sodium carbonate	
	(ii) Sodium hydrogen carbonate	
	(iii) Sodium sesquicarbonate	
501	POTASSIUM CARBONATES	Acidity regulator, stabilizer
	(i) Potassium carbonate	
	(ii) Potassium hydrogen carbonate	
503	AMMONIUM CARBONATES	Acidity regulator, raising agent
	(i) Ammonium carbonate	
	(ii) Ammonium hydrogen carbonate	
504	MAGNESIUM CARBONATES	Acidity regulator, anticaking agent, colour retention agent
	(i) Magnesium carbonate	
	(ii) Magnesium hydrogen carbonate	
505	FERROUS CARBONATE	Acidity regulator
507	HYDROCHLORIC ACID	Acidity regulator
508	POTASSIUM CHLORIDE	Gelling agent,
509	CALCIUM CHLORIDE	Firming agent
510	AMMONIUM CHLORIDE	Flour treatment agent,
517	MAGNESIUM CHLORIDE	Firming agent,
512	STANNOUS CHLORIDE	Antioxidant, colour retention agent
513	SULPHURIC ACID	Acidity regulator
514	SODIUM SULPHATES	Acidity regulator
515	POTASSIUM SULPHATES	Acidity regulator
516	CALCIUM SULPHATE	Flour treatment agent, sequestrant, firming agent
517	AMMONIUM SULPHATE	Flour treatment agent, stabilizer
518	MAGNESIUM SULPHATE	Firming agent.
519	CUPRIC SULPHATE	Colour fixative, preservative
520	ALUMINIUM SULPHATE	Firming agent
521	ALUMINIUM SODIUM SULPHATE	Firming agent
522	ALUMINIUM POTASSIUM SULPHATE	Acidity regulator, stabilizer
523	ALUMINIUM AMMONIUM SULPHATE	Stabilizer, firming agent

524	SODIUM HYDROXIDE	Acidity regulator
525	POTASSIUM HYDROXIDE	Acidity regulator
526	CALCIUM HYDROXIDE.	Acidity regulator, firming agent
527	AMMONIUM HYDROXIDE	Acidity regulator
528	MAGNESIUM HYDROXIDE	Acidity regulator, colour retention agent
529	CALCIUM OXIDE	Acidity regulator, flour treatment agent,
530	MAGNESIUM OXIDE	Anticaking agent
535	SODIUM FERROCYANIDE	Anticaking agent
536	POTASSIUM FERROCYANIDE	Anticaking agent
537	FERROUS HEXACYANOMANGANATE	Anticaking agent
538	CALCIUM FERROCYANIDE	Anticaking agent
539	SODIUM THIOSULPHATE	Antioxidant, sequestrant
541	SODIUM ALUMINIUM PHOSPHATE	Acidity regulator, emulsifier
	(i)Acidic	
	(ii)Basic	
542	BONE PHOSPHATE (essentially Calcium phosphate, tribasic)	Emulsifier, anticaking agent, water retention agent
550	SODIUM SILICATES	Anticaking agent
	(i)Sodium silicate	
	(ii)Sodium metasilicate	
551	SILICON DIOXIDE AMORPHOUS	Anticaking agent
552	CALCIUM SILICATE	Anticaking agent
553	MAGNESIUM SILICATES	Anticaking agent, dusting powder
	(i)Magnesium silicate	
	(ii)Magnesium trisilicate	
	(iii)Talc	
554	SODIUM ALUMINOSILICATE	Anticaking agent
555	POTASSIUM ALUMINIUM SILICATE	Anticaking agent
556	CALCIUM ALUMINIUM SILICATE	Anticaking agent
557	ZINC SILICATE	Anticaking agent
558	BENTONITE	Anticaking agent
559	ALUMINIUM SILICATE	Anticaking agent
560	POTASSIUM SILICATE	Anticaking agent
570	FATTY ACIDS	Foam stabilizer, glazing agent, antifoaming agent
574	GLUCONIC ACID (D-)	Acidity regulator, raising agent
575	GLUCONO DELTA-LACTONE	Acidity regulator, raising agent
576	SODIUM GLUCONATE	Sequestrant,
577	POTASSIUM GLUCONATE	Sequestrant
578	CALCIUM GLUCONATE	Acidity regulator, firming agent.
579	FERROUS GLUCONATE	Colour retention agent
580	MAGNESIUM GLUCONATE	Acidity regulator, firming agent,

585	FERROUS LACTATE	Colour retention agent
620	GLUTAMIC ACID (L(+))	Flavour enhancer,
621	MONOSODIUM GLUTAMATE	Flavour enhancer
622	MONOPOTASSIUM GLUTAMATE	Flavour enhancer,
623	CALCIUM GLUTAMATE	Flavour enhancer,
624	MONOAMMONIUM GLUTAMATE	Flavour enhancer
625	MAGNESIUM GLUTAMATE	Flavour enhancer,
626	GUANYLIC ACID	Flavour enhancer
627	DISODIUM 5'-GUANYLATE	Flavour enhancer
628	DIPOTASSIUM 5'-GUANYLATE	Flavour enhancer
629	CALCIUM 5'-GUANYLATE	Flavour enhancer
630	INOSINIC ACID	Flavour enhancer
631	DISODIUM 5'-INOSINATE	Flavour enhancer
632	POTASSIUM INOSINATE	Flavour enhancer
633	CALCIUM 5'-INOSINATE	Flavour enhancer
634	CALCIUM 5'-RIBONUCLEOTIDES	Flavour enhancer
635	DISODIUM 5'-RIBONUCLEOTIDES	Flavour enhancer
636	MALTOL	Flavour enhancer
637	ETHYL MALTOL	Flavour enhancer
640	GLYCINE	Flavour modifier
641	L-LEUCINE	Flavour modifier
900	POLYDINETHYLSILOXANE	Antifoaming agent, anticaking agent.
901	BEESWAX, WHITE AND YELLOW	Glazing agent, release agent /emulsifier
902	CANDELILLA WAX	Glazing agent
903	CARNAUBA WAX	Glazing agent
904	SHELLAC	Glazing agent
905	MINERAL OIL, FOOD GRADE	Glazing agent, release agent, sealing agent
906	BENZOIN GUM	Glazing agent
907	REFINED WAX	Release agent
908	RICE BRAN WAX	Glazing agent
909	SPERMACETI WAX	Glazing agent
910	WAX ESTERS	Glazing agent
913	LANOLIN	Glazing agent
915	GLYCEROL -, METHYL - OR PENTA - ERITHRYTOL ESTERS OF COLOPHANE	Glazing agent
916	CALCIUM IODATE	Flour treatment agent
917	POTASSIUM IODATE	Flour treatment agent
918	NITROGEN OXIDES	Flour treatment agent
919	NITROSYL CHLORIDE	Flour treatment agent

920	L-CYSTEINE AND ITS HYDROCHLORIDES - SODIUM AND POTASSIUM SALTS	Flour treatment agent
921	L-CYSTINE AND ITS HYDROCHLORIDES - SODIUM AND POTASSIUM SALTS	Flour treatment agent
922	POTASSIUM PERSULPHATE	Flour treatment agent
923	AMMONIUM PERSULPHATE	Flour treatment agent
924	POTASSIUM BROMATE	Flour treatment agent
925	CHLORINE	Flour treatment agent
926	CHLORINE DIOXIDE	Flour treatment agent
927	AZOOICARBONAMIDE	Flour treatment agent
928	BENZOYL PEROXIDE	Flour treatment agent, preservative
929	ACETONE PEROXIDE	Flour treatment agent
930	MONOISOPROPYL CITRATE	Preservative
940	DICHLORODIFLUOROMETHANE	Propellant, liquid freezant
941	NITROGEN	Packing gas, freezant
942	NITROUS OXIDE	Propellant
943	BUTANE	Propellant
944	PROPANE	Propellant
945	ISOBUTANE	Propellant
950	ACESULFAME POTASSIUM	Sweetener
951	ASPARTAME	Sweetener, flavour enhancer
952	CYCLAMIC ACID (and Na, K, Ca salts)	Sweetener
953	ISOMALT (ISOMALTITOL)	Sweetener, anticaking agent, bulking agent, glazing agent
954	SACCHARIN (and Na, K, Ca salts)	Sweetener
957	THAUMATIN	Sweetener, flavour enhancer
958	GLYCYRRHIZIN	Sweetener, flavour enhancer
959	NEOHESPERIDINE DIHYDROCHALCONE	Sweetener
965	MALTITOL AND MALTITOL SYRUP	Sweetener, stabilizer, emulsifier
966	LACTITOL	Sweetener, texturizer
967	XYLITOL	Sweetener, humectant, stabilizer, emulsifier, thickner
999	QUILLAIA EXTRACTS	foaming agent
1000	CHOLIC ACID	Emulsifier .
1001	CHOLINE salts and esters	Emulsifier
	(i)Choline acetate	Emulsifier
	(ii)Choline carbonate	Emulsifier
	(iii)Choline chloride	Emulsifier
	(iv)Choline citrate	Emulsifier
	(v)Choline tartrate	Emulsifier
	(vi)Choline lactate	Emulsifier

1200	POLYDEXTROSES A AND N	Bulking agent, stabilizer, thickener, humectant, texturizer
1201	POLYVINYLPIRROLIDONE	Bodifying agent, stabilizer
1202	INSOLUBLE POLYVINYLPIRROLIDONE	Colour stabilizer, colloidal, stabilizer
1503	CASTOR OIL	Release agent
1518	TRIACETIN	Humectant
1519	TRIETHYL CITRATE	Foam stabilizer
1520	PROPYLENE GLYCOL	Humectant, wetting agent

ENZYMES

1100	AMYLASE	Flour treatment agent
1101	Proteases	Flour treatment agent, Flavour enhancer, stabilizer, tenderizer (?)
	(i)protease	
	(ii)papain	
	(iii)bromelain	
	(iv)ficin	
1102	GLUCOSE OXIDASE	Antioxidant
1103	INVERTASE	Stabilizer
1104	LUPASE	Flavour enhancer
1105	LYSOZYME	Preservative

Note - The chemical names given by alphabetical identification in brackets ((i), (ii), (iii), etc) throughout this list identify the actual food additives with separate specifications which are included under the more descriptive name as shown opposite the identification number.

¹ Sodium tartrates; (i) Monosodium tartrate; (ii) Disodium tartrate
² As above

SUPPLEMENTARY LIST - MODIFIED STARCHES

EXPLANATORY NOTE

The Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1 - 1985) specifies that modified starches may be declared as such in the list of ingredients. However, as some countries presently require the specific identification of modified starches the following numbers are provided as a guide and as a means of facilitating uniformity. Where these starches are specifically identified in the list of ingredients then it would be appropriate to include them under the relevant class name eg Thickener.

1400	DEXTRINS, ROASTED STARCH WHITE AND YELLOW	Stabilizer, thickener, binder
1401	ACID-TREATED STARCH	Stabilizer, thickener, binder
1402	ALKALINE TREATED STARCH	Stabilizer, thickener, binder
1403	BLEACHED STARCH	Stabilizer, thickener, binder
1404	OXIDIZED STARCH	Emulsifier, thickener, binder
1405	STARCHES, ENZYME-TREATED	Thickener
1410	MONOSTARCH PHOSPHATE	Stabilizer, thickener, binder
1412	DISTARCH PHOSPHATE ESTERIFIED WITH SODIUM TRIMETASPHOPHATE; ESTERIFIED WITH PHOSPHORUS-OXYCHLORIDE	Stabilizer, thickener, binder
1413	PHOSPHATED DISTARCH PHOSPHATE	Stabilizer, thickener, binder
1414	ACETYLATED DISTARCH PHOSPHATE	Emulsifier, thickener
1420	STARCH ACETATE ESTERIFIED WITH ACETIC ANHYDRIDE	Stabilizer, thickener
1421	STARCH ACETATE ESTERIFIED WITH VINYL ACETATE	Stabilizer, thickener
1422	ACETYLATED DISTARCH ADIPATE	Stabilizer, thickener, binder
1440	HYDROXYPROPYL STARCH	Emulsifier, thickener, binder
1442	HYDROXYPROPYL DISTARCH PHOSPHATE	Stabilizer, thickener
1450	STARCH SODIUM OCTENYL SUCCINATE	Stabilizer, thickener, binder, Emulsifier

FOOD ADDITIVES NOT INCLUDED IN THE INS
ON WHICH MORE INFORMATION IS REQUESTED

<u>FOOD ADDITIVE</u>	<u>TECHNOLOGICAL FUNCTION</u>	<u>PROPOSED BY</u>
AMMONIUM FUMARATE	Acidity regulator	Australia
AMMONIUM MALATE	Acidity regulator	Australia
ARABINOGALACTAN	Thickener, gelling agent, stabilizer	Australia, USA, Canada
BAKERS YEAST GLYCAN	Thickener, gelling agent, stabilizer	USA, Canada
CALCIUM BROMATE	Flour treatment agent	USA
CALCIUM GLYCEROPHOSPHATE	Thickener, gelling agent, stabilizer	Canada
CALCIUM HYPOPHOSPHITE	Thickener, gelling agent, stabilizer	Canada
CALCIUM LACTOBIONATE	Stabiizer	USA
CALCIUM PEROXIDE	Flour treatment agent	USA, Canada
CARBAMIDE (UREA)		Norway, Sweden, USA, Australia
CHLOROPENTAFLUOROETHAN E	Propellant	Canada
ETHOXYLATED MONO AND DIGLICERIDES	Emulsifier	USA
GUM GUAICUM	Preservative	Canada
METHYLESTERS OF FATTY ACIDS	Glazing agent	USA
METHYL GLUCOSIDE – COCONUT OIL ESTER	Emulsifier	USA
METHYLPHENYLPOLYSILOXAN E	Antifoaming agent	Australia
OAT GUM	Thickener, stabilizer	USA, Canada
OCTAFLUOROCYCLOBUTANE	Propellant	Australia, Canada, NZ
PEPTONES	Emulsifier	USA
POLYETHYLENE GLYCOL	Antifoaming agent	Canada, Australia
SODIUM DITHIONITE	Preservative	Canada
SUCCISTEARIN	Emulsifier	USA
SUPERGLYCERINATED HYDROGENATED - RAPESEED OIL	Emulsifier	USA
TRIETHANOLAMINE		Australia

**ALINORM 89/12A
APPENDIX VI
ANNEX II**

**TABLE OF FUNCTIONAL CLASSES ¹
AND SUB-CLASSES OF FOOD ADDITIVES**

Functional Classes (for labelling purposes)	Sub-Classes (Technological functions)
1. Acidity Regulator	Buffer, buffering agent, acid, base, alkali, pH adjusting agent
2. Anticaking Agent	Anticaking agent, drying agent, dusting powder, anti-stick agent, release agent
3. Antifoaming agent	Antifoaming agent
4. Antioxidant	Antioxidant, antioxidant synergist, sequestrant
5. Bulking Agent	Bulking Agent, filler
6. Sweetener	Sweetener, artificial sweetener, nutritive sweetener
7. Colour	Colour
8. Colour Retention Agent	Colour fixative, colour stabilizer
9. Emulsifier	Emulsifier, plasticizer, dispersing agent, surface active agent, surfactant, wetting agent.
10. Emulsifying Salt	Melding salts, sequestrant
11. Flavour enhancer	Flavour enhancer, flavour modifier
12. Flour treatment Agent	Bleaching agent, dough conditioner, flour improver
13. Gelling Agent	Gelling Agent
14. Glazing Agent	Coating, sealing agent, polish
15. Preservative	Antimicrobial preservative, antimycotic agent, bacteriophage control agent, packing gas, chemosterilant/wine maturing agent, disinfestation agent
16. Propellant	Propellant, packing gas
17. Stabilizer	Binder, firming agent, density adjusting agent, water retention agent, foam stabilizer
18. Thickener	Thickening agent, texturizer, bodying agent
19. Raising agent	Leavening agent, raising agent
20. Foaming Agent	Whipping agent, aerating agent
21. Humectant	Moisture/Water retention agent, wetting agent
22. [Acidifier/Acid/Food Acid]	Acidifier
23. [Firming Agent]	Firming Agent

¹ The following class titles may be used for food additives falling in the respective classes and appearing in lists of food additives permitted generally for use in foods:

Flavour(s) and Flavouring(s)
Modified Starch(es)

The expression "flavours" may be qualified by "natural", "nature identical", "artificial" or a combination of these words as appropriate.

Additions and Deletions to
Codex List B

The following additions, deletions and editorial changes should be made to the full text of Codex List B available as Appendix V, ALINORM 87/12.

<u>ADDITIONS</u>	<u>Status of Additions</u>	<u>JECFA Ref.</u> ¹
<u>Colours:</u>		
- Brown FK	- 30th JECFA ADI withdrawn	B ₁ 12
- Carbon Black	- 31st JECFA No ADI allocated	B ₁ 13
- Citranaxanthine	- 31st JECFA No ADI allocated	B ₁ 13
<u>Anti-oxydants:</u>		
- Dodecyl Gallate	- 30th JECFA: ADI withdrawn	B ₁ 12
- Octyl Gallate	- 30th JECFA: ADI withdrawn	B ₁ 12
<u>Emulsifiers:</u>		
- Processed Euchema Seaweed	- 31st JECFA: No ADI allocated	B ₁ 13
<u>Enzyme Preparations:</u>		
- Cellulose from Pennicillum Funicolosum	- 31st JECFA: No ADI allocated	B ₁ 13
- Pectinase from Aspergillus Alianceus	- 31st JECFA: No ADI allocated	B ₁ 13
<u>Miscellaneous:</u>		
- Hydrocarbon Waxes	- 30th JECFA: No ADI allocated	B ₁ 12
- Petroleum Jelly	- 30th JECFA: No ADI allocated	B ₁ 12
- 4-hydroxymethyl.2, 6-di-tert- butylphenol	- 31st JECFA: No ADI allocated	B ₁ 13
<u>DELETIONS</u>		
- Polyglycerolesters of fatty esters is on List A		
- Protease from Asp. Niger	- 31st JECFA: allocated full ADI	13
- Beet Red	- 31st JECFA: allocated full ADI	13
- Maltitol	- 33rd JECFA	14
<u>EDITORIAL CHANGES</u>		
Colours - specify Carotene (natural) in:		
Carotenes (natural	- algae	
	- vegetable (31st JECFA)	13
Xanthopylls in:		
Xanthopylls	- mixed carotenoids	
	- Tagetes extract	

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12. Evaluation of Certain Food Additives (30th Report of the Joint FAO/WHO Expert Committee on Food Additives - WHO Technical Report Series N° 751, 1987)
13. Evaluation of Certain Food Additives (31st Report of the Joint FAO/WHO Expert Committee on Food Additives - WHO Technical Report Series N2 759, 1987)
14. Evaluation of Certain Food Additives (33rd Report of the Joint FAO/WHO Expert Committee on Food Additives) WHO Technical Report Series N2 776, 1989)

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APPENDIX VIII

INVENTORY OF PROCESSING AIDS

This will be issued separately.

ALINORM 89/12A
APPENDIX IX

Proposed Draft

GUIDELINE LEVELS FOR CERTAIN CONTAMINANTS

(At Step 3 of the Procedure)

Aflatoxin B1

Groundnuts (for human consumption) 5 ug/kg

Note: This Guideline level is based on a defined sampling plan, to be determined, and recognized method of analysis (see par. 117-125 of the present report).

Cadmium

Fish and Fishery Products 0.1 mg/kg

Molluscs, Crustaceans and Products 1.0 mg/kg

Vegetables 0.1 mg/kg

Cereals and products 0.05 mg/kg *

Liver, Kidney and Offal Products 2.0 mg/kg

Lead

Fruit and Vegetables 0.5 mg/kg

Beverages (except tea and coffee) 0.3 mg/kg

Canned food (except canned beverages) 1.0 mg/kg

Cereals and products 0.5 mg/kg *

Note:

Levels for lead included in Codex Standards which have been endorsed and adopted by the Commission remain unaffected. Values for cereals pulses and legumes (indicated above by an asterisk) are provisional levels at step 3 of the procedure under consideration by the Codex Committee on Cereals, Pulses and Legumes.

Proposed Draft

GUIDELINE LEVELS FOR CERTAIN CONTAMINANTS

(Advanced to Step 5 of the Procedure)

Methylmercury	Proposed guideline level
All fish except predatory fish	0.5mg/kg
Predatory fish (such as shark, swordfish, tuna, pike and others)	1 mg/kg

Note:

The proposed Guideline levels are intended for methyl mercury in fresh or processed fish and fish products moving in international trade. Lots should be considered as being in compliance with the proposed guideline levels if the level of methyl mercury in the analytical sample, derived from the composite bulk sample, does not exceed the above proposed levels. Where these proposed Guideline levels are exceeded, governments should decide whether and under what circumstances, the food should be distributed within their territory of jurisdiction and what recommendations, if any, should be given as regards restrictions on consumption, especially by vulnerable groups such as pregnant women.

Vinyl chloride monomer

Proposed Guideline level in food	0.01 mg/kg
Proposed Guideline level in food packaging material	1.0 mg/kg

Acrylonitrile

Proposed Guideline level in food	0.02 mg/kg
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ALINORM 89/12A
APPENDIX XI

FOOD ADDITIVES AND CONTAMINANTS PROPOSED BY CCFAC
FOR PRIORITY EVALUATION BY JECFA

Food Additives

Dimethyl Dicarbonate	
Dicotyl Sodium Sulfosuccinate	Proposed by the USA
Chymosin A	
Gellan gum	Proposed by The Netherlands
Chymosin B	
Iso-Ascorbic acid (for re-evaluation)	Proposed by the CCPMPP

Contaminants

Nitrite	
Nitrate	Proposed by The Netherlands
Nitrosamines	
Solanine	Proposed by Finland
Benz(a) pyrene	Proposed by The Netherlands
Cyanogenic glucosides	
Ochratoxins	Proposed by the Secretariat