

**codex alimentarius commission**

FOOD AND AGRICULTURE  
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NATIONS

WORLD HEALTH ORGANIZATION

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**ALINORM 89/12**

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

**CODEX ALIMENTARIUS COMMISSION**

**Eighteenth Session**

**Geneva, 3-14 July 1989**

**REPORT OF THE TWENTIETH SESSION OF THE**  
**CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS**

The Hague, 7-12 March 1988

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## **Introduction**

1. The Codex Committee on Food Additives and Contaminants held its twentieth Session in The Hague, The Netherlands, from 7 - 12 March, 1988, courtesy of the Government of The Netherlands. Mr. A. Feberwee (The Netherlands) acted as Chairman. The Session was attended by 170 participants, representing 35 member countries and 1 observer country and 25 international organizations. (See Appendix I for the List of Participants, including the Secretariat).

### **EXTRACT OF TOE OPENING SPEECH BY MR. J.P. VAN ZUTPHEN, DIRECTOR-GENERAL OF THE MINISTRY OF AGRICULTURE AND FISHERIES OF THE NETHERLANDS**

2. In his welcoming remarks the Director-General reminded the Committee that the first meeting of the CCFA was also held in the Ridderzaal. Scheduling this 20th Session in the "Hall of Knights"- the centre of the Dutch democracy - underlined the high value placed by the government of The Netherlands on the work of Codex Alimentarius.

3. While comparing the agenda of this Session with the one used at the Committee's first Session, the Director-General was struck by the obvious shift to topics with a more policy-like character, in the initial phase of these meetings the endorsements of food additive Commodity Standard provisions by Codex were "the bread and butter" of the agenda. Today the emphasis was on horizontal topics such as: intake studies of food additives and contaminants and, international numbering system of food additives and a procedure for priority setting for the safety evaluation of flavouring substances.

4. The Director-General felt that the decision of the Codex Alimentarius Commission in July 1987 to add "Contaminants" to the name of this Committee, was a good one. This was also a recognition of the work that had been carried out for many years by this Committee in this field. However, much work still has to be done on contaminants. Data must be collected on the actual content of various contaminants in food and feed and on national regulations concerning contaminants. These data together with toxicological data, might, where necessary, result in guideline levels. The attention paid to mycotoxins was well warranted since this was a very important area, not only for the industrialized world, but especially for developing countries. The CCFAC activities on mycotoxins such as setting limits, selecting appropriate analytical methods and sampling procedures were well in line with the other actions by FAO, WHO and UNEP in this field.

5. Although the Chernobyl accident happened almost two years ago, until now FAO and WHO had not succeeded in formulating joint proposals for standards concerning the contamination of food by radionuclides. The FAO-interim levels, in the mean time, had proved to be very useful. The Director-General stated that the Netherlands continues to feel that Codex Alimentarius should draw up standards on radionuclides in food on the basis of joint proposals by FAO and WHO.

6. The tendency towards deregulation in many parts of the world was clearly illustrated by the change in activities of Codex Alimentarius over the past years from product standards to subjects such as additives, contaminants, residues, labelling etc. Also in the European Community, the afore-mentioned tendency was reflected in a change from the so-called recipe type of food legislation to horizontal legislation. Future European Community legislation would focus on four specific fields, one of which will be food additives. The EEC-Commission had taken it on itself to streamline legislation on

food additives before 1992. A major task would be the harmonization of conditions of use. It went without saying that consumer protection thereby was a basic principle. For the EEC, as for other parts of the world, the work of JECFA and CCFAC, was essential in this respect.

7. The Director-General - in view of the new name of the Committee - on purpose dwelt on the subject of contaminants. But this might certainly not lead to the suggestion that he underrated the importance of work on additives. He wished the Committee a productive meeting in the inspiring environment of "de Ridderzaal".

### **APPOINTMENT OF RAPPORTEURS**

8. Mr. R. 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.

### **ADOPTION OF THE AGENDA.**

9. The Committee adopted the provisional agenda (CXFAC 88/1) including all changes listed in the List of Documents {CX/FAC 88/1-Add. I).

### **CONSIDERATION OF REPORTS OF JECFA**

10. The thirtieth and thirty-first reports of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) were introduced by the Joint Secretariat of JECFA, Drs. A. Randell and G. Gheorghiev (FAO), and Dr. J.L. Herrman (WHO). It was noted that these reports had been published by WHO as Technical Report Series 751 and 759, respectively.

11. At its thirtieth meeting, JECFA evaluated several antioxidants, flavouring agents, food colours/Sweetening agents, thickening agents, and the contaminant lead, particularly as it related to infants and children. Several miscellaneous food additives including sulfur dioxide were also considered.

12. At the thirtieth JECFA BHA, BHT, and TBHQ, which had previously been allocated a group ADI, were evaluated separately. All were given temporary ADIs. Similarly, the gallates (dodecyl, octyl, and propyl), which had previously been allocated a group ADI, were evaluated separately. Propyl gallate received an ADI, but for dodecyl and octyl gallate the ADI was withdrawn. The representative of the EEC requested that the information reviewed by JECFA during its evaluation of the gallates be made available so that the EEC Scientific Committee for Food could reconsider its own position on these substances. The WHO representative replied that the EEC could write to WHO requesting the working papers, which could than be made available.

13. The establishment of specifications for identity and purity was considered an important part of the evaluation process. At the thirtieth Session, JECFA paid considerable attention to the preparation of practical methods of analysis for additives. Difficulties were encountered in the preparation of specifications for mineral oils and related substances and more information was requested.

14. The thirtieth JECFA also approved a document titled "Principles for the Safety Assessment of Food Additives and Contaminants in Food", which was published in 1987 in the WHO Environmental Health Criteria Series No. 70.

15. The delegation of Egypt asked whether aspartame would be re-evaluated by JECFA. The delegation of the U.S. replied that he was unaware of any new toxicological data on this compound since its last evaluation. The WHO representative replied that

aspartame was not on the agenda of a future meeting; but that if significant new toxicological information had become available, the CCFAC or member governments could request its re-evaluation by JECFA.

16. The thirtieth JECFA report included an annex that contained matters arising from sessions of the Codex Committee on Food Additives. The toxicological monographs considered at the thirtieth JECFA had been published by the Cambridge university Press as WHO Food Additives Series No. 21, and specifications had been published in FAO Food and Nutrition Paper No. 37. The paper titled "Exposure of infants and children to lead" will be published by FAO in the Occasional Papers Series.

17. At its thirty-first meeting, JECFA evaluated several enzyme preparations, flavouring agents, food colours, several miscellaneous food additives including monosodium glutamate and aflatoxins. Enzymes derived from Aspergillus oryzae were considered to be acceptable for use in food, since different varieties of this organism were used in certain parts of the world in the preparation of foods. ADIs were established for those enzymes derived from Aspergillus niger, since this organism was a contaminant of food and hazardous components may be present that should be controlled. Two other enzymes from lesser-known microorganisms were allocated temporary ADIs. The Association of Microbial Food Enzyme Producers (AMFEP) indicated inter alia that this was the first time that JECFA has established numerical ADIs for enzyme preparations and that it is inappropriate to do so, because it felt that toxic contaminants should be controlled by specifications. The WHO representative pointed out that the thirty-first JECFA recommended that the general specifications for enzymes used in food processing be reviewed taking into consideration the presence of hazardous contaminants. At that time it is possible that JECFA might decide to review its position on the ADIs.

18. It was noted that not enough information had been supplied for the preparation of enzyme specifications, and that there was a need for reviewing the present general standard for enzymes to assure more information on monitoring the production and the purity of the strain. The Committee was informed by AMFEP that this organization could supply additional information to JECFA.

19. The Committee noted that substances extracted from natural products should not be considered as automatically safe and should be characterized by appropriate specifications.

20. The toxicological monographs considered by the thirty-first JECFA would soon appear as No. 22 in the WHO Food Additives Series, to be published by the Cambridge University Press, and specifications would be published in the FAO Food and Nutrition Paper Series.

### **MATTERS OF INTEREST ARISING FROM CODEX AND OTHER SESSIONS**

21. The Committee had before it document CX/FA 88/4 containing Matters of Interest arising from Codex and other 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.

### **Developments concerning Radionuclide Contamination of Foods**

22. The Committee was informed concerning the work of FAQ and WHO following the Chernobyl nuclear reactor accident in April 1986. FAO convened an expert

consultation in December 1986 that published a report titled Recommended Limits for Radionuclide Contamination of Foods. This report recommended the use of Interim International Radionuclide Action Levels (IRALF) for foods moving in international trade. These recommendations were based on the primary intervention levels for protection of the public in the case of an accidental release of nuclear material established by the International Commission of Radiological Protection. The levels recommended by the expert consultation were proposed by FAO to be applicable to international shipment of foods. It was pointed out that limits relating to international trade would have to be considered separately from intervention levels needed to protect consumers in the vicinity of nuclear accidents or in areas where contamination was so high that it would necessitate destruction of the contaminated food.

23. The Committee was further advised that WHO had prepared guidelines for derived intervention levels. WHO'S Executive Board, durings its 81st Session in January 1988, had reviewed a report on this issue and had requested the Director General of WHO to continue to cooperate with FAO with the aim to arrive at a Joint FAO/WHO recommendation for maximum levels of radionuclides in food for subsequent consideration by the Codex Alimentarius Commission.

24. The Committee was informed that the Joint FAO/WHO proposals would be worked out at a meeting of the FAO/WHO Secretariat to be held in Rome 8-10 March 1988. The Executive Committee of the CAC at its 35th Session in July 1988 would review the Joint proposals and advise how these should be advanced for consideration by the Commission. It was very probable that the Executive Committee might ask the CCFAC to review the proposals prior to consideration by the Commission. Awaiting the adoption by the CAC of the Joint FAO/WHO proposals, they could be considered as "Interim Codex Proposals" and used by such of the member governments who wish to use them.

25. The delegation of Egypt stressed the importance of taking into account nutritional status and other considerations when establishing safety factors for radionuclides. It was pointed out that the safety factors of radionuclides were under continual review by the International Commission on Radiological Protection (ICRP).

#### **Misleading information concerning the use of Food Additives in Food**

26. The Committee noted that the subject was discussed both at its 19th Session and at the 17th Session of the CAC. The CAC noted that the documents of Codex and JECFA provided adequate information on the safe use of food additives and that governments could use this information in an appropriate way to counteract misleading information being spread among its citizens.

27. The Committee noted that the brochures and pamphlets prepared by some governments in this regard would be reviewed by the Regional Coordinating Committee for Europe with a view to proposing a coordinated approach.

28. The Committee recalled its discussion at its 19th Session at which several delegations held the view that the practice by industry of claiming that food additives were not present in certain foods (negative claims) resulted in concern by consumers about food additives. The Secretariat brought the attention of the Committee to the general guidelines on claims elaborated by CCFL, which covered the subject of negative claims.

29. The Committee noted that WHO, in partial response the request made at the 17<sup>th</sup> Session of the Commission, prepared a pamphlet titled "In Point of Fact No. 51/1987",

which was presently available in English and French. The pamphlet explained the procedures followed by the organization for the safety evaluation of food additives and was designed to alleviate fears among consumers on the safety in use of food additives.

#### **Other Matters**

30. The Committee was informed that there was unanimous support of the Coordinating Committee for Asia for CCFAC to undertake work on establishing food additive provisions in non-standardized foods.

#### **CONSIDERATION OF INTAKE OF FOOD ADDITIVES AND CONTAMINANTS**

31. The Committee had before it the report of the ad hoc Working Group on Intake of Food Additives and Contaminants (CX/FAC 88/5-Add. 3) which was introduced by the chairman of the Group, Mr. M. Fondu (Belgium). The Working Group reviewed all the documents, CX/FAC 88/5, Intake of Certain Food Additives; CX/FAC 88/5-Add. 1, Dietary intake of Cadmium, Lead and Mercury and CVFAC 88/5-Add. 2, Guidelines for a Simple Evaluation of Food Additive Intake and Government Comments on the Guidelines which were available to the Committee.

#### **Level of Tin ingested from cans stored in hot climates with special attention to intake by children and total intake**

32. The Committee noted that very little information was received on the subject from the Governments in response to the CL 1987/25. The Committee was informed that JECFA would discuss the problem of acute toxicity of tin at its next meeting (1988) and that the Coordinating Committee for Asia would review the maximum levels of tin in Commodity Standards at its next session. The Committee agreed to await the deliberations of JECFA on acute toxicity of tin before taking any action. The Committee also noted that Thailand had provided JECFA with data on the subject of acute toxicity of tin in humans.

#### **National regulations (or modifications) on intense sweeteners and intake of intense sweeteners**

33. The Committee noted that a number of countries had issued new authorizations for the use of intense sweeteners in foods. As regards aspartame, information received from the U.S.A. indicated that intake of this additive in normal and special groups of populations like diabetics was well below the ADI.

34. The Committee agreed that in view of recent developments in different countries on the authorized use of intense sweeteners (Aspartame, Saccharin, Acesulfame, Cyclamate and Thaumatin) information should be sought by means of a CL to member governments on the national regulations and results of intake studies. The Committee noted that some of the intense sweeteners were used at home and agreed that information on the intake at home of these sweeteners should also be requested.

35. The delegation of Egypt informed the Committee that information should also be sought on two other intense sweeteners, Miraculin and Monellin. The Committee noted that these sweeteners had not yet been evaluated by JECFA and agreed not to include them in the CL at this point.

#### **Levels of bixin in foods in which the use of annatto as food colour is permitted**

36. From a study of the new authorizations issued by countries, the Committee noted that some foodstuffs like sugar confectionery, flour confectionery and cheese could contain rather high levels of bixin and norbixin. The Committee could not endorse these

additives in many cheese standards, since the additives had a specific ADI and their maximum use was governed by Good Manufacturing Practice, the Committee was gathering more information on the intake and the actual level of these additives in cheese.

37. The Committee noted that the information made available by IDF (CX/FAC 88/5A) on the content of bixin and norbixin in cheese was inadequate to determine the intakes of these additives from cheese.

38. The Committee also noted that the ADI of bixin might have been higher if results of feeding studies with animals carried out with diets containing higher levels of the additive had been available to JECFA for its evaluation.

39. The Committee agreed that information should be sought from member governments on new authorizations for the use of annatto in foods and on the intake of this additive. The Committee also agreed to bring the attention of the Milk Committee to the need for more exact information on the use levels of bixin in cheese. The Committee accepted the offer of the observer from the IDF to provide information.

### **Amaranth**

40. The Committee noted that no additional information was received on the intake of the food additive "Amaranth" from food since the last session of CCFAC. It agreed that a circular letter should be sent out again asking member governments to provide information on new authorizations for the use of "Amaranth" in food and results of any studies on the intake of the additive.

### **Intake of BHA-BHT from chewing gum and foods other than fats and oils**

41. The Committee noted that from information received from member governments it seemed evident that in some countries oils and fats were not the only important group of foodstuffs responsible for the intake of these additives. In view of the increased authorizations for the use of these additives in food and the lowering of the ADI of these additives, the Committee agreed that more information should be sought by means of a CL regarding the intake of these additives, indicating, if possible the relative contribution of the foodstuffs and in which foods the food additive is used.

42. As regards chewing gum, the Danish delegation indicated that according to unpublished studies, 1-15% of BHT is ingested during chewing (the rest of the additive remaining in the gum base). The French delegation reported a figure of 1% for ingestion of BHT from chewing gum. The Committee considered that the differences in ingestion of BHT from chewing gum reported by the two delegations might have been due to the differences in the reporting of data or in the gum base used. One analysis might have been carried out on the gum base and the other on the basis of the whole chewing gum which would also include the essential oil. The delegation of Denmark agreed to provide more information on this subject.

43. The Committee also noted that both BHA and BHT are used in packaging materials and could migrate into foodstuffs. The delegation of Belgium considered it of interest to know at what level these antioxidants were used in packaging materials and the level of migration into foodstuffs.

### **Other matters**

44. The delegation of Italy informed the Committee that in its country, Erythrosine is authorized for use in a number of foods and proposed that the Committee should gather data on the intake of this additive. The Committee was informed that JECFA would be

reevaluating Erythrosine at its next meeting and agreed to await JECFA's evaluation before taking any action.

#### **Dietary Intake of Cadmium, Mercury and Lead:**

##### **Dietary Intake of Cadmium**

45. The Committee noted from recent data submitted to Global Environmental Monitoring System (GEMS) that mean intake of cadmium exceeded the PTWI for several population groups, in particular infants and children. Although low levels of Cd (0.05 mg/kg) were found in cereals, the fact that they were consumed regularly in large amounts made them the largest contributor to the intake of the contaminant through food. The Committee also noted that Cd is scheduled for reevaluation by the 33rd Meeting of JECFA.

##### **Dietary Intake of Mercury**

46. The dietary intake of Hg by populations in Australia, Canada and USA amounted to only 10% of the PTWI and the Committee noted that the low intakes could be attributed to low levels of Hg in fish, coupled with low levels of consumption of fish (20 g/day). No information was received from member countries regarding intake of Hg by pregnant women.

##### **Dietary Intake of Lead**

47. In Cuba mean/media intakes of 12-18 yr old urban students exceeded the PIWI, while intakes of infants and children were well below the PTWI for this population group. Mean intakes for the adult population in all other countries participating in the GEMS programme were well below the PTWI of 50 mg/kg body weight. Specific foods that were identified as being particularly high in lead content were canned foods, wine and legumes.

48. The delegation of Switzerland brought the attention of the Committee to the review of heavy metals in cereals carried out by CCCPL. The subject would be discussed at its next session to be convened later this year.

49. Since a small number of replies were received from member countries in response to the Circular Letter sent out last year (CL 1987/25), the Committee agreed to repeat its request for information regarding total intake of Cadmium, Lead and Mercury. The Committee considered it important to collect information on levels of these contaminants in different foodstuffs in order to identify those that are responsible for high intake of these contaminants. Data on concentration of these contaminants in different animal tissues were also considered to be of interest. Dr. Gorchev (WHO) agreed to collate the information received and to prepare a paper on the subject for the next (21st) Session of CCFAC.

#### **Guidelines for a simple evaluation of Food Additive Intake**

50. The Committee noted that the Guidelines for a Simple Evaluation of Food Additive Intake were elaborated in response to requests by a number of countries who had difficulties in carrying out such studies, which were normally very expensive and time consuming (ALINORM 85/12, para 46.). The Guidelines described a stepwise approach to determine whether food additive intake exceeded the acceptable daily intake (ADI) allocated to the food additive, using increasingly more accurate estimates of intake by use of simple techniques which were not expensive. The Committee noted that these guidelines were meant to provide guidance to such of those member governments which would like to estimate food additive intakes among their population,

51. The Committee noted that the first draft of the guidelines prepared by the delegation of Belgium and subsequently modified to align it with the "Guidelines for predicting dietary intake of pesticide residues" was discussed at length by the working group on intake of food additives and contaminants. The Committee agreed to the changes in the text proposed by the Working Group.

52. The Committee agreed not to advance the guidelines through the Codex procedure at this stage, but to append the guidelines (Appendix II), with the preface proposed by the working Group, to this report and seek comments from member governments by means of a Circular Letter. The Committee agreed to delete from the guidelines the appendix which gives an example of a calculation of the intake of benzoic acid and consider how it can include a sample calculation in the guidelines at its next (21st) session. The Committee encouraged member countries to use the guidelines to estimate food additive intake and report their experience to the next session of CCFAC.

53. The Committee agreed to consider at its next session whether to advance the guidelines through the Codex step procedure or submit them, with the approval of the Commission, to governments as an advisory document.

54. While reviewing the guidelines the Committee noted the definition of ADI contained in the WHO Environmental Health Criteria, document no. 70, Principles for the Safety Assessment of Food Additives and Contaminants in Food, Geneva 1987. ADI was defined as: "An estimate by JECFA of the amount of a food additive, expressed on a body weight basis, that can be ingested daily over a life time without appreciable risk". This definition differed from the definition given in earlier JECEA texts in which the word "appreciable" was not included. In the view of the Committee, the two definitions were different. The Committee agreed to bring this to the attention of JECFA for clarification and for an expressed view of whether the new definition of ADI would be applicable to all food additives reviewed earlier.

#### **Establishment of an ad hoc Working Group on Food Additive Intake**

55. The Committee reinstated the ad hoc Working Group on Food Additive and Contaminant Intake with Belgium as Chairman. The following countries and organizations indicated their interest to participate in the Working Group: Australia, Belgium, Canada, Denmark, Finland, Fed Rep. of Germany, France, Italy, Japan, Malaysia, Spain, Sweden, Switzerland, The Netherlands, Thailand, UK, USA, EEC, CIAA, MARINALG, IFGMA, IOCU, International Food Additive Council, FAO and WHO.

#### **Regular Reviews of Food Additive Provisions in Codex Standards**

56. The Committee had before it document CX/FA 88/10-Part 1, prepared by the Secretariat, which outlined two possible approaches to meeting the need for maintaining the up-to-date status of food additives in Codex Standards: i) review on a case-by-case basis, or ii) the development of general provisions for the use of food additives. The review on a case-by-case basis, using the current procedures for the review and endorsement of food additives was described in detail, including aspects of technological justification, toxicological assessment and nomenclature, and the procedures which would need to be followed by the Committee and the commodity committees which had been responsible for the development of the specific standard. The second approach would allow for simplifying food additive provisions in Codex standards. It would list each additive under its class name or two or more class names for multifunctional additives, and it would provide maximum levels of use with deviations being specified.

57. It was also noted that the second approach could be extended, in principle, to cover foods which were not standardized by Codex, and therefore could provide the basis for guidance on the use of food additives on a horizontal level.

58. Many delegations expressed the opinion that the second approach, described would be insufficient to ensure that the use of food additives would be properly controlled. Particular attention was drawn to the possibility that a considerable number of additives might be permitted without consideration of their technological justification; and that the general outline contained in the paper was oversimplified and did not provide for a difference in toxicity properties of individual additives.

59. The representative of IOCU expressed that organization's concern that there was a tendency for too many additives to be included in Codex standards and for permitting the free use of all additives cleared by JECFA. The representative also drew attention to the need to take into account regional differences which dictated different conditions of use in some cases and importance of technological justification. These views were supported by several delegations. The delegations of Italy and Poland reserved their position with regard to the development of general provisions.

60. Several of the delegations drew attention to the difficulties of proceeding with a review on a case-by-case basis and considered that perhaps an intermediate approach could be followed, including carrying out a case-by-case review, as a first step, on a limited number of commodities.

61. The representative of the EEC, and the delegations of Australia and the USA drew attention to the future role of the Committee in the current legislative environment where more emphasis was being paid to horizontal, or general requirements. They proposed that a detailed working paper should be prepared indicating how the Committee could approach such a problem and which would take into account how practical considerations and the legitimate concerns of consumers might be addressed. It was noted that other aspects, such as labelling, might have to be taken into account as well.

62. Several delegations requested and the Committee agreed that it would be essential to analyze the extent of current food additive provisions endorsed by the Committee and examine possible mechanisms and procedures for considering food additives inside and outside the usual framework of Codex Standards, taking into account questions related to:

- the additives to be considered, whether those on Codex List A only or Codex List A with certain additions;
- the toxicological status of each additive
- the conditions of use;
- the estimated dietary intake, and regional differences in intake patterns;
- whether or not current food additive provisions were among the reasons for non-acceptance of Codex standards;
- technological need of the additive;
- other factors, such as nutritional status; and
- the timeframe in which such work could be carried out.

63. The Committee decided that a Consultant should prepare a Working Paper for presentation to the 21st Session of the CCFAC on the future activities of the Committee in regard to the establishment and regular review of provisions relating to food additives

in Codex Standards, and the possible mechanism for establishment of general provisions for the use of food additives in non-standardized foods as a horizontal approach in the light of changing requirements in international trade it was agreed that before preparing the working paper, the consultant would seek as broad an input as is practicable.

64. The possibility of establishing an ad hoc Working Group or sending out a CL asking for government comments was discussed, but it was agreed to await the consideration of the consultant's paper at the next session before taking further action.

### **ENDORSEMENT OF FOOD ADDITIVE PROVISIONS IN CODEX COMMODITY STANDARDS**

65. The Committee had before it document CX/FAC 88/10-Part II prepared by the Secretariat. The decisions of the Committee concerning the endorsement of postponement of the endorsement of food additive provisions are indicated in this report {Appendix III -Part I).

#### **Codex Committee on Cereals, Pulses and Legumes**

##### **Food Additive Provisions in Wheat Flour**

66. The Committee noted that consequent to the decisions of the 17th Session of CAC the food additive provisions in wheat flour were before them for the third time for reconsideration of endorsements. Introducing the paper, the Secretariat summarized for the Committee the basic philosophy behind the recommendations of, the Secretariat. The paper had taken into consideration the general principles for the use of food additives elaborated by Codex. The recommended use of an additive was restricted to such of the wheat flours in which the additive was needed for a technological function. It was suggested that inclusion of such an additive in the food additive provisions of the standard could be supported if a clause was inserted in the food labelling section of the standard to the effect that wheat flour containing certain additives with a specific use should be appropriately labelled as to its intended end use. Also the Secretariat reminded the Committee that when the subject was considered by the 19th Session of CCFA, the Committee had expressed the view that the food additive section might be redrafted indicating the type of flour in which the food additive was permitted.

67. The delegation of the USA informed the Committee that it had discussed the Secretariat's paper with the Chairman of CCCPL, who proposed that this Committee consider the food additive provisions as proposed by the CCCPL or, in the event the CCCPL's proposal could not be endorsed, the CCCPL would review the Secretariat's paper and submit comments on it to the next CCEAC, The Committee accepted the latter proposal.

68. The delegation of Australia requested clarification. of what JECFA meant in its 29<sup>th</sup> report when it stated that "when restricted to use in cake flour, the use of chlorine at levels of up to 2.5 g/kg flour could be acceptable". The Australian delegation was of the opinion that this was not the way an ADI normally was expressed, and it was difficult to relate this figure to. the total acceptable intake. The Committee decided to refer the question to JECFA for clarification.

69. The delegation of Egypt expressed the view that total carbohydrate intake in the diet and chlorine content of drinking water should be taken into consideration while arriving at recommended use levels of chlorine in wheat flour.

## **Committee on Code of Principles Concerning Milk and Milk Products**

### **Standards for Cheese**

70. The Secretariat proposed that the Committee temporarily endorse karaya gum in the standard for creamed cottage cheese and endorse xanthan gum in the Standard for processed cheese preparations, cheese foods and cheese spreads. The Committee agreed to the Secretariat's proposal.

### **Codex Committee on Foods for Special Dietary use**

#### **Standard for Follow-up Formula**

71. The Secretariat informed the Committee that it had already endorsed L (+) Lactic Acid and L (+) Lactic Acid producing cultures in Infant Formula Standards, and proposed the endorsement of the provisions in the Codex Standard for Follow-up Formulae. The Committee agreed to the Secretariat's proposal.

72. The delegation of Egypt expressed the view that JECFA should draw up microbiological specifications for the cultures used in food processing.

### **ACTION NEEDED BY CCFAC RESULTING FROM CHANGE IN ADI STATUS OF FOOD ADDITIVES**

73. The Committee had before it document CX/FAC 88/10-Part III, prepared by the Secretariat. The document presented the action needed to be taken by CCFAC resulting from changes in the ADI status of food additives. The decisions of the Committee are tabulated in Appendix III, Part 2 of this report.

74. At its 30th Meeting, JECFA separated the ADIs for BHA, BHT TBHQ, allocated an ADI for propyl gallate and withdrew the ADI for octyl and dodecyl gallates. in view of these changes, this Committee decided to endorse the amended provision for propyl gallate and temporarily endorse the amended provisions for BHA, BHT and TBHQ in Codex Standards for fats and oils, where appropriate.

75. At its 31st Meeting, JECFA lowered the ADI of Canthaxanthin from 0-0.05 to 0-0.05 mg/kg bodyweight and changed it from a full ADI to a temporary ADI based on results of new studies. This Committee decided not to endorse revisions to Codex Standards pending review by the Commodity Committees and pending the submission of information

concerning direct and indirect uses of Canthaxanthin to the Working Group on Food Additive Intake.

76. At its 30th Meeting, JECFA recommended a change from temporary ADI to full ADI for Fast Green FCF and Polyvinylpyrrolidone (PVP) based on the evaluation of new data. The ADI for Fast Green FCF was increased to 0-25 and for PVP to 0-50 mg/kg body weight. None of the Codex Standards elaborated by the Codex Commodity Committees contained any provisions for PVP, This Committee agreed to amend the provisions for Fast Green FCF in Codex Standards from temporary endorsement to full endorsement. Maximum levels of use for Fast Green FCF in the Commodities need not be reviewed by the Commodity Committees since the earlier ADI was not lowered but increased.

77. At its 30th and 31st Meetings, JECFA recommended an ADI of "not specified" for Xanthan Gum, Glucono-delta-Lactone, Mineral Oil, Beet Red, and Glutamic Acid and its Salts/This Committee agreed that these substances should be reviewed by the Commodity Committees in view of these changes.

78. The 30th Meeting of JECFA considered turmeric to be a food and not a food additive and therefore concluded that it was not appropriate to allocate an ADI. Based on JECFA's decision this Committee concluded that the food additive provisions for turmeric should be withdrawn from the Codex Standards for Minarine and Pickled Cucumbers. It was noted, however, that turmeric could continue to be added to these and other food as an ingredient. However, some delegations requested that this substance should be resubmitted to JECFA for reconsideration.

79. The 30th Meeting of JECFA lowered the allocated ADI of Erythrosine from 0-1.25 (temp) to 0-0.6 (temp). This Committee agreed that the revised maximum levels for this substance should be reviewed by the Codex Commodity Committees. At its 31st Meeting JECFA allocated an ADI of "not specified" for Beet Red. This Committee decided to recommend the reinstatement of this provision in the Codex Standard for Edible Ices and Ice Mixes.

#### **Consideration of Class Names and International Numbering System**

80. The Committee had before it the report of the ad hoc Working Group on Class Names and International Numbering System (INS), which was introduced by the Chairman of the Group, Mr. L.J. Erwin (Australia). The Working Group considered the documents CX/FAC 88/9, which contained the responses of member governments to CL 1987/59, CX/FAC 88/9A containing the comments from USA, CX/FAC 88/9 Add-1 containing the comments from Sweden, which were available to the Committee.

81. The Committee noted that the purpose of the INS was to provide recognized international numbers to identify food additives in compliance with the Codex General Standard for Labelling. This required food additives to be designated in the list of ingredients by the functional class name together with either the specific name or the INS number. On the other hand, it was noted that all ingredients other than food additives had to be included by name only without any reference to function.

82. The Committee expressed the view that the present definition for "food additive" made it difficult to identify those substances which should be considered as food additives for inclusion in the INS. At present a number of substances included in the INS could be more appropriately regarded as foods. Some substances had been identified as food additives and included in the INS on the basis that they had been toxicologically evaluated by JECFA. JECFA also expressed the view that certain substances, such as amylose and amylopectin, should be regarded as foods rather than food additives. It was agreed that the above question regarding the definition and correct labelling of food additives would be considered as a separate item under future work.

83. The Committee agreed that amylose and amylopectin (418) and gelatine (441) be deleted from the INS and that all the modified starches (1400 to 1450) be taken out of the INS. The latter was in accordance with the General Standard for Labelling which did not require the specific identification of the modified starches in the list of ingredients. A number of delegations supported retention of the identification numbers for the modified starches since, in some countries they had to be specifically identified in labelling under national legislation. To provide for this, it was decided that substances 1400-1450 could be listed in an annex to the INS. The Committee agreed that the annex should include a preface to make it clear why the modified starches were not included in the INS. It was pointed out that, if modified starches were specifically identified in labelling, they could be included under the appropriate class name e.g. thickener.

84. It was proposed that the term hydrogenated glucose syrup (965) should be deleted from the list. It was recognized that the term covered more products than those covered by 965 which was more properly identified as a maltitol based product. It was decided that the term be retained pending the forthcoming review by JECFA, after which a final decision could be taken.

85. It was agreed that a number should be provided for the natural carotene and that 160(a) would be sufficient identification for all carotenes for the purposes of labelling. However, the list should provide further information for regulatory authorities and industry in that there were separate specifications for synthetic Beta-carotene and natural extracts of carotene. This could be achieved as follows:

Number	Name of Food Additive	Specification	Technical Function
160(a)	Carotenes	(i) Beta-carotene (synthetic) (ii) natural extracts of carotene	Colour

86. An INS set out in the above manner would provide the name or number to be used for labelling in the first two columns with the more detailed chemical name provided under the specification heading. It would also provide for a clearer characterization of the phosphates as proposed by the UK Chemical Industries Association (CX/FAC 88/9 pages 3-6). It was agreed that a revised INS should be prepared in the above format.

87. The Federal Republic of Germany proposed that provision be made in the INS for an abbreviated chemical name. It was decided to await the revised INS before taking this matter further. As proposed by the Netherlands, it was agreed that processing aids such as activated vegetable carbon (153) and hexane (905) be deleted.

88. It was noted that both furcellaran and carrageenan were correctly identified as number 407 since both were covered by the one specification. Similarly, since JECFA made no distinction between pectin and amidated pectin both were covered by number 440. It was decided that all the salts of fatty acids (with base Al, Ca, Mg, Na, K and NH4) should be covered under 470. This would result in deletion of 571-573 covering ammonium, magnesium and aluminium stearates. Number 570 in the INS was changed from stearic acid to cover all the fatty acids.

89. The Committee did not support the Norwegian proposal to include certain commonly used flavours (vanillin etc.) in the INS. The Committee considered the labelling of certain candies which comprised polyols as the major constituent and which were presently labelled under the class name sweeteners. It was decided that for the present this was more meaningful to the consumer than including them under a class name such as bulking agent.

90. The IOFI's proposal to delete maltol (636) and ethyl maltol (632) from the INS was not accepted. It was agreed that the Carrier Solvents 1500-1502, 1504-17 should be deleted as no specific identification in labelling was required since carrier solvents were an integral component of flavourings which are not required to be identified by labelling. In any case a residue of the carrier solvents in the food is a result of carry over and will therefore not require labelling.

91. The Committee noted that the table attached as Appendix IV, Part 1 to this report, provided, by the observer from AMFEP identified those enzymes which function as food additives with their technological function. All the enzymes have specifications elaborated by JECFA. The Committee agreed that comments should be sought from member governments and from the CCFL on this list of enzymes.

92. There was general support for the principle of a table of functional classes and sub-classes as proposed by the USA. It was reiterated that the list of functional classes for labelling purposes should be restricted to a minimum and that they must be descriptive and meaningful to the consumer.

93. It was agreed that the term colour preservative be deleted as it was covered by the term colour retention agent. Decolouring agent was also deleted as this was a function of

a processing aid (e.g. activated vegetable carbon).

94. Colour stabilizer was included in square brackets as a functional class as this was considered more descriptive than including the related sub-classes (colour fixative, colour retention agent) under stabilizer. The two subclasses were also included in square brackets under the class name colour.

95. Sequestrant was included as a sub-class under both antioxidant and stabilizer. Packing gas was included as a<sup>1</sup> sub-class under preservative and propellant.

96. Consideration was given to the Australian proposal that the functional class "sweetener" did not distinguish sweet foods such as sugar from the food additive sweeteners. It was noted that this problem was greater in the English language. The Austrian delegation drew the attention of the Committee to the fact that difficulties also arose when the term sweetener with its different subclasses was translated into other languages, e.g. the German language.

97. The observer from IOCU considered that sweeteners were adequately identified as food additives when they were declared under the functional classname sweetener in conjunction with their identification number or name. Sweet foods would be declared in the list of ingredients only by their specific names without any reference to the functional class sweetener. The Committee agreed with IOCUs view. The observer from the IOCU expressed concern, however, that some manufacturers were deliberately confusing consumers by adopting an inconsistent approach to the use of numbers and; specific names for food additives. The present system which allowed this should be amended to ensure that a consistent approach of either number or specific names be used in ingredient lists. The Committee agreed that the CCFAC should bring this concern to the attention of the next meeting of the CCFL.

98. The Committee considered nine class names proposed by Canada. Although recognized in Canadian food laws, it was decided that most could not be accommodated in the table of classes and sub-classes. There was some support for the proposal of Canada and Finland that emulsifying salts (used in labelling of processed cheese) should be included under the class name emulsifier. However, it was pointed out that the salts functioned as a melting agents and not as emulsifiers. It was decided that, for the present, the terra emulsifying salt be retained in the list but consideration should be given to determining a more appropriate functional class name.

99. A revised "Table of Functional Classes and Sub-classes of Food Additives "is included as Appendix IV, Part 2; It was agreed that the table should be referred to the

next meeting of CCFL with a request for its views on the appropriateness of the functional classes for labelling purposes.

100. The Committee reviewed the additional food additives proposed for inclusion in the INS. It noted that many of these were already covered since they were included in the related specifications. This would be made clear in the revised INS described above which would include a listing of all specifications covered by specific numbers.

101. The Committee noted that many of the substances proposed for inclusion were either no longer manufactured and/or used in the food industry. Consequently, it was decided that the proposing countries should be requested to review them in order to ascertain if they should be included in the INS. If no relevant information is received in response to the circular letter, the additive will be deleted. Tentative numbers were agreed for the remaining substances, which appeared to warrant inclusion in the INS.

102. The Committee agreed that a circular letter be issued to member governments and comments sought on:

- i) Updated INS in the proposed format and including all the new numbers allocated to such of the food additives proposed by member governments for inclusion in the INS.
- ii) List of food additives proposed for inclusion but for which the Committee did not allocate numbers.
- iii) Functional class names especially those with square bracket and
- iv) List of Enzymes which are food additives.

103. The Committee agreed that the international Numbering System and functional Class Names for Food Additives, which would be finalized at the next (21st) Session of CCFAC, should be submitted to the Commission for adoption. It also agreed that the document which provided information on how food additives should be specifically identified in the list of ingredients should be recommended to CCFL for annexation to the Codex General Standard on Labelling.

104. The Committee agreed that the International Numbering System also provided a very useful reference list of food additives for CCFAC.

#### **Establishment of an ad hoc working Group on International Numbering System and Class Names**

105. 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, Austria, Belgium, Brazil, Canada, Denmark, Finland, France, Federal Republic of Germany, Japan, The Netherlands, New Zealand, Portugal, Sweden, Switzerland, Thailand, UK, USA, AMFEP, CIAA, EEC, IFAC, IFG, IFGMA, IOCU and FAO.

#### **REVISIONS TO CODEX LIST B**

106. The Committee had before it document CX/FAC 88/2 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 and 31st meetings of JECFA. The revisions to Codex List B are included in Appendix V.

107. 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 revisions in Codex List B that was Appendix V of Alinorm 87/12.

### **CONSIDERATION OF FLAVOURS**

108. The Committee had before it documents CX/FAC 88/6-Part I, and addenda 1, 2, 3 and 4 which summarized government comments on an approach to priority setting for the 'safety evaluation of flavouring substances, submitted in response to CL 1987/26-FA, document CX/FAC 88/6-Add. 1 (Room document), Report of the ad hoc Working Group on Flavours, and document CX/FAC 88/6-Add. 1, Appendix 1 (Room Document), Priority Ranking System for Flavours (Method 4).

109. The Committee noted that additional comments were received from the United Kingdom, Joint Council of Europe/Commission of the European Communities, IOFI and FIVS and considered by the ad hoc Working Group on Flavours.

110. The Chairman of the Working Group, Mr. J.P. Goddijn (The Netherlands) introduced the report of the working Group and described Method 4 of the Priority Ranking System for Flavours (Appendix VI). The Working Group had expressed a preference for Method 4 over three other methods introduced at the working group meeting.

111. Considerable discussion took place as to which, groups of substances the priority ranking system should be applied. The WG recommended that, as a first step, flavouring substances included in Codex List B plus lists of artificial and nature-identical substances submitted by IOFI (Appendix VI) should be considered. The delegation of the UK expressed reservations as to the limited scope of the proposed list because it was arbitrary, overly restrictive and only included one-tenth of the flavouring substances used. The delegation suggested that the proposed priority ranking method should be submitted to JECFA for examination, and then JECFA might be asked to state which substances they would limit for priority ranking. The observer from IOFI indicated, however, that their lists represented 90% by weight of all defined single flavouring substances used in the United States and included top priority substances for evaluation. The delegation of the USA agreed that the listing proposed recognizes the most important substances on a toxicological basis, and is adequate as a first step. The observer from the EEC also indicated that extensive work was carried out regarding the priority ranking system in a workshop sponsored by the EEC and Council of Europe Secretariat and that the partial list was adequate as a first step towards eventual inclusion of all flavouring substances. The delegation of Belgium also agreed to this concept, but indicated that the consumption ratio figures should include data from other regions besides the USA and should also include specific substances used exclusively outside of the USA. The observer from IOFI indicated that the lists were developed based on US data as this was the only information available at the time, but that they were conducting a survey in Europe to collect data regarding nature-identical flavouring substances.

112. The Committee concluded that as a first step it should consider flavouring substances included on Codex List B plus the lists of artificial and nature-identical flavouring substances submitted by IOFI (Appendix VI to this report). The Committee also endorsed the proposed system for priority ranking and agreed that it should be submitted to JECFA for its opinion and in particular whether the adjustment for toxicological data was appropriate. It was agreed that JECFA should consider whether the safety evaluation of flavouring substances could be carried out using criteria based

on less extensive toxicological data. As a second step, it was agreed to include consumption ratio data on flavourings produced in Europe and other regions and eventually to submit all flavouring substances to the proposed flavour priority ranking system.

113. The Chairman of the WG indicated that the JECFA Secretariat would be invited for applying the system to the established lists, requesting JECFA's evaluation of the substances of highest priority as soon as possible.

114. The Committee decided not to reinstate the ad hoc Working Group on Flavours and expressed its appreciation for the extensive work accomplished under the working group chairman. The working Group chairman also expressed his appreciation to all parties involved in the completion of its tasks.

#### **CONSIDERATION OF SPECIFICATIONS OF IDENTITY AND PURITY OF FOOD ADDITIVES**

115. The Committee had before it documents CX/FAC 88/7 the report of an ad hoc Working Group, CX/FAC 88/7 Add. 1, comments of The Netherlands on the publication of Codex Advisory Specifications and CX/FAC 88/7 Add. 2A secretariat documents listing and cross referencing JECFA and CODEX Advisory Specifications. Sessions of the Working Group were co-chaired either by Dr. J. Modderman (USA) or Dr. I. Meyland (Denmark). In introducing the report of the Working Group its Chairman, Dr. J. Modderman (USA), restated that the tasks of the Group were to consider the statements of the 34th Executive Committee and the 17th Codex Commission on the publication of Codex Specifications and to evaluate the comments on JECFA specifications published in FAO Food and Nutrition Papers 34 and 37.

116. The Committee reiterated that there was a need for easier access to Codex Specifications which was important if these specifications were to be accepted by Governments. In its opinion this could be achieved by separate publication of the Codex Specifications. The Secretariat stated that it was examining ways and means to have a consolidated publication of all JECFA Specifications which would indicate which specifications had been adopted as Codex Advisory Specifications. In the meanwhile the Secretariat would prepare for the next session of CCFAC an information document containing JECFA Specifications. The Committee expressed agreement with this proposal.

117. The Committee also noted the opinion expressed by the WG and several delegations that the reference list of JECFA and Codex Standards prepared by the secretariat could be a good starting document which should be extended to include amendments and corrigenda, together with the ADI for the corresponding substances. The WG drew the attention of the Committee to certain omissions and discrepancies in the Codex Referenced list and noted that these would be reviewed at the next CCFAC session.

118. The Committee decided that the status of Codex Advisory Specifications should be withdrawn from Aluminium Sodium Sulphate and Aluminium Sulphate, which had been proposed as JECFA tentative specifications (FNP 7).

119. The Committee noted the difficulties that arose in defining the status of Codex Specifications and their implementation caused by (A) the changing ADI Status of the corresponding substances, (B) whether the substances were permitted in Codex Standards, and (C) the change by JECFA in status from "Food Additive" to "Food" or "Food ingredient". The Committee noted several cases involving such changes. The

Committee agreed that a Circular Letter should be sent to member governments requesting opinions on these matters,

120. The Committee accepted the evaluation by the WG of the comments on JECFA Specifications in FNP 34 and, 37 as shown in Appendix VII and will recommend to the Commission the adoption of those in categories I and II as Codex Advisory Specifications.

121. The Committee expressed its appreciation for the work of the ad hoc Working Group and reinstated it under the chairmanship of Dr. John Modderman (USA) with the following membership; Denmark, Fed. Rep. of Germany, Finland, France, Switzerland, United Kingdom, EEC, IFG, ISO, MARINALG and FAO.

### **SAMPLING PLANS FOR THE DETERMINATION OF CONTAMINANTS IN FOOD**

#### **Government comments on sampling plans for contaminants and compliance criteria for contaminants in food**

122. The Committee had before it documents CX/FAC 88/14 and CX/FAC 88/18-Add. 4. The Committee was informed by Dr. Slorach, chairman of the ad hoc Working Group, on industrial and environmental contaminants that a general approach in checking for compliance in food had not been possible and that sampling plans had to be established on a case-by-case basis. In their replies to CL 1987/22-FA most countries considered the composite sampling plan adopted for pesticide residues (CAC/PR 5-1984) appropriate for the environmental contaminants (Eg, Cd and Pb), but not for aflatoxins. In this regard it was pointed out that expertise for sampling from bulk consignments of cereals, pulses and legumes rested with the CCCPL.

123. The delegation of The Netherlands informed the Committee that they were developing a Code of Practice for sampling and analysis of food for aflatoxin in which also sampling of bulk consignments was considered.

124. The delegation of Switzerland requested clarification of the status of the sampling plans after submission to CAC. It was explained by the Secretariat that methods of analysis and sampling are an integral part of Codex Standards when maximum levels of contaminants are defined. When a standard did not include mandatory limits, methods of analysis and sampling were guidelines and as such were advisory. The Committee agreed that where environmental contaminant limits were guidelines the sampling plans were advisory.

125. The Committee agreed to submit the sampling plan for the environmental contaminants Pb., Cd. and Hg to the CCMAS and later to the Commission for adoption.

126. The Committee further discussed the procedure that should be followed in devising a sampling plan for aflatoxins. The Secretariat explained that, in principle, both committees, CCCPL and CCMAS had to be involved and that consultation could be completed within one year.

127. The delegation of Australia expressed doubts about whether the terms of reference of CCCPL included groundnuts, since groundnuts are considered to be legumes, the Secretariat considered that they are part of the CCCPL's responsibility.

128. Dr. Slorach informed the Committee that the CCCPL was carrying out a survey on the aflatoxin content of cereals, pulses and legumes, the results of which would be available in 1988. This Committee would then be in an excellent position to deal with a sampling plan for aflatoxins.

129. The delegation of the United States drew the attention of the Committee to the basic problem that sampling plans were related to levels of safety, e.g. the probability of finding the defect. The Committee should decide on a reasonable compromise with reference to agricultural practice. The delegation of The Netherlands informed the Committee that in the Code of Practice they were developing, the relation of sampling plans with levels of safety would be addressed. The delegation assured the Committee that the Code of Practice would be available to the CCCPL for reference at its next session.

130. The Committee agreed to refer the problem of a sampling plan for aflatoxin to the CCCPL for consideration at its next session, with the request to comment quickly to the CCFAC.

## **CONSIDERATION OF INDUSTRIAL AND ENVIRONMENTAL CONTAMINANTS IN FOOD**

### **Guideline levels for Aflatoxins in Food and Feed**

131. The Committee had before it documents CX/FAC 88/18 and CX/FAC 88/18A which contained the responses of member countries to CL 1987/24-FA to which the delegation of Argentina offered additional information and also the consideration of the paper by the ad hoc Working Group on Contaminants (CX/FAC 88/18-Add.4).

132. In introducing the section of the WG report concerning the guideline levels for aflatoxins in food and feed, Prof. S. Slorach, the chairman of the Working Group, noted that the guideline level was intended for control of aflatoxins in food and feed moving in international trade. Sample lots should be considered as being in compliance with the guideline levels, if the levels of aflatoxin did not exceed the guideline levels. When these guideline levels were exceeded, governments could decide whether the food should be distributed within their jurisdiction and, whether any recommendations should be given relative to restrictions on consumption.

133. Several delegations expressed the opinion that the proposed guideline level of 15 ugA9 as the sum of aflatoxin B1, B2, G1 and G2 was too high, especially for cereals. The delegation of Egypt drew attention to the fact that cereals are staple foods in many countries of the world and expressed the need for establishing a separate level for cereals.

134. The Committee noted that the WG considered several different proposals, including whether or not the limits should apply to aflatoxin B1 only, or to aflatoxins B1, B2, G1, G2 or to a combination of these. The possibility of proposing specific guideline levels for nuts (oil seeds) and nut products and a separate level for cereals and their products was also considered.

135. The Committee also discussed the single level of 5 ug/kg of total B1, B2, G1 and G2 for nuts, oil seeds, cereals and their products (e.g. peanut butter proposed by the Working Group. The delegate of Denmark confirmed that the analytical method can detect this level. The delegation of Italy expressed its reservation on the application of the guideline levels to secondary products.

136. The delegations of Malaysia, Thailand, Brazil and The Netherlands expressed their view that the level of 5 ug/kg of aflatoxin as a sum of B1, B2, G1 and G2 was too low. The delegation of the Netherlands stated that this level was not acceptable because, in its opinion, it was not possible at this stage to adopt sufficiently reliable inspection methods which would justify rejection procedures based on these levels.

137. The delegation of the USA expressed the view that the discussions concerning the guideline level were premature because the level was not linked to a sampling plan and more information was needed concerning the levels permitted by different governments. It suggested that a review by the CCCPL might provide this additional information.

138. The delegation of the Netherlands informed the Committee that in The Netherlands a Code of Practice in this field was presently being developed for use by trade and industry. Several delegations expressed an interest in the Code of Practice and the delegate of Switzerland informed the Committee that such a system had been introduced in its country and expressed the usefulness of stringent guideline levels.

139. The Committee decided to seek comments for the proposed guideline levels of aflatoxins (5 ug/kg for the sum of aflatoxins B1, B2, G1 and G2) for nuts, oil seeds, cereals and their products (Appendix VIII) for human consumption at Step 3.

140. With regard to the proposed guideline levels (Appendix VIII) for animal feed, the Committee noted that these were generally accepted with some reservations. The delegation of Austria pointed out that, in this country, a uniform guideline level of 50 ug/kg for total aflatoxins (B1, B2, G1 and G2) for all feedstuffs is being applied. The delegation of Denmark expressed its reservation on the guideline level for fish feed since trout was found to be highly susceptible to aflatoxins. The delegation of Sweden expressed its reservation to the level for feed for dairy cattle stating that, in its view, the aflatoxin level permitted in feed for dairy cattle should be lower than the proposed level. The delegation of Finland expressed its reservation on the level of 200 ug/kg for maize. The observer of the IDF informed the Committee that it would bring to the attention of its national Committees the concern expressed by Sweden about the need for lower levels of aflatoxin for feed meant for dairy cattle. Several delegations commented that it was difficult to exercise control of differing aflatoxin levels for various feed and uses especially at the point of import, when the final destination of the feed was not known.

141. The observer from EEC confirmed that the guideline levels for aflatoxin in feed, under consideration by the Committee, were indeed accepted by the Community and included in the various directives issued by the Community on the subject. The Community directives also covered fish feed.

142. The Committee agreed to seek comments on the guideline levels for aflatoxin for various animal feedstuffs at Step 3.

#### **Methods of Analysis for the determination of aflatoxin in Milk and Milk products**

143. The Committee had before it document CX/FAC 88/18-Add.4 the report of the ad hoc Working Group on Industrial and Environmental Contaminants and CX/FAC 88/18-Add. 1, a working paper prepared by Canada on methods of analysis for the determination of aflatoxin M1 in milk and milk products.

144. Prof. S.A. Slorach, chairman of the Working Group, reminded the Committee of its discussions at its last session when it expressed the view that a reliable method of analysis for aflatoxin in milk should be available before setting up guideline levels for aflatoxin in milk and milk products.

145. The observer of the IDF informed the Committee that the provisional IDF 111-1982 standard for the analysis of aflatoxin in milk and milk products was updated **and** would be adopted at the IDF meeting to be held in Budapest in September 1988. The detection level of this updated method is 0.005 ug/l.

146. The Committee noted that the IDF method was closely in line with the AOAC/ISO procedures and that there was good coordination between AOAC, ISO and IDF on elaboration of Methods of Analysis for Milk and Milk Products.

147. The Committee noted that the paper CX/FAC 88/18-Add. 1 prepared by Canada considered both aflatoxins M1 and M4 in milk while the IDF method analysed only aflatoxin M1 in milk and milk products. The Committee decided to send the updated IDF method to the Steering Committee of the Joint FAO/WHO Committee on the Code of Principles Concerning Milk and Milk Products for adoption. The CCMAS would be asked later to review the IDF method and the Canadian paper CX/FA 88/18-Add. 1.

148. The Committee agreed to discuss at its next session guideline levels for aflatoxin in milk and milk products/ and the question of whether analysis for aflatoxin M1 alone was adequate, or whether aflatoxin M4 should also be taken into consideration. The Committee also agreed to discuss the question of sampling at its next session.

#### **Methods of Analysis for the determination of aflatoxin in food and feed**

149. The Committee agreed that the method of analysis for the determination of aflatoxin in food and feed was part of a guideline level and thus advisory. The Committee also agreed that CCMAS should be requested to review the available methods for comment. For that purpose the Secretariat should collect the available information.

#### **REPORT OF THE JOINT FAO/WHO FOOD CONTAMINATION MONITORING PROGRAMME**

150. The Committee had before it document CX/FAC 88/18 Add. 2 on the subject and noted that the Joint UNEP/FAO/WHO Food Contamination Monitoring Programme (JFCMP) which is part of the Global Environment Monitoring Systems (GEMS), established by the United Nations Environment Programme (UNEP). GEMS/Food was providing information on trends and levels of food contamination to enable appropriate follow-up action by governments and international organizations for the protection of public health. At present the project was implemented through cooperation with 35 countries and is open to any country wishing to participate. The Committee was informed that the most recent contaminants for which data have been requested include lead, cadmium, mercury, tin, aflatoxins, PCBs and pesticide residues. Not all countries submit data on all contaminants; usually a selection is made reflecting national priorities.

151. In addition, data on specific contaminants in various food commodities as well as in the diet, are collected from Codex Contact Points upon request from various Codex Committees to support their work on international standards for contaminants in foods.

#### **ROLE OF THE CCFAC CONCERNING TECHNOLOGICAL AND ENVIRONMENTAL CONTAMINANTS IN STANDARDIZED AND NON-STANDARDIZED FOODS**

152. The Committee had before it documents CX/FAC 88/18-Add. 3, prepared by the Secretariat, and CX/FAC 88/18-Add. 3A, prepared by The Netherlands, and comments of the ad hoc Working Group on Contaminants on this subject.

153. The Committee noted that its terms of reference allowed it to establish levels for contaminants (including environmental contaminants) in specific food items and animal feed, and that its terms of reference did not restrict such consideration to contaminant levels proposed by Codex Commodity Committees for inclusion in Codex standards. In extending its work to non-standardized food, the Committee might consider keeping the overall number of contaminant limits for food to a minimum. This would depend on the

nature and origin of the contaminant, and would have to take into account the same factors which the Committee currently considers in its endorsement procedures.

154. The Working Group had proposed, however, that the number of different limits to be established should be considered on a case-by-case basis, especially for technological contaminants which might be a determinant of quality.

155. Several delegations supported the view that all contaminants which were to be considered should be examined on a case-by-case basis with regard to specific food items, and that the number and nature of the limits would be determined in each case taking into account technological, toxicological and, on occasion, economic aspects. The Committee agreed with this point of view.

156. The Committee discussed a number of proposals, based on those presented by The Netherlands in document CX/FAC 88/18-Add. 3A, for contaminants to be given priority consideration. Considerable discussion centered on whether or not certain naturally occurring toxic substances could be considered as contaminants within the Committees terms of reference. Nitrates in leafy vegetables were mentioned as occurring partially from natural origin and partially from agricultural practices. It was agreed to inform the Commission that the Committees' future work could include the establishment of levels for such substances and to request the Commissions' opinion in this regard. In the meantime, it was agreed to request JECFA to re-evaluate aspects of the toxicology of nitrates, nitrites and nitrosamines. The delegation of The Netherlands informed the Committee that detailed toxicological studies of nitrates were being carried put, and would be completed by the end of 1989.

157. The Committee, after considering the established priorities of the Joint FAO/WHO Food Contamination Monitoring Programme for certain contaminants and food groups, agreed that lead, cadmium and aflatoxin should be priorities for CCFAC. The delegation of Sweden suggested that particular attention should be paid to lead in infant foods. Other delegations suggested that patulin (a mycotoxin) and ethylcarbamate should be considered important. It was noted that neither substance had been evaluated by JECFA, and that toxicological data on ethylcarbamate were still being developed. The delegation of The Netherlands stated that recent toxicological data on patulin could be submitted to JECFA in the near future. The delegation of the Federal Republic of Germany stated that a five year food contamination monitoring programme had recently been initiated that would give a clearer indication of intake figures for the FRG.

158. The Committee decided to proceed with the elaboration of maximum or guideline levels for lead and cadmium at its next session and requested the Secretariat to obtain information, by means of a circular letter, on maximum or guideline levels for three contaminants currently applied by governments in the foods listed in Appendix IX. It was noted that such information would serve to update the paper prepared by Dr. H. Mollenhauer (ref. ALINORM 85/12) for the Committee in 1984. It was also noted that the Council of Europe had recently compiled a detailed listing of lead, cadmium and mercury levels applied in several of its member countries. The Committee accepted the offer of the delegation of Sweden to summarize the replies to the Circular Letter.

159. The Committee also agreed to ask the opinions of governments on future contaminant priorities, and requested the Secretariat to establish a draft priority list which could be circulated to governments for comments. The results of this survey would be included in a working paper for consideration by the next session of the Committee. The Chairman of the WG drew attention to the need to develop methods of analysis and sampling at the same time as priorities were being established.

### **Guideline Levels for Mercury in Fish**

160. The Committee "noted the decision reported in paragraph 224 of the report of the Seventeenth Session of the Codex Alimentarius Commission (ALINORM 87/39) that the decision on whether or not to send the guideline levels should be sent for comments at Step 3, should be postponed until the new evaluation of mercury and methyl mercury would be available from JECFA. It proposed that in order to accelerate a decision the matter might be taken up by the Executive Committee at its 35th Session, which could have available the opinions of JECFA and the 18th Session of the Committee on Fish and Fishery Products.

161. The Committee agreed that the ad hoc Working Group on Industrial and Environmental Contaminants had essentially completed its task in preparing the Committee's programme of work in this area. It was decided that technical matters should be handled by the formation of an ad hoc Working Group on Sampling the existing Working Group on Intake and the new Working Group on Methods of Analysis (see para 178).

162. Committee established a new Working Group on Sampling with the delegations of the Netherlands, United Kingdom, Switzerland, USA, Fed Rep. of Germany, Denmark, Sweden Australia Spain Thailand, Italy, Malaysia, Canada and the observers of IFG and ISO as members. The Federal Republic of Germany and The Netherlands volunteered to act as later date working group. The Chairmanship of the Working Group will be decided at a

### **PRIORITIES, PACKAGING MATERIALS AND METHODS OF ANALYSIS FOR FOOD ADDITIVES**

#### **Food Packaging Materials**

163. The Committee had before it document CX/FAC 88/11 summarizing comments from governments received in response to CL 1987/28-FA on the subject "Approaches to limiting the occurrence of certain migrants in foods from food packaging materials". The report was presented by Dr. B.L. Huston, Chairman of the ad hoc Working Group,

164. The Committee agreed that the control of vinyl chloride monomer (VCM) should be based on control of VCM in food contact packaging material and in food and proposed guideline levels of 1 ppm for VCM in PVC food packaging materials and 0.01 ppm for VCM in food. The Committee noted that this level was at the limit of analytical detection for many foods and that more information would be needed on the lowest reliable detection levels for different methods of analysis.

165. In regard to acrylonitrile (ACN) the Committee noted that control of this substance in foods was the preferred option of most governments and proposed a guideline level of 0.02 ppm ACN monomer in foods. It was noted that the guideline level for ACN in food was near the detection limit for most available methods.

166. The Committee agreed to seek comments at Step 3 from member governments on the guideline levels for VCM and ACN. At the same time information on available reliable methods of analysis which would allow detection at these levels would be requested.

167. The delegation of Egypt, while concurring with the conclusions of the Committee, brought its attention to the environmental problems encountered when PVC material was burnt in incinerators.

## **Methods of Analysis of Food Additives**

168. The Committee had before it document CX/FAC 88/11, containing a summary of governments' responses to CL 1987/29-FA to which the delegation of Argentina provided additional information. In the light of responses received from governments, the Committee updated document CX/FA 87/11-Add. 2, which was the major list of methods of analysis compiled at its previous sessions.

169. The Committee agreed that it would be best to submit the updated document on methods of analysis for food additives to CCMAS for endorsement.

170. The Committee noted that before CCMAS would endorse a method of analysis it requires information relating to specificity, accuracy, precision (repeatability, reproducibility) and results of collaborative studies. The Committee was informed that AQAC and the Nordic Committee of Food Analysis could make available to CCMAS information on methods elaborated by these organizations.

171. The Committee discussed whether to submit the methods of analysis for food additives contained in CX/FA 87/11-Add 2 Appendix I to the CCMAS for endorsement.

172. The delegation of Canada offered to collect the necessary data required for evaluation by the CCMAS. As the data would not be available prior to the forthcoming session of the CCMAS this year, the delegation of Canada proposed that the exercise could be completed by CCMAS at its 1990 session.

## **Prioritizing of Food Additives for Method Development**

173. The Committee had before it document CX/FAC 88/19A prepared by Canada which presented a list of priorities for methods development based on the criteria established at the 19th session of the Committee. Using the information contained in the FAO/WHO Food Additives Data System together with additional JECFA Reports, weightings were given to different aspects of the criteria outlined in the working paper. On that basis, the following groups of food additives could be placed in priority order: Antioxidant, Food colours, Preservatives, Firming agents, Emulsifiers, Thickener, Extraction solvent, Sequestrant, Neutralizing Agent, Stabilizer, Buffering Agent, Alkali, Binders, Texturizers, Yeast Food, Raising Agent, Anticaking Agent, Carriers, Flavouring Agents, Flour Treatment Agent, Humectant, Flavour Enhancers, Sweetener.

174. The Committee commended Canada for its approach to prioritizing food additives for methods development. The Committee, however, expressed the view that prioritizing food additives by groups suffered from a weakness in that it did not take into consideration the desirability to consider individual food additives for specific reasons such as safety and trade implications. The Committee agreed that the exercise should be discontinued.

## **Food additives and contaminants proposed by CCFAC for Priority Evaluation by JECFA**

175. The Committee had before it document CX/FAC 88/20, which summarized responses received from the International Olive Oil Council (IOOC) and the USA regarding food additives to be included on the Codex Priority List.

176. The delegation of Sweden requested that sodium thiocyanate be reviewed in the light of the decision of the 29th Session of JECFA that a review of the thiocyanate/hydrogen peroxide/lactose peroxidase system for raw milk preservation

should be undertaken once guidelines for its use had been prepared. It was reported that IDF had prepared such guidelines which could be reviewed by CCFH.

177. The Codex Priority List as adopted by the Committee is given in Appendix X. This list has taken into account the priorities of all the working groups.

### **Establishment of a working Group on Methods of Analysis**

178. The Committee noted that the WG on Priorities had completed its work on packaging materials. Future work on Packaging Materials and Priorities would be handled by the plenary. The Committee noted that problems on methods of analysis for food additives and contaminants in food that arose from time to time should be handled by a group with expert knowledge on the subject. The Committee agreed to establish an ad hoc Working Group on Methods of analysis under the chairmanship of Canada. The membership of the Working Group would be as follows: Austria, Denmark, Fed. Rep. of Germany, Finland, France, Italy, The Netherlands, Portugal, Spain, Switzerland, Thailand, USA, AOAC, IFG, ISO and the Nordic Committee on Food Analyses.

### **Future work**

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

180. The delegation of the Netherlands informed the Committee that more recent developments in the area of nutrition and biotechnology had resulted in the appearance of new classes of substances used as minor and major constituents of the diet, e.g. products with decreased fat and sugar content. These new foods, as well as other new products of biotechnological origin, might deserve consideration by the CCFAC. This might be especially important when newly developed products are substituted for traditional foods. It was suggested that the Committee should study this question.

181. Following the discussions the delegation of the Netherlands agreed to prepare a paper on the subject that would cover the following points for consideration at the next session of the Committee:

- i) Objective of the paper
- ii) Inventory of substances which are of importance
- iii) Background philosophy about identity questions
- iv) Aspects of interest to consumers
- v) An approach to the safety assessment of these newly developed products.

182. Some delegations were of the opinion that the paper should consider the broader aspects of food and food additives that might lead to a change in the present definition of food additives and approach to their regulation.

183. The Committee agreed with the preparation of a paper by the delegation of the Netherlands and indicated that it would like to have their paper well in advance of the next session. The Committee also recalled earlier discussions (see para 82) on difficulties experienced in the interpretation of the definition of food additive. The Secretariat agreed to prepare a paper listing past decisions of the Committee on the subject and indicating trends.

### **OTHER BUSINESS**

184. Some delegations brought the attention of the Committee to the difficulties faced by them in participating at Working Group meetings. Some of these WGs were very large and it was difficult for some countries to participate without interpretation into

languages other than English. It was suggested that some changes would facilitate the Working Group meetings, for example, it should be made clear who is speaking on behalf of each member country, and the speaker's affiliation (member country or international organization) should be identified by the Chairman of the WG prior to speaking.

185. The Chairman of the Committee, Mr. A. Feberwee, informed the Committee that interpretation facilities at Working Group meetings would be very difficult organizationally. He, however, assured the Committee that he would review the situation and try to make improvements.

#### **DATE AND PLACE OF NEXT SESSION**

186. The Committee noted that its next Session would be held in The Hague in the Netherlands Congresgebouw from March 13 - 18, 1989. The Working Group meetings would be held from March 9 - 11, 1989.

## **SUMMARY STATUS OF WORK**

Subject Matter	Step	Action by	Reference
Consideration of JECFA Reports	-	21st CCFAC	Continuing Activity
Intake of Food Additives and Contaminants	-	a) Governments b) 21st CCFAC	ALINORM 89/12 (paras31-49)
Guidelines for Simple Evaluation of Food Additive Intake	-	a) Governments b) 21st CCFAC	ALINORM 89/12, Appendix II (paras50-53)
Review of Food Additive Provisions in Codex Standards	-	a) FAO b) 21st CCFAC	ALINORM 89/22 (paras 56-64)
Endorsement of Provisions for Food Additives and Contaminants in Codex Commodity Standards	-	21st CCFAC	Continuing Activity
Action needed by CCFAC resulting from change in ADI Status of   Food Additives	-	21st CCFAC	Continuing Activity
Consideration of Class Names and International Numbering System	-	a) Governments b) 21st CCFAC	ALINORM 89/12 (paras 80-105)
Revisions to Codex List B	-	a) Governments b) 21st CCFAC	Continuing Activity
Consideration of Flavours	-	a) 33rd JECFA b) 21st CCFAC	ALINORM 89/12 (paras 108-114)
Consideration of Specifications Of Identity and Purity of Food Additives	-	a) Governments b) 21st CCFAC	Continuing Activity
Sampling Plans for the determination of Contaminants in Food	-	for Hg,) a) CCMAS Cd, Pb b) 18th CAC  for a) 6th CCCPL aflatoxins b) 21st CCFAC	ALINORM 89/12 (para 125)  ALINORM 89/12 (para 130)
Guideline levels for Aflatoxin in Cereals, Pulses and Legumes in animal Feed	3	a) Governments b) 21st CCFAC	ALINORM 89/12 Appendix VIII (para 139) j
Methods of Analysis for the determination of Aflatoxin in Milk & Milk Products	-	a) Steering Committee Milk & Milk Prod b) 16th CCMAS c) 21st CCFAC	ALINORM 89/12 (para 147)
Methods of Analysis for the determination of Aflatoxin in Food and Feed	-	a) 16th CCMAS b) 21st CCFAC	ALINORM 89/12 (Para 149)

Report of the Joint FAO/WHO Food Contaminants on Monitoring Programme	-	21st CCFAC	Continuing Activity
Guideline levels for Cd and Pb in Food	-	a) Governments b) 21st CCFAC	ALINORM 89/12 (Para 158)
Priorities for consideration of Contaminants	-	a) Governments b) 21st CCFAC	ALINORM 89/12 (Para 159)
Guideline levels for VCM and ACN in Foods and Packaging Materials	-	a) Governments b) 21st CCFAC	ALINORM 89/12 (Para 166)
Methods of Analysis for Food Additives	-	a) CCMAS b) 24th CCFAC	ALINORM 89/12 (PARA 172)
Food Additives for Priority Evaluation by JECFA	-	a) Governments b) 21st CCFAC	Continuing Activity
Consideration of New Foods of origin	-	a) Netherlands b) 21st CCFAC	ALINORM 89/12 (Para 183)

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**GUIDELINES FOR FOOD ADDITIVE INTAKE**

**Preface**

Different approaches exist as regard the estimation of food additive intake. Some of them being very expensive and time consuming. A number of countries have therefore difficulties in initiating such studies and have asked, the Committee to prepare guidelines for simple evaluation of food additive intake (ALINORM 85/12, para 46).

The Guidelines describe a stepwise approach to determine whether the food additive intake exceeds the acceptable daily intake (ADI allocated to the food additive, using increasingly more accurate estimates of intake by use of simple techniques which are not expensive.

These guidelines are meant to provide guidance to such of those member governments which would like to carry out food additive intake studies amongst their populations

**1. INTRODUCTION**

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

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 (CC/FAC). 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 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, CC/FAC 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 No. 70, Principles for the Safety Assessment of Food Additives and Contaminants in Food, Geneva, 1987). As regards food additives, the ADI is expressed in milligrammes of the additive per kilogramme 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).

To take into consideration the fact that the ADI is established over a lifetime, a body weight of 60 kg is generally used. However, in some countries, and especially in the developing ones, a 50 kg body weight could better represent the average body weight of the population over a lifetime period.

### 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.

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 population 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;
- (d) the additive does not undergo a decrease in level as a result of cooking, etc.;
- (e) all foods permitted to contain the additive are ingested.

### 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 the actual use of the additive by industry, according to Good Manufacturing Practice (GMP), or an approximation as close as possible to the actual use level.

## 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%, 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 ( $10 \times 10$ ) which assumes that the human is 10 times more sensitive than the 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. It is, for instance, pure hypothesis to consider that the human being is 10 times more sensitive to the additive than the animal used for the experimentation.

It is therefore not necessary to try to obtain a maximum of accuracy in the elaboration of the intake of additives. When precise data on consumption of foodstuff exist, they should be used. When such precise data do not exist, approximations can be adequate to guarantee 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).

More details regarding this problem can be found in "Principles for the Safety Assessment of Food Additives and Contaminants in Food", Environmental Health Criteria No. 70, WHO, Geneva 1987, pp. 77-79.

#### 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 Dietary Intakes of Chemical Contaminants", WHO Offset Publication No. 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 additives 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 on 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 No. 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, in most cases, 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 dietary intake.

## 5. SIMPLE APPROACH TO THE EVALUATION OF FOOD ADDITIVE INTAKE

### 5.1 Identification of Additives for intake Evaluations

The following priority list can be used to decide for which additives intake evaluations 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 bw/day).

A low priority can be given to additives having received a non-specified ADI when they are used as additives and according to the GMP principle.

## 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 prolonged 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 eaters.

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:

- is the designation of the foodstuffs in which the additive is authorized not too broad, and is the additive used in all the subclasses of this category, e.g.:
  - sugar confectionery
  - soft drinks
  - soups

#### 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 EDI 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 home.

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.

ALINORM 89/12  
APPENDIX III-PART 1

**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 20th session.

Abbreviations used

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

Contents

<u>Committee/Commodity</u>	<u>Session</u>	<u>Document</u>
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I. Milk and Milk Products	21st	CX 5/70
II. Foods for special dietary use	15th	ALINORM 87/26

I. COMMITTEE ON MILK AND MILK PRODUCTS

Standard "Cottage Cheese and Creamed Cottage Cheese"

<u>Food Additives</u>	<u>Maximum Level in the finished product</u>	<u>Paragraph</u>	<u>Status of Endorsement</u>
Karaya gum	5 g/kg singly or in combination	70	TE

Standard A-8 "Processed Cheese Preparation"

Xanthan gum	8 g/kg singly or in combination	70	E
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II. CODEX COMMITTEE ON FOODS FOR SPECIAL DIETARY USE

Draft Standard for Follow-up Formula (ALINORM 87/26, Appendix III)

<u>Food Additives</u>	<u>Maximum Level in 100 ml of Product</u>	<u>Paragraph</u>	<u>Status of Endorsement</u>
L (+) Lactic Acid			E
L (+) Lactic Acid producing cultures	Limited by GMP	71	E

**ALINORM 89/12**  
**APPENDIX III-PART 2**

**CHANGE IN STATUS OF ENDORESMENT OF FOOD ADDITITIVE RESULTING  
 FROM CHANG IN  
 ADI STATUS**

Codex Standards for Fats and Oils 1)

- 1) The revised endorsements are applicable to the following Codex standards on fats and oils.

	Old Provision	Maximum Level in the Final Product	
		Amended Provision	Status of Endorsement
Propyl Gallate	) 100 mg/kg	100 mg/kg	E
Octyl Gallate	) individually or in combination	---	NE
Dodecyl Gallate	) combination	---	NE
Butylated Hydroxytoluene	) 200 mg/kg	75 mg/kg	
Butlyated Hydroxyanisole	) individually ) or in combination	175 mg/kg	TE
Tertiary Butyl Hydro-Quinone	) ---	120 mg/kg	TE
Combination of BHA, BHT, TBHQ and gallates	) 200 mg/kg singly ) or in combination ) with BHA, BHT ) and gallates not to exceed 100 mg/kg	200 mg/kg with individual limits not to be exceeded.	TE
Edible Soya Bean Oil		CODEX STAN 20-1981	
Edible Arachis Oil		CODEX STAN 21-1981	
Edible Cottonseed Oil		CODEX STAN 22-1981	
Edible Sunflowerseed Oil		CODEX STAN 23-1981	
Edible Rapeseed Oil		CODEX STAN 24-1981	
Edible Maize Oil		CODEX STAN 25-1981	
Edible Sesamseed Oil		CODEX STAN 26-1981	
Edible Safflowerseed oil		CODEX STAN 27-1981	
Edible Mustardseed Oil		CODEX STAN 34-1981	
Edible Low Erucic Acid Rapeseed Oil		CODEX STAN 123-1981	
Edible Coconut Oil		CODEX STAN 124-1981	
Edible Palm Oil		CODEX STAN 125-1981	
Edible Palm Kernel Oil		CODEX STAN 126-1981	
Edible Grapeseed Oil		CODEX STAN 127-1981	
Edible Babassu Oil		CODEX STAN 128-1981	
Lard		CODEX STAN 28-1981	
Rendered Fork Fat		CODEX STAN 29-1981	
Premier Jus		CODEX STAN 30-1981	
Edible Tallow		CODEX STAN 31-1981	
Margarine		CODEX STAN 32-1981	
Minarine		CODEX STAN 135-1981	
Codex General Standard for Edible Fats and Oils not covered by individual Standards		CODEX STAN 19-1981	

Canthaxanthin

Commodity	Maximum Level of Use	Status of Endorsement
1. Edible Fats and Oils <sup>1)</sup>	Limited by GMP	
2. Canned Shrimp or Prawns	30 mg/kg, final product, singly or in combination with other colours	NE
3. Quick Frozen Shrimps or Prawns	30 mg/kg singly, 6r in combination with other colours, in heat-treated products only	NE
4. Jams (Fruit preserves) and jellies	200 mg/kg/ singly or in combination with other colours	NE
5. Bouillons and Consommes	30 mg/kg on a ready-to-eat basis	NE
6. Edible Ices and Ice Nixes	100 mg/kg in final product, (total amount of colours 300 mg/kg)	NE

<sup>1)</sup> Encompasses all Codex Standards for fats and oils

Fast Green FCF

Commodity	Maximum Level of Use	Status of Endorsement
1. Canned Apple Sauce	200 mg/kg/ singly or in combination with other colours	E
2. Canned Pears	200 mg/kg/ singly or in combination with other colours	E
3. Jams (Fruit Preserves) and Jellies	200 mg/kg/ singly or in combination with other colours <sup>1)</sup>	E
4. Citrus Marmalade	100 mg/kg, singly or in combination with tartrazine, in Lime Marmalade only	E
5. Canned Mature Processed Peas	200 mg/kg, singly or in combination with other colours	E
6. Pickled Cucumbers	300 mg/kg, singly or in combination with other colours	E
7. Edible Ices and Ice Mixes	100 mg/kg in the final product (Total amount of colours 300 mg/kg)	E

Maximum levels of use for FCF in the Commodities need not be reviewed by the Commodity Committees since the earlier ADI was not lowered but increased.

**ALINORM  
89/12 APPENDIX IV-PART I**

List of Enzymes which are Food Additives

<u>NAME OF FOOD ADDITIVE</u>	<u>SPECIFICATION</u>	<u>TECHNOLOGICAL FUNCTION</u>
AMYLASE	JECFA 1)	Flour treatment agent
PROTEASE	JECFA 1)	Flour treatment agent
PAPAIN	JECFA 1)	Stabilizer 2)
GLUCOSE OXIDASE	JECAF 1)	Antioxidant 3)
INVERTASE	JECFA 1)	Stabilizer 4)
LIPASE	JECFA 1)	Flavour enhancer 5)
PROTEASE	JECFA 1)	Flavour enhancer 5)

- 1) General food enzyme specifications made by JECFA FAO Food and Nutrition Paper 31/2 (1984) p. 129
- 2) Chillproofing of beer
- 3) In soft drinks and egg powder
- 4) In confectionery
- 5) In maturing of cheese

**ALINORM 89/12  
APPENDIX IV-PART 2**

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

<u>FUNCTIONAL CLASSES</u> (Functional classes for labelling purposes)	<u>SUB-CLASSES</u> (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
3. ANTIFOAMING AGENT	antifoaming agent
4. ANTIOXIDANT	antioxidant, antioxidant synergist, sequestrant
5. BULKING AGENT	bulking agent
6. SWEETENER	sweetener, artificial sweetener, nutritive sweetener
7. COLOUR	colour, colour adjunct (colour fixative, colour retention agent) [colour fixative, colour retention agent]
8. COLOUR STABILIZER]	emulsifier, plasticizer, dispersing agent, surface active agent, surfactant
9. EMULSIFIER	for processed cheese only
10. EMULSIFYING SALT	flavour enhancer
11. FLAVOUR ENHANCER	bleaching agent, dough conditioner, flour improver
12. FLOUR TREATMENT AGENT	[gelling agent]
13. [GELLING AGENT]	coating, sealing agent, polish, dusting agent, release agent
14. GLAZING AGENT	antimicrobial preservative, antimycotic agent, bacteriophage control agent, chemosterilant/wine maturing agent, disinfection agent, antimycotic, packing gas
15. PRESERVATIVE	propellant, packing gas
16. PROPELLANT	binder, firming agent, density adjusting agent, sequestrant
17. STABILIZER	

18 THICKENER	thickening agent, gelling agent, texturizer, filler, bodying agent
19 RAISING. AGENT	leavening agent, raising agent
20 FOAMING AGENT	whipping agent, aerating agent
21 HUMECTANT	moisture/water retention agent, wetting agent

**ALINORM 89/12  
APPENDIX V**

UPDATING OF CODEX LIST B

Additions to Codex List B1:

Colours:

- Brown FK (U.K.)
- Carbon Black
- Citranaxahthin
- 30th JECFA: ADI withdrawn
- 31st JECFA: No ADI allocated
- 31st JECFA: No ADI allocated

Anti-oxidants:

- Dodecyl Gallate
- Octyl Gallate
- 30th JECFA: ADI withdrawn
- 30th JECFA: ADI withdrawn

Emulsifiers:

- Processed Euchema Seaweed
- 31st JECFA: No ADI allocated

Enzyme Preparations:

- Cellulose from *Pennicillium*  
*Funicolosum*
- 31st JECFA: No ADI allocated
- Pectinase from *Aspergillus*  
*Alliaceus*
- 31st JECFA: No ADI allocated

Miscellaneous:

- Hydrocarbon Waxes
- Petroleum Jelly
- 4-hydroxymethyl-2,6-di-tert-butylphenol
- 30th JECFA: no ADI allocated
- 30th JECFA: no ADI allocate
- 31st JECFA: no ADI allocated

Deletions Codex List B:

- Polyglycerolesters of fatty esters (EFEMA) is on List A
- Protease from *Asp. Niger*
- Beet Red
- 31st JECFA - to List A
- 31st JECFA - to List A

"Editorial" changes to List B:

- Colours - specify Carotene (natural) in:  
Carotenes (natural)
- algae
- vegetable {31st JECFA}
- Xanthophylls in:  
Xanthophylls
- mixed carotenoids
- Tagetes extract

## **PRIORITY RANKING SYSTEM FOR FLAVOURS**

### **A description of the Method**

In essence, the method of ranking is quite simple. It consists of the sequential application of a series of five discrete steps as follows:

#### **A. Step N° 1: Creation of an Inventory of Substances**

First it is necessary to create an inventory of the substances in order to apply the ranking method. (For this purpose we have used the Chemical Abstract Service (CAS) Registry Number as well as other current identification numbers \*).

\* For the purposes of the Codex Committee on Food Additives and Contaminants, the phase I inventory includes Codex List B flavouring substances and a list of flavours submitted by IOFI.

#### **B. Step N° 2: Hybrid Priority Levels.**

Two different but tested methods are used for providing an initial determination of the presumptive concern of each compound on the inventory. Because most flavours lack toxicological feeding studies, the initial assignment of presumptive concern must be based upon other data that are available. Both methods chosen make use of estimates of probable addition levels to food and the compounds' chemical structures. The first method is the so-called FEMA decision tree method. the second method is the so-called FDA redbook method of chemical structure category assignment which is described in the U.S. Food and Drug Administration's guideline entitled "Toxicological Principles for the Safety Assessment of Direct Food Additives and Colour Additives used in Food (The "Redbook"). in both cases flavours are assigned to one of three chemical structure categories corresponding to "low", "intermediate", or "high" presumptive toxicity. In both systems, these structure assignments are then combined with the estimates of human exposure (via purposeful addition to food) to categorize coimpounds into initial "concern levels". In the case of the FEMA decision tree, the method of concern level assignment results in compounds being assigned to one of four concern levels\* In the case of the FDA approach, the method results in assignment to one of three concern levels and is described in the FDA Redbook. In both methods the assignment to concern level is more heavily dependent upon exposure estimates than on the chemical structure categories. Nevertheless, the methods are significantly different in their approaches; both systems were developed independently and each has attributes that complement the other. For this reason, the ad hoc Working Group decided to use a combination of these two approaches.

The two concern level assignment schemes are combined into a single system of "hybrid priority levels". Because there are four FEMA levels and three Redbook levels, it is straightforward to define hybrid priority levels by numerals that are simply the sums of the respective numbers characterizing the separate levels.

The "hybrid priority levels", with Level 7 being the highest, are defined as noted in Table 1 below where RCL denotes the Redbook Concern Level and FCL denotes the FEMA Concern Level, respectively.

**TABLE I**  
Merging Algorithm for Hybrid Priority Levels

<b><u>HYBRID PRIORITY LEVEL</u></b>	<b><u>RCL</u></b>	<b><u>FCL</u></b>
7	3	and 4
6	3	And 3
	2	or 4
5	3	and 2
		or
	2	and 3
		or
	1	and 4
4	3	and 1
		or
	2	and 2
		or
	1	and 3
3	2	and 1
		or
	1	and 2
2	1	and 1

C. Step N° 3: Application of Consumption Ratio.

The third step in setting priorities for flavours is to address the question of the ease of risk reduction and the occurrence of certain flavours naturally in food. The so-called "consumption ratio" provides a convenient means of taking this into account. The concept of the consumption ratio was originally introduced by J. Stofberg. It is defined as the ration of the per capita intake resulting from a flavour's natural occurrence in food to the per capita intake of the flavour from intentional addition to food. Thus, a large CR signifies that the human intake from natural occurrence of the compound in food is much greater than the intake that results from its intentional addition to food.

The effect of CR on the assignment of flavours to priority levels depends upon whether the levels are initially high or low. If the hybrid priority level is low, a high CR means that the greater intake from natural sources will probably not increase the presumptive risk sufficiently to demand immediate scrutiny. However, if the hybrid level of the flavour is initially high, a large value for CR implies an even larger level of risk demanding scrutiny. For these reasons the following use of the CR value in modifying initial hybrid priority level assignment is applied:

1. Any substance placed in hybrid priority level 7 should not have that priority reduced by the CR; the estimate of risk alone should rule. The presumptive risk is in no way reduced by heavy intake from natural sources; if anything, it is increased. But there is no need for a still higher priority than the highest already available. Thus all substances in hybrid priority level 7 remain there.
2. Those few substances in hybrid priority level 6 with a CR higher than 100 should have that intake from natural sources reviewed by increasing the level by 1 to level 7. Consumption ratios of less than 100 should have no effect.

3. At level 5, CR should be "neutral", i.e., without effect.
4. At level 4 and below, the CR should reduce the hybrid level of concern by the logarithm of the CR rounded to the nearest integer.

Thus, the actual CRs and resulting reductions are as follows:

CR		Log CR	Level reduction for 4 and below
>	3200	≥ 4	-4, not < 0
<	3200	3	-3, not < 0
≥	320		
<	320	2	-2
≥	32		
<	32	1	-1
≤	3.2		

Specific examples of applying CR values to adjust hybrid priority levels are described in Section IV below.

#### D. Step N° 4: Adjustment for Toxicological Data

The general guidelines for adjusting the hybrid priority levels based on existing toxicological data are as follows:

1. Seriously adverse data not previously evaluated by JECFA raise the substance to the highest priority level.
2. Adverse data weigh much more heavily than favourable data of equal quality.
3. Suggestively adverse data not clearly overridden by substantially more data of higher quality raise the substance by three priority levels, or to the highest level.
4. Data by non-oral routes or in non-mammalian species are given weight only in the absence of oral data, unless there are data indicating relevance to ingestion.
5. Data from short-term (mutagenicity) tests have no weight unless, in the absence of chronic data, the results from two or more different tests are positive for mutagenicity.
6. A prior JECFA review that resulted in setting either a specific Allowable Daily Intake (ADI) (not temporary ADI), or an "ADI not specified" reduces the priority level to zero.
7. Data from chronic studies of at least moderate quality, showing no adverse effects at feeding levels 1000x probable daily intake, reduce the priority of a substance by three levels, but not below zero.
8. Data from subchronic studies of at least moderate quality, showing no adverse effects at feeding levels 1000x probable daily intake, from substances in priority levels five and below reduce the priority by three levels, but not below zero.
9. Data from LD<sub>50</sub> tests have weight only in absence of data from repeated dose studies, and then only if the LD<sub>50</sub> is less than 100 mg/kg, in which case they raise the priority to the highest priority level.
10. "Mixed" data, generally favorable but of poor quality and thus raising or leaving some questions, have no impact.
11. Data of poor quality have no weight unless seriously adverse (see guideline 1).

**FLAVOURING SUBSTANCES TO BE CONSIDERED  
FOR PRIORITY SETTING FOR SAFETY EVALUATION**

(Provisional List, See Paragraph 112)

ACETALDEHYDE	α-AMYLCINNAMYL ISOVALERATE
ACETALDEHYDE BENZYL METHOXYETHYL ACETAL	AMYL FORMATE
ACETALDEHYDE PHENETHYL PROPYL ACETAL	ISOAMYL FORMATE
ACETANISOLE	ISOAMYL 4-(2-FURAN) BUTYRATE
ACETOPHENONE	ISOAMYL 3-(2-FURAN) PROPIONATE
3-ACETYL-2,5-DIMETHYLTHIOPHENE	AMYL HEXANOATE
3-ACETYL-2,5-DIMETHYLFURAN	2-AMYL-5 OR 6-KETO-1,4-DIOXANE
ALLYL ANTHRANILATE	ISOAMYL PHENYLACETATE
ALLYL BUTYRATE	ISOAMYL PROPIONATE
ALLYL CINNAMATE	ISOAMYL PYRUVATE
ALLYL CROTONATE	ISOAMYL ISOVALERATE
ALLYL CYCLOHEXANEACETATE	AMYLHEPTIN CARBONATE
ALLYL CYCLOHEXANE BUTYRATE	ANETHOLE
ALLYL CYCLOHEXANEHEXANOATE	ANISYL ALCOHOL
ALLYL CYCLOHEXANEPROPIONATE	ANISYL FORMATE
ALLYL CYCLOHEXANEVALERATE	ANISYL PHENYLACETATE
ALLYL DISULFIDE	ANISYL PROPIONATE
ALLYL 2-ETHYLBUTYRATE	BENZALDEHYDE
ALLYL 2-FUROATE	BENZALDEHYDE GLYCERYL ACETAL
ALLYL HEPTANOATE	BENZALDEHYDE PROPYLENE
ALLYL HEXANOATE	LYCOL ACETAL
ALLYL α-IONONE	2-BENZOFURANCARBOXALDEHYDE
ALLYL NONANOATE	BENZOIN
ALLYL OCTANOATE	BENZYL ACETATE
ALLYL PHENOXACETATE	BENZYL ALCOHOL
ALLYL PHENYLACETATE	BENZYL BENZOATE
ALLYL PROPIONATE	BENZYL BUTYL ETHER
ALLYL SORBATE	BENZYL BUTYRATE
ALLYL ISOTHIOCYANATE	BENZYL ISOBUTYRATE
ALLYL THIOPROPIONATE	BENZYL CINNAMATE
ALLYL TIGLATE	BENZYL 2,3-DIMETHYLCROTONATE
ALLYL 10-UNDECBNATE	BENZYL ETHYL CARBINOL
ALLYL ISOVALERATE	BENZYL ISOEUGENOL
ISOAMYL ACETATE	BENZYL FORMATE
ISOAMYL ACETOACETATE	3-BENZYL-4-HEPTANONE
AMYL BUTYRATE	BENZYL PHENYLACETATE
ISOAMYL BUTYRATE	BENZYL PROPIONATE
α-AMYLCINNAMALDEHYDE	BENZYL SALICYLATE
α-AMYLCINNAMALDEHYDE IMETHYL ACETAL	BENZYL ISOVALERATE
ISOAMYL CINNAMATE	BENZYLIDENMETHIONAL
α-AMYLCINNAMYL ACETATE	BIPHENYL
α-AMYLCINNAMYL ALCOHOL	BIS (2-METHYL-3-FURYL) DISULFIDE
α-AMYLCINNAMYL FORMATE	BIS (2-METHYL-3-FURYL) TETRASULFIDE
	BIS (2,5-DIMETHYL-3-FURYL) DISULFIDE

ISOBORNYL ACETATE  
ISOBORNYL BUTYRATE  
ISOBORNYL FORMATE  
ISOBORNYL PHENYLACETATE  
ISOBORNYL PROPIONATE  
ISOBORNYL ISOVALERATE  
2,3-BUTANEDITHIOL  
1,2-BUTANEDITHIOL  
1,3-BUTANEDITHIOL  
BUTAN-3-ONE-2-YL BUTANOATE  
DI-(BUTAN-3-ONE-I-YL) SULFIDE  
BUTYL ACETATE  
ISOBUTYL ACETATE  
BUTYL ACETOACETATE  
ISOBUTYL ACETOACETATE  
BUTYL ANTHRANILATE  
ISOBUTYL ANTHRANILATE  
2-BUTYL-2-BUTENAL  
ISOBUTYL 2-BUTENOATE  
BUTYL BUTYRATE  
BUTYL BUTYRYLGLYCOLLATE  
BUTYL BUTYRYLLACTATE  
2-SEC-BUTYLCYCLOHEXANONE  
2-(2-BUTYL)-4,5-DIMETHYL-3-THIAZOLINE  
BUTYL ETHYL MALONATE  
ISOBUTYL 2-FURANPROPIONATE  
BUTYL LACTATE  
BUTYL LEVULINATE  
ISOBUTYL N-METHYLANTHRANILATE  
2-BUTYL-5 OR 6-KETO-I, 4-DIOXANE  
BUTYL PHENYLACETATE  
ISOBUTYL PHENYLACETATE  
ISOBUTYL SALICYLATE  
BUTYL SALICYLATE  
BUTYL STEARATE  
2-ISOBUTYLTHIAZOLE  
BUTYL 10-UNDECENOATE  
BUTYL ISOBUTYRATE  
 $\alpha$ -BUTYLCINNAMALDEHYDE  
 $\alpha$ -ISOBUTYLPHENETHYL ALCOHOL  
D-CAMPHOR  
CARVACRYL ETHYL ETHER  
CARVONE  
CARVYL PROPIONATE  
CARYOPHYLLENE ALCOHOL  
ACETATE  
CEDRYL ACETATE  
1,4-CINEOLE  
CINNAMALDEHYDE  
CINNAMALDEHYDE ETHYLENE  
GYLCOL ACETAL  
CINNAMIC ACID  
CINNAMYL ACETATE  
CINNAMYL ALCOHOL  
CINNAMYL ANTHRANILATE —  
PROHIBITED  
CINNAMYL BUTYRATE  
CINNAMYL ISOBUTYRATE  
CINNAMYL CINNAMATE  
CINNAMYL FORMATE  
CINNAMYL PHENYLACETATE  
CINNAMYL PROPIONATE  
CINNAMYL ISOVALERATE  
CITRAL  
CITRAL DIETHYL ACETAL  
CITRAL DIMETHYL ACETAL  
CITRAL PROPYLENE GLYCOL  
ACETAL  
CITRONELLAL  
DL-CITRONELLOL  
CITRONELLYL ACETATE  
CITRONELLYL ACETATE  
CITRONELLYL FORMATE  
CITRONELLYL PHENYLACETATE  
CYCLGHEXANEACETIC ACID  
CYCLOHEXANECARBOXYLIC ACID  
CYCLOHEXANEETHYL ACETATE  
CYCLOHEXYL ACETATE  
CYCLOHEXYL ANTHRANILATE  
CYCLOHEXYL BUTYRATE  
CYCLOHEXYL CINNAMATE  
CYCLOHEXYL FORMATE  
CYCLOHEXYL HEXANOATE  
CYCLOHEXYL ISOVALERATE  
CYCLOHEXYL MERCAPTAN  
CYCLOHEXYLMETHYL PYRAZINE  
CYCLOHEXYL PROPIONATE  
CYCLOPENTANETHIOL  
 $\phi$ -DAMASCONE  
 $\lambda$ -DECALACTONE  
 $\phi$ -DECALACTONE  
 $\epsilon$ -DECALACTONE  
DECANAL DIMETHYL ACETAL  
DEHYDRODIHYDROIGNOL  
DEHYDRODIHYDROIONONE  
DIACETYL  
DIALYL POLYSULFIDES  
DIBENZYL DISULFIDE  
DIBENZYL ETHER  
4,4-DIBUTYL- $\lambda$ -BUTYROLACTONE

DIBUTYL SEBACATE  
DICYCLOHEXYL  
DISULFIDE  
I,2-(DI (I-ETHOXY) ETHOXY)  
PROPANE  
DIETHYL MALONATE  
DIETHYL SEBACATE  
DIHYDROCOUMARIN  
5,7-DIHYDRO-2-METHYLTHIENO (3,4-D)  
PYRIMIDINE  
2,4-DIMETHYL-5-ACETYLTHIAZOLE  
2,4-DIMETHYLBENZALDEHYDE  
4,5-DIMETHYL-2-ISOBUTYL-3-THIAZOLINE  
3,5-DIMETHYL-1, 2-CYCLOPENTADIONE  
2,5-DIMETHYL-2,5-DIHYDROXY-1,-DITHIANE  
4,5-DIMETHYL-2-ETHYL-THIAZOLINE  
2,5-DIMETHYL-3-FURANTHIOL  
2,6-DIMETHYL-4-HEPTANOL  
2,6-DIMETHYL-5-HEPTENAL  
2,6-DIMETHYL-3-((2-METHYL-3-FURYL) THIO)-4-HEPTANONE  
2,6-DIMETHYLOCTANAL  
2,4-DIMETHYL-2-PENTENOIC ACID  
 $\alpha$ ,  $\alpha$ -DIMETHYLPHENETHYL ACETATE  
 $\alpha$ ,  $\alpha$ -DIMETHYLPHENETHYL BUTYRATE  
 $\alpha$ ,  $\alpha$ -DIMETHYLPHENETHYL FORMATE  
DIMETHYL PHENYLETHYL CARBINYL ACETATE  
DIMETHYL SUCCINATE  
2,5-DIMETHYL-3-THIOFUROYLFURAN  
2,5-DIMETHYL-3-THIOISOVALERYLFURAN  
 $\alpha,\alpha$ -DIMETHYLBENZYL ISOBUTYRATE  
3,7-DIMETHYLOCTA-2,6-DIENYL  
2-ETHYLBUTANOATE  
1,3-DIPHENYL-2-PROPANONE  
SPIRO (2,4-DITHIA-1-METHYL-8-OXABICYCLO[3.3.0] OCTANE-3,3 - SEE GRAS 5  
DODECA-3,6-DIONAL  
 $\lambda$ -DODECALACTONE

$\phi$ DECALACTONE  
 $\epsilon$ -DODECALACTONE  
DODECYL ISOBUTYRATE  
ESTRAGOLE  
P-ETHOXYBENZALDEHYDE  
7-ETHOXY-4-METHYL-COUMARINE  
0-(ETHOXYMETHYL) PHENOL  
2-ETHOXYTHIAZOLE  
ETHYL ACETOACETATE  
ETHYL 2-ACETYL-3-PHENYLPROPIC»IATE  
ETHYL ACONITATE (MIXED ESTERS)  
ETHYL ANTHRANILATE  
ETHYL BENZOATE  
ETHYL BENZOYLACETATE  
 $\alpha$ -ETHYL BENZYL BUTYRATE  
2-ETHYLBUTYL ACETATE  
ETHYL BUTYRATE  
ETHYL ISOBUTYRATE  
2-ETHYLBUTYRIC ACID  
ETHYL BUTYRYLLACTATE  
ETHYL CINNAMATE  
ETHYL CYCLOHEXANECARBOXYLATE  
ETHYL CYCLOHEXANEPROPIONATE  
ETHYL 2,4-DIOXOHEXANOATE  
ETHYL N-ETHYLANTHRANILATE  
ETHYL 2-ETHYL-3-PHENYLPROPANOATE  
ETHYL FORMATE  
ETHYL 2-FUFANPROPIONATE  
ETHYL FURFURACRYLATE  
ETHYL 8-FURFURYL-8-THIOPROPIONATE  
ETHYL HEFTANOATE  
2-ETHYL-2-HEPTENAL  
ETHYL HEXANOATE  
ETHYL 3-HYDROXYBUTYRATE  
3-ETHYL-2-HYDROXY-4-MEWLCYCLOPENT-2-EN-1-ONE  
5-ETHYL-2-HYDROXY-3-METHYLCYCLOPENT-2-EN-1-ONE  
5-ETHYL-3-HYDROXY-4-METHYL-2-(5H)-FURANONE  
ETHYL LAURATE ETHYL EVULINATE ETHYL MALTOL  
ETHYL 2-MERCAPTOPROPIGNATE  
ETHYL METHYL PHENYGLYCIDATE  
ETHYL 2-ETHYLBUTYRATE  
ETHYL 2-METHYL PENTANOATE  
ETHYL 2-METHYL-4-PENTENOATE

ETHYL 2-METHYL-3-PENTENOATE  
ETHYL (4-METHYLTHIO)-BUTYRATE  
ETHYL 3-METHYLTHIOPROPIONATE  
2-ETHYL-(3 OR 5 OR 6)-MOP (85%)  
AND  
2-METHYL-(3 OR 5 OR 6)-MOP (13%)  
ETHYL MYRISTATE  
ETHYL NITRITE  
ETHYL NONANOATE  
ETHYL 2-NONYNOATE  
ETHYL OLEATE  
ETHYL 4-PHENYLBUTYRATE  
ETHYL 3-PHENYLGLYCIDIATE  
ETHYL PROPIONATE  
N-ETHYL -2-ISOPROPYL-5-  
METHYLCYCLOHEXANE  
CARBOXAMIDE  
ETHYL THIOACETATE  
2-ETHYLTHIOPHENOL  
ETHYL (P-TOLYLOXY) ACETATE  
2-ETHYL-1,3,3-TRIMETHYL-2-  
NORBORNANOL  
ETHYL 10-UNDECENOATE  
ETHYL ISOVALERATE  
ETHYL VANILLIN  
ETHYLENE GLYCOL BRASSYLATE,  
CYCLIC DIESTER  
ETHYLENE TRIDECANEDIOATE  
EUCALYPTOL  
EUGENOL  
ISOEUGENOL  
ISOEUGENYL BUTYLETHER  
ISOEUGENYL ETHYL ETHER  
EUGENYL FORMATE  
ISOEUGENYL FORMATE  
EUGENYL METHYL ETHER  
ISOEUGENYL METHYL ETHER  
ISOEUGENYL PHENYLACETATE  
2-FURANMETHANETHIOL FORMATE  
FURFURYL ISOPROPYL SULFIDE  
FURFURYL THIOPROPIONATE  
2-  
FURFURYLIDENE BUTYRALDEHYD  
E  
GERANYL ACETOACETATE  
GERANYL FORMATE  
GERANYL PHENYLACETATE  
GLUCOSE PENTAACETATE  
GUAIYL ACETATE  
 $\alpha$ -HEPTALACTONE  
HEPTANAL DIMETHYL ACETAL

HEPTANAL GLYCERYL ACETAL  
(MIXED 1,2 AND 1,3 ACETALS)  
2,3-HEPTANEDIOTO  
4-HEPTANOL  
TRANS-3-HEPTENYL ACETATE  
TRANS-3-HEPTENYL 2-  
METHYLPROPANOATE  
HEPTYL CINNAMATE  
3-HEPTYLDIHYDRO-5-METHYL-2(3H)-  
FURANONE  
 $\lambda$ -HEXALACTONE  
CIS-3-HEXENAL  
TRANS-2-HEXENOIC ACID  
3-HEXEN-I-OL 2-HEXEN-I-YL  
ACETATE  
CIS-3-HEXEN-I-YL-ACETATE  
 $\alpha$ -HEXYLCINNAMALDEHYDE  
HEXYL FORMATE  
HEXYL 2-FUROATE  
HEXYL-2-METHYL-3(4)-PENTENE  
HEXYL PROPIONATE  
2-HEXYLIDENE CYCLOPENTANONE  
HYDROQUINONE MONOETHYL  
ETHER  
HYDROXYCITRONELLAL  
HYDRQXYCITRONELLAL DIETHYL  
ACETAL  
HYDROXYCITRONELLAL DIMETHYL  
ACETAL  
HYDROXYCITRONELLOL  
2-HYDROXY-2-CYCLOHEXEN-1-ONE  
6-HYDROXY-3,7-  
DIMETHYLOCTANOIC ACID  
LACTONE  
2-HYDROXYMETHYL-6,6  
DIMETHYLBICYCLO  
(3.1.1) HEPT-2-ENYL FORMATE  
3-(HYDROXYMETHYL)-2-OCTANONE  
4-(P-HYDROXYPHENYL)-2-  
BUTANONE  
2-HYDROXY-3,5,5-TRIMETHYL-2-  
CYCLOHEXENONE  
5-HYDROXYUNDECANOIC ACID  
LACTONE  
INDOLE  
 $\alpha$ -IONONE  
 $\beta$ -IONONE  
 $\lambda$ -IONONE  
ISOJASMONE  
2-KETO-4-BUTANETHIOL  
LACTIC ACID

LAURYL ALCOHOL  
LEVULINIC ACID  
LICORICE  
INALOOL  
LINALYL ACETATE  
LINALYL ANTHRANILATE  
LINALYL CINNAMATE  
LINALYL PHENYLACETATE  
LINALYL PROPIONATE  
MALTOL  
MALTYL ISOBUTYRATE  
MENTHOL  
MENTHYL ACETATE  
MENTHYL ISOVALERATE  
2-MERCAPTO THIOPHENE  
2-MERCAPTO-3-BUTANOL  
3-MERCAPTO-2-BUTANONE  
2-MERCAPTOMETHYL PYRAZINE  
2,3 OR 10-MERCAPTOPINANE  
3-MERCAPTO-2-PENTANONE  
2-MERCAPTOPROPIGNIC ACID  
P-METHOXYBENZALDEHYDE  
CHMETHOXYCINNAMALDEHYDE  
P-METHOXY- $\alpha$ -  
    METHYL CINNAMALDEHYDE  
(2 OR 5 OR 6)-  
    METHOXY-3HMErrHYPYRAZINE  
(MIXTURE OF ISOMERS)  
4-(P-METHOXYPHENYL)-2-  
    BUTANONE  
1-(p-METHOXYPHENYL)-1-PENTEN-3-  
    ONE  
2-METHOXY-(3 OR 5 OR 6)-  
    ISOPROPVLPYUAZINE  
METHOXYPYRAZINE  
4-METHYL-5- (( $\beta$ -ACETOXYETHYL)  
    THIAZOLE-3-METHI;  
-5-ETHYLPHENOL  
METHYL ANTHRANILATE  
METHYL BENZOATE  
 $\alpha$ -METHYLBENZYL ACETATE  
 $\alpha$ -METHYLBENZYL ALCOHOL  
 $\alpha$ -METHYLBENZYL BUTYRATE  
 $\alpha$ -METHYLBENZYL ISOBUTYRATE  
METHYL BENZYL DISULFIDE  
 $\alpha$ -METHYLBENZYL FORMATE  
 $\alpha$ -METHYLBENZYL PROPIONATE  
4-METHYLBIPHENYL  
2-METHYLBUTYL ACETATE  
METHYL-ISOBUTYLCARBINYL  
    ACETATE

METHYL P-TERT-  
    BUTYLPHENYLACETATE  
METHYL ISOBUTYRATE  
 $\alpha$ -METHYLCINNAMALDEHYDE  
P-METHYLCINNAMALDEHYDE  
METHYL CINNAMATE  
METHYLCYCLOPENTENOLONE  
METHYL DISULFIDE  
2-METHYL-(3 OR 5 OR 6)-  
    ETHOXYPYRAZINE  
2-METHYL-3-FURANTHIOL  
METHYL FURFURACRYLATE  
2-METHYL-3 OR 5 OR 6-  
    (FURFURLTHIO) PYRAZINE  
(MIXTURE OF ISOMERS)  
METHYL 2-FUROATE  
3-((2-METHYL-3FURYL) THIO)-4-  
    HEPTANONE  
4-((2-METHYL-3-FURYL) THIO)-5-  
    NONANONE  
5-METHYL-2,3-HEXANEDIONE  
5-METHYL-5-HEXEN-2-ONE  
 $\alpha$ -METHYL- $\beta$ -HYDROXYPROPYL  
METHYL-3-WERCAPTOFROPYL  
    SULFIDE  
METHYL- $\alpha$ -IOONONE  
METHYL- $\beta$ -IONONE  
METHYL- $\phi$ -IONONE  
 $\alpha$ -ISOMETHYLIQNGNE  
 $\beta$ -ISOMETHYL IONONE  
METHYL O-METHOXYBENZOATE  
2-METHYL-5-METHOXYTHIAZOLE  
METHYL N-METHYLBUTYRATE  
METHYL 2-METHYL-3-FURYL  
    DISULFIDE  
METHYL 4-(METHYLTHIO) BUTYRATE  
2-METHYL-5-(METHYLTHIO) FURAN  
METHYL 3-  
    METHYLTHIOPROPIONATE  
METHYL MYRISTATE  
METHYL ( $\beta$ -NAPHTYL KETONE  
METHYL 2-NONYNOATE  
2-METHYLOCTANAL  
METHYL 2-OCTVNOATE  
4-METHYLPENTANOIC ACID  
2-METHYL-4-PERNENOIC ACID  
2-METHYL-2-PENTENOIC ACID  
4-METHYL-2-PENTYL-1,3-DIOKOLAN  
( $\beta$ -METHYLPHENETHYL ALCOHOL  
 $\alpha$ -WETHYX.PHENETHYL BUTYRATE  
2-METHYL-4-PHENYL-2-BUTANOL

3-METHYL-4-PHENYL-3-BUTENE--2'-ONE  
2-METHYL-4-PHENYL-2-BUTYL ISOBUTYRATE  
3-METHYL-2-PHENYLBUTYRALDBHYDE  
2-METHYL-4-PHENYLBUTYRALDEHYDE  
METEJYL 4-PHENYLBUTYRATE  
4-METHYL-PHENYL-2-PENTANONE  
3-METHYL-5-PROPYL-2-CYCLOHEXEN-I-ONE  
2-METHYLPROPYL--3-METHYLBUTYRATE  
2-METHYL-3-(P-ISOPROPYLPHENOL) PROPIONALDEHYDE  
3-(2-METHYLPROPYL) PYRIDINE  
2-(2-METHYLPROPYL) PYRIDINE  
2-1-METHYLPROPYL) THIAZOLE  
METHYL SALICYLATE  
4-METHYL-5-THIAZOLEETHANOL  
4-METHYL-5-THIAZOLEETHANO<I>ACETATE  
4-(METHYLTHIO) BUTANAL  
3-(METHYLTHIO) BUTANAL  
4-(METHYLTHIO)-2-BUTANE  
METHYL 2-THIOFUROATE  
3-(METHYLTHIO)-1-HEXANOL  
4-(METHYLTHIO)-4-METHYL-2-PENTANONE  
(METHYLTHIO) METHYL PYRAZINE  
(MIXTURE- OF ISOMERS)  
3-(METHYLTHIO) PROPIONALDEHVDE  
2-METHYL-3-TOLYPROPIIC3NALDEHYDE  
(MIXED 0-, M-, P-)  
2-METHYLUNDECANAL  
METHYL 2-UNDECYNOATE  
METHYL ISOVALERATE  
2-METHYLVALERIC ACID  
6-METHYLCOUMARIN  
4-(3,4-METHYLENEDIOXYPHENYL)-2-BUTANONE  
3-(5-METHYL-2-FURYL)-BUTNAL  
3-METHYLTHIOPROPYL ISOTHIOCYANATE  
MYRISTALDEHYDE  
2-NAPHTHALENTHIOL  
β-NAPHTHYL ANTHRANILATE  
β-NAPHTHYL ISOBUTYL EHTER  
β-NAPHTHYL ETHYL ETHER  
NEROL  
2,6-NONADIENAL DIETHYL ACETAL  
λ-NONALACTONE  
1,3-NONANEDIOL ACETATE (MIXED ESTERS)  
NONANEDIOL-1,4-ACETATE  
1,9-NONANE DITHIOL  
NONANOYL 4—HYDROXY-3-METHGXYBENZYIAMIDE  
2-TRANS-6-TRANS-OCTADIENAL  
λ-OCTALACTONE  
OCTANAL  
OCTANAL DIMETHYL ACETAL  
1 OCTANEDITHIOL  
3-OCTANON-I-OL  
2-OCTENAL  
6-OCTENAL3-OCTEN-2-OL  
OCTYL ACETATE  
OCTYL FORMATE  
OCTYL HEPTANOATE  
OCTYL PHENYLACETATE  
PARALDEHYDE  
2,3-PENTANEDIONE  
2-PENTENOIC ACID  
PENTYL 2-FURYL KETONE  
PHENETHYL BUTYRATE  
PHENETHYL ANTHRANILATE  
PHENETYL 2-FURQATE  
PHENETHYL SENECIOATE  
PHENOXYACETIC ACIT  
2-PHENOXYETHYL ISOBUTYRATE  
PHENYLACETALDEHYDE 2,3-BUTYLENE GLYCOL  
ACETAL  
PHENYLACETALDEHYDE GLYCERYL ACETAL  
PHENYLACETIC ACID  
4-PHENYL-2-BUTANOL  
4-PHENYL-3-BUTEN-2-OL  
4-PHENYL-2-BUTYL ACETATE  
2-PHENYL-3-CARBETHOJCY FURAN  
PHENYL DISULFIDE 2-PHENYL-3-(2-FURYL)-PROP-2-ENAL  
1-PHENYL-3-METHYL-3-PENEANOL  
5-PHENYL PENTANOL  
2-PHENYL-4-PENTANAL  
3-PHENYL-1-PROPANOL  
2-PHENYLPROPIONALDEHYDE

2-PHENYLPROPIONALDEHYDE  
DIMETHYL ACETAL  
3-PHENYULPROPYL ACETATE  
2-PHENYLPROPYL BUTYRATE  
3-PHENYLPROPYL FORMATE  
3-PHENYLPROPYL HEXANOATE  
2-PHENYLPROPYL ISOBUTYRATE  
3-PHENYLPROPYL PRIONATE  
3-PHENYLPROPYL ISCWALERATE  
3-PHENYLPROPYL CINNAMATE  
I-PHENYL-3(5)-PROPYLPYRAZOLE  
2-(3-PHENYULPROPYL)  
TETRAHYDROFURAN  
PHENYLACETALDEHYDE  
DIISONBUTYL ACETAL  
3-PHENYL-4-PENTENAL  
PIPERONAL  
PIPERONYL ACETATE  
PIPERONYL ISOBUTYRATE  
PIPERONYL FORMATE  
1,2-PROPANEDIOL  
PROOPENYLGUAETHOL  
CIS-5-ISOPROPENYL-CIS-2-  
METHYLCYCLOPENTAN-  
CARBOXALDEHYDE  
PROPYL ACETATE  
ISOPROPYL ALCOHOL  
P-PROPYLANISOLE  
PROPYL BUTYRATE  
PROPYL CINNAMATE  
ISOPROPYL CINNAMATE  
PROPYL 2-FURANACRYLATE  
PROPYL 2-METHYL-3-FURYL  
DISULFIDE  
 $\alpha$ -PROPYLPHENETHYL ALCOHOL  
O-PROPYLPHENOL  
P-  
ISOPROPYLPHENYLACETALDEHY-  
DE  
ISOPROPYL PHENYLACETATE  
3-(P-ISOPROPYLPHENYL)  
PROPIONALDEHYDE  
PROPYL PROPIONATE  
PROPYL THIOACETATE  
ISOPROPYL TIGLATE  
PROPYLENE GLYCOL DIBEKFOATE  
3-ROPYLIDENEPTHALIDE  
PSEUDOCYCLOCITRAL  
PYRAZINE ETHANETHIOL  
PYRAZINYL METHYL SULFIDE  
2-PYRIDINEMETHANETHIOL  
QUININE SULFATE  
ISOQUINOLINE  
RESORCINOL DIMETHYL ETHER  
RHODINYL ACETATE  
RHODINYL PHENYLACETATE  
SANTALYL PHENYLACETATE  
SUCROSE OCTAACETATI  
 $\alpha$ -TERPINEOL  
 $\beta$ -TERPINEOL  
TERPINYL ACETATE  
TERPINYL ANTHRANILATE  
TERPINYL ISOBUTYRATE  
TERPINYL CINNAMATE  
TETRAYDRO-PSEUDO-I0N0NE  
TETRAHYDROFURFURYL ACETATE  
TETRAHYDROFURFURYL ALCOHOL  
TETRAHYDROFURFURYL BUTYRATE  
TETRAHYDROFURFURYL  
CINNAMATE  
TETRAHYDROFURFURYL  
PROPIONATE  
TETRAHYDROLINALOOL  
TETRAMETHYL  
ETHYLCYCLOHEXENONE  
(MIXTURE OF  
ISOMERS) 1,5,5,9-TETRAMETHYL-13-  
OXATRICYCLO  
(8.3.0.0.(4,9)) TRIDECANE  
THIAMINE HCL  
2-THIENYL DISULFIDE  
THIogeraniol  
Thioguaiacol  
TOLUALDEHYDE GLYCERYL ACETAL  
TOLUALDEHYDES (MIXED O, M, I>)  
P-TOLYLACETALDEHYDE  
O-TOLYL ACETATE  
P-TOLYL ACETATE  
4-(P-TOLYL)-2-BUTANONE  
P-TOLYL ISOBUTYRATE  
P-TOLYL PHENYLACETATE  
2-(P-TOLYL)-PROPIONALDEHYDE  
TRIDeca-4,7 DIENAL  
2,6,6-TRIMETHYL-1-CYCLOHEXEN-1-  
ACETALDEHYDE  
2,6,6-TRIMETHYL - 1 & 2-  
CYCLOHEXEN-1-CARBQXALDEHYDE  
2,6,6-TRIMETHYLCYCLOHEX-2-ENE-  
1,4\*DIGNE  
3,5,5-TRIMETHYLHEXANAL  
3,5,5-TRIMETHYL-1-HEXANAOL  
TRIMETHYLAMINE

1,2,3-TRIS ((1'-ETHOXY) ETHOXY)-  
PROPANE  
2,3-UNDECADIONE  
 $\lambda$ -UNDECALACTCW  
10-UNDECENAL  
9-UNDECENAL  
10-UNDECEN-1-YL ACETATE  
VALENCENE  
VANILLIDENE ACETONE  
VANILLIN  
VANILLIN ACETATE  
VERATRALDEHYDE  
VETIVERYL ACETATE  
ZINCERON

**ALINOKM 89/12**  
**APPENDIX VII**

**SPECIFIC TECHNICAL COMMENTS AND CLASSIFICATION FOR MONOGRAPHS**

A. Food and Nutrition Paper No. 34 (1986)

Relative to the methods of analysis in the annexes to FNP 34, an inconsistency was noted between the limit for ethylenamine in immobilized enzyme preparations and the limit of the test in Annex II. It is recommended that the method in Annex II be referred to JECFA.

The Committee recommended the following:

Category I (recommended for adoption by the Commission)

Ammonium hydrogen carbonate

Diethyl tartrate

Glucose isomerase from *Streptomyces rubiginosus* <sup>1)</sup>

Potassium sulfate

Potassium sulfate

<sup>1)</sup> Supersedes the earlier Codex Advisory Specification for *Streptomyces rubiginosus* glucose isomerase in FAO Food and Nutrition Paper No. 19, (1981)

Category II (recommended for adoption by the Commission after editorial changes)

Aluminium ammonium sulfate

Carbohydrase (α-amylase) from *Bacillus licheniformis*

Carrageenan

Dipotassium 5'guanylate

Dipotassium 5'inosinate

Eugenyl methyl ether

5'-guanylic acid

Hydrogen peroxide

5'-Inosinic acid

Nitrous oxide - Figure for Method of Assay omitted

Pentapotassium triphosphate

Polydimethylsiloxane

Saffron

Sodium aluminium phosphate, acidic

Tragacanth gum

Category III (not recommended for adoption)

Recommended change

- |                         |   |
|-------------------------|---|
| Ethyl alcohol           | - review the limit for methyl alcohol (Poland, EC)  |
| Gum arabic              | - consider requirement for measurement of optical rotation as a Characterisation Test as in previous specification (FNP 28) (INGAR) |
| Gum ghatti              | - No ADI has been established by JECFA  |
| Hydroxypropyl cellulose | - review requirement for test for propylene chlorohydrins and review the precision of the method of detection (EC, IFG)             |

Hydroxypropylmethyl cellulose - same comments as for Hydroxypropyl cellulose  
Turmeric oleoresin - review Assay and Description

Category IV (Revised at 30th, or 31st Session of JECFA, or on agenda for 33rd Session of JECFA)

Bone phosphate	(c)
Brown PK	(a)
Butylated hydroxyanisole	(a)
Fast Green FCF	(a)
Hydrogenated glucose syrups	(b)
insoluble polyvinylpyrrolidone	(b)
Isomalt	(c)
Karaya gum	(c)
Modified starches	(c)
Saccharin	(c)
salts of fatty acids	(c)
Sorbitol	(c)
Xanthan gum	(a), (c)

- a) revised at the 30th Session of JECFA  
b) revised at the 31st Session of JECFA  
c) to be considered at the 33rd Session of JECFA

Category V (tentative specifications)

Caramel colour  
Carbon dioxide  
Carthamus yellow  
Ethyl hydroxyethyl cellulose  
Polyvinylpyrrolidone  
Quillaia extract  
Sorbitan monolaurate  
Sorbitan mono-oleate  
Sucrose acetate isobutyrate

B. Food and Nutrition Paper No. 37 (1987)

It was noted that normality (N) was often used in FNP 37, whereas the ISO convention is to use molarity (M). Relative to the methods of analysis in the annexes, the Committee recommended that the methods for "Identification of gum constituents" (with editorial changes) and "Nickel in polyols" should be included in the next revision of the General Methods (FAO Food & Nutrition Paper No. 5).

It was recommended that the method "Limit test for solvent residues" should be written with a more precise description of the methodology.

The Committee recommended the following:

Category I (recommended for adoption by the Commission)

Tara gum  
Tocopherol concentrate, mixed

Category II (recommended for adoption by the Commission after editorial changes)

Calcium disodium ethylenediaminetetraacetate

Fast Green FCF - water has been omitted from the list of principal uncoloured components in the definition.

Heptanes

Sodium dihydrogen citrate

Sodium fumarate

DL-Sodium malate

Tertiary butylhydroquinone

Tocopherol, d, l-Alpha

Category III (not recommended for adoption)

Brown FK

- The Committee noted that the specification was intended to assist in the identification of appropriate materials to be used in further toxicological studies, but queried whether the product was adequately defined. No ADI has been established by JECFA.

Butylated hydroxytoluene

- review requirement for the limit phenolic impurities (EC, USA)

Curcumin

- review the limit for sulphated ash
- consider the use of isopropanol and ethyl acetate as additional extraction solvents (NATCOL)

Dodecyl gallate

- review limit for sulphated ash (Canada)
- review discrepancy between drying temperatures used in the method of assay and determination of melting range (Finland) No ADI has been established by JECFA

Glucono-d-dactone

- consider including maximum limit for lead
- review melting range in identification test C (misprint?)

Lithol rubine BK

- since the ADI for this substance has been withdrawn, the Committee agreed that the specification should not be recommended for adoption by the Commission.

- No ADI has been established by JECFA.

Octyl gallate

- same comments as for Lithol rubine BK

Polyvinylpyrrolidone

- review method of assay (nitrogen determination), compare with method used for insoluble polyvinyl-pyrrolidone in FNP 34 p. 127.

Category IV (on agenda for 33rd Session of JECFA)

Butylated hydroxyanisole

d-Carvone

1-Carvone

Erythrosine

Mannitol

Xanthan gum

Category V (tentative specifications)

Blackcurrant extract  
Carob bean gum  
Citric and fatty acid esters of glycerol  
Lecithin  
Lecithin, Partially hydrolyzed - (misprint tentative omitted)  
Mineral oil  
Paraffin wax  
Petroleum jelly  
Processed Eucheuma Seaweed  
Sulfur dioxide  
Talc  
Tocopherol, d-Alpha concentrate  
Turmeric colour

The Committee recommended that specifications in Categories I and II (provided editorial changes are made) be adopted by the Commission as Codex Advisory Specification

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**APPENDIX VIII**

Nuts, oilseeds, cereals and their products	5 µ/g/kg Total aflatoxins B1, B2, G1, G2
	- Straight feedingstuffs 50 µg/Kg (B <sub>1</sub> )
	- Complete feedingstuffs for cattle, sheep and goats (except dairy cattle, calves and lambs) 50 µg/Kg (B <sub>1</sub> )
	- Complete feedingstuffs for pigs and poultry (except young animals) 20 µg/Kg (B <sub>1</sub> )
	- Other complete feedingstuffs 10 µg/Kg (B <sub>1</sub> )
Various animal feedstuffs as established by the EEC	- Supplementary feedingstuffs for cattle, sheep and goats (except dairy animals, calves and lambs) 50 µg/Kg (B <sub>1</sub> )
	- Supplementary feedingstuffs for pigs and poultry (except young animals) 30 µg/Kg (B <sub>1</sub> )
	- Other supplementary feedingstuffs 10 µg/Kg (B <sub>1</sub> )
	- Groundnut, copra, palm kernel, cotton seed, babassu, maize and products derived from the processing thereof 200 µg/Kg (B <sub>1</sub> )

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APPENDIX IX

CONTAMINANTS AND FOODS UNDER CONSIDERATION BY THE JOINT FAO/WHO  
FOOD CONTAMINATION MONITORING PROGRAMME \*)

\*) Pesticides under consideration by the Programme have been excluded from this list.

Lead	Canned: fruit, fruit juice including concentrates, infants food and juices, vegetables, milk, fish and meat (indicate whether cans are lead-soldered or otherwise)
	cereals, flours, legumes and pulses, fresh fruit, meat, fish, potatoes and other vegetables of major dietary importance, molluscs, crustaceans, kidney and spices
Cadmium	Molluscs, crustaceans, cereal grains, cereal flours, potatoes, and other vegetables of major dietary importance and kidney
Tin (total)	Food and beverage (beer, soft drinks, juices) in tin plate cans (indicate whether lacquered or not)
Mercury (total)	Fish and fish products (excluding shellfish)
Total aflatoxins or aflatoxin B1	Groundnuts, tree nuts; legumes and pulses, maize and other grains of major dietary importance whether food or animal feed; spices and herbs
Aflatoxin M1	Milk and milk products, eggs

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APPENDIX X

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

Ferrous Lactate (proposed by IOOC)	
Sucrose Esters of Fatty Acids (proposed by USA - specifications only)- request to add maximum residual solvent levels -to the specifications	
Gum Arabic	
Modified Starches (Specifications only)	
Carob Bean Gum (Specifications only)	WG on Specifications
Citric and Fatty Acid Esters of Glycerol (Specifications only)	
Patulin	
Nitrite	
Nitrate	proposed by The Netherlands
Nitrosamines	