

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS ORGANISATION DES NATIONS UNIES POUR L'ALIMENTATION ET L'AGRICULTURE

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### JOINT FAO/WHO CODEX ALIMENTARIUS COMMISSION

Sixth Session

CODEX COMMITTEE ON FOOD ADDITIVES

Report of the Fifth Session, 18-22 March 1968

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#### **ALINORM 69/12**

#### INTRODUCTION

The Committee met in Arnhem, the Netherlands, from 18-22 March 1968 for the fifth time, under the Chairmanship of Professor M.J.L. Dols, Chairman of the Committee. At the Session government experts and advisers from Australia, Belgium, Canada, Cuba, Denmark, Federal Republic of Germany, Finland, France, Guatemala, Ireland, Italy, Japan, the Netherlands, New Zealand, Philippines, Poland, Sweden, Switzerland, United Kingdom, U.S.A. and Venezuela were present. A complete list of Participants, including officers of FAO and WHO and Observers from seven non-governmental organizations is set out in Appendix I.

#### **AGENDA**

2. The Committee had before it a provisional agenda (CCFA/68/1) and adopted it without re-arrangement of the items.

#### ANTIBIOTICS USED IN ANIMAL FEEDS

- 3. The Committee had before it a paper prepared and introduced by the Delegation of the U.S.A., entitled "Antibiotics used as animal feed adjuncts or for veterinary therapeutics" (CCFA/67/20) containing proposals that there should be "no residue" of antibiotics in human food at the time of consumption, that the Joint FAO/WHO Expert Committee on Food Additives be requested to assemble analytical methods of acceptable degrees of sensitivity for determining the "no residue" level of specific antibiotics and their significant degradation products in edible animal products, and that the Expert Committee be requested to report on the safety of these "no residue" values.
  - The Committee also had before it papers entitled "Memorandum on the addition of antibiotics to animal feedstuffs" (cCPA/67/20 (i)) and "Antibiotics in Animal Feedstuffs" (CCFA/67/20 (2)) prepared by the Benelux and the Netherlands respectively.
- 4. The Committee discussed the problems associated with the meaning of the term "no residue" of antibiotics and their degradation products in food. It was pointed out that residues in trace amounts would be often found in food' for human consumption produced from animals which were fed antibiotics for zoo-technical purposes. The Committee agreed that the value of the "no residue" level depended on the sensitivities of the analytical methods used and that for this reason appropriate methods of analysis would have to be agreed upon.
- 5. The Committee requested delegations attending the Session and other interested participants to supply to the Secretariat of the Joint FAQ/WHO Expert Committee on Food Additives details of methods of analysis used in the determination of antibiotic residues in food by the middle of May 1968. The Committee noted that specific methods of analysis were desirable. The Secretariat of WHO pointed out that the antibiotics which were proposed for referral to the Joint FAQ/WHO Expert Committee on Food Additives by the Delegation of the U.S.A. would be dealt with, together with specifications of purity and other aspects of the use of antibiotics in animal feeds, at the next meeting of the Joint Expert Committee in 1968. These antibiotics are: bacitracin, chlortetracycline, dihydrostrep-tomyoin, erythromyoin, neomycin, novobiocin,

- nystatin, oleandomycin, oxytetra-cycline, penicillin, polymyxin, streptomycin, tetracycline and tylosin.
- 6. The question was raised whether this Committee should deal with maximum levels of use of antibiotics in animal feed or only maximum levels in food for human consumption or both It was pointed out that it would be desirable to deal with both these aspects. The Committee agreed that the recommendations of the Joint FAO/WHO Expert Committee on Food Additives should be awaited and that these could be considered at the next session of this Committee.
- 7. The Committee expressed its appreciation for the work which was put into the preparation of the working papers on the problem of antibiotics used in animal feeds and decided to refer them to the Joint FAO/WHO Expert Committee on Food Additives for consideration.

#### ANIMAL FEED ADJUNCTS

- 8. The Committee had before it a paper entitled "Animal Feed Adjuncts" (CCPA/67/21) prepared by the Delegation of Israël, containing information on the use and legal control in various countries of hormones, chemotherapeutic substances, coccidiostats, nutritional adjuncts and a number of other feed additives. In the absence of the Delegation of Israël, the paper was introduced by the FAO Secretariat. In addition, the. Committee had before it an application for authorization to use BHT as a stabilizer in foodstuffs destined for animals, submitted by the Société Française D'Organo-Synthèse.
- 9. During the discussion of the above papers, the Delegate of New Zealand pointed out that in his country selenium was permitted in animal feed in view of the fact that there was a soil deficiency in this element in some parts of his country. The Delegation of New Zealand further pointed out that there was no real need for the use of hormones in animal production. The Delegation of the United Kingdom pointed out that those feed adjuncts which may leave significant residues in food for human consumption, would be of special interest. The Committee agreed to ask the Delegation of Israël to prepare a further summary of animal feed adjuncts leaving residues and to indicate the levels found. The Delegation of the U.S.A. indicated that in his country residues of animal feed adjuncts were controlled. where necessary, by a "no residue" clause similar to the antibiotics mentioned in paragraphs 3 and 4 above. In this connection the Delegation of the United Kingdom proposed that the methods of analysis recommended by the Joint FAO/WHO Expert Committee on Food Additives be referred by this Committee to the Codex Committee on Methods of Analysis and Sampling. The Secretariat pointed out that this may represent a problem from a procedural point of view and that this matter could be brought to the attention of the Executive Committee.
- 10. The Committee acknowledged the receipt of the <u>paper on BHT</u>. In this connection the <u>general problem was raised</u> whether this Committee should propose that the use of a food additive be allowed in animal feeds if it has already been permitted in food for human consumption. The Committee was of the opinion that in view of the fact that additives used in animal feed may leave residues of the feed adjuncts and their metabolites in food for human consumption, the use of such feed additives would have to be considered. The Committee agreed that the feed adjuncts contained in the paper prepared by the Delegation of Israël, with the exception of the chemotherapeutic agents, should be given a low priority and that those food additives which had already been

cleared from a toxicological point of view used in animal feed, such as BHT, should be given a lower priority.

#### **SOLVENT RESIDUES**.

11. The Committee considered a paper (CCFA/67/22) prepared by the Secretariat, on solvent residues remaining in food from extraction processes. The Secretariat suggested that the Committee might wish to exclude a priori all the aromatic solvents. The Committee decided that such an exclusion would be unnecessarily restrictive. It was pointed out that problems did arise especially with regard to solvent residues in the extraction of cocoa products. The Delegation of Switzerland agreed to draw up a list of solvents, with the help of the Delegation of the United Kingdom, paying special attention to solvents used in extraction processes in respect of cocoa products. Participants were requested to send information to the Delegation of Switzerland before 1 July 1968. The working paper on solvents should be sent to the Secretariat of the Codex Committee on Food Additives, with copies to the Chief, Joint FAO/WHO Food Standards Program, FAO, Rome, by 1 November 1968.

#### **DEFINITIONS**

- 12. The Committee discussed a paper prepared by the Secretariat containing definitions proposed on the basis of government comments (CCFA/67/18(1) and (CCPA/67/18(4)• The question was raised whether the Committee should propose a definition, as recommended by the Codex Alimentarius Commission, to cover all matters dealt with by the Committee. The Secretariat drew the Committee's attention to the Format for Codex Standards which contained, among others, sections entitled "Food Additives", "Contaminants" and "Pesticide Residues". The Committee decided not to propose such a general definition. It was agreed that a single definition should embrace food additives which were intended to be components of food and which had a technological, including organoleptic, function, and substances which were used during the production of food, with the exception of pesticide residues defined elsewhere. As regards contaminants the Committee agreed that these were substances whose presence in food were not intentional and therefore should be defined separately.
- Report of the Joint Meeting of the FAO Working Party on Pesticide Residues and the WHO Expert Committee on Pesticide Residues, CX 4/40.3.
- 13. The Commission had requested at its fifth session that the Codex Committee on Food Additives consider whether or not in its view, and taking into account the work of the Joint FAO/IAEA/WHO Expert Committee on Irradiated Food, the irradiation of food should fall within its term of reference. Concerning this question, it was pointed out to the Committee that the above Joint FAO/IAEA/WHO Expert Committee would meet in 1969 to consider this problem. The Committee agreed that food irradiation should fall within its terms of reference and that the report of the above Joint Expert Committee should be referred to it for consideration.
- 14. As regards the inclusion of irradiation into the definition of <u>food additive</u> the Committee decided that it would be more appropriate to define food irradiation as a process applied to food (see Appendix II).

#### GENERAL PRINCIPLES FOR THE! USE OF FOOD ADDITIVES

- 15. The Committee discussed the papers CCFA/67/18(2) and CCFA/67/18(4) prepared by the Secretariat on the basis of document SP 10/50-GP, March 1966, which was before the Committee at its third session, and which was subsequently sent to governments for comment. The Secretariat pointed out that the text of the General Principles for Food Additives represented in the above papers, took into consideration, as far as possible, the various comments received from governments. The Committee discussed the General Principles in detail; the text, amended in the light of the new definitions for food additive and contaminant and the discussion, appears in Appendix II.
- 16. The Delegation of the Netherlands was of the opinion that in paragraph 1, reference should be made to the justification for the use of food additives if they make the production of the food more economical. Following a discussion on this matter, the Committee decided not to include such a reference in the General Principles.
- 17. With regard to paragraph 1(e), the Committee agreed to a rephrasing which relates the hazard to the health of the consumer to the level of use of a food additive rather than the food additive itself.
- 18. With respect to paragraph 2, the Committee agreed to omit the second part of the sentence relating to toxic substances since, in its opinion, this was adequately covered in other parts of the General Principles.
- 19. In paragraph 5(a) the Committee agreed to omit the reference to the evaluation of carcinogenic risk since this would be automatically included in toxicological evaluation.
- 20. The Committee decided to amend paragraph 6 in view of the fact that lists of food additives, which at present were not part of Codex Commodity Standards, were being elaborated (e.g. flour-treatment agents, food colures, anti-caking agents).
- 21. With reference to paragraph 7(a) the Committee noted that the intention of that paragraph was to ensure that food additives were not consumed in excess of ADI by special groups in the community and amended the paragraph accordingly.
- 22. The Committee also considered Annex III of working paper CCFA/67/18(4) containing matters of a procedural nature. The Secretariat drew the Committee's attention to the fact that paragraph 1 of Annex III dealt with the working relationship between the Codex Committee on Food Additives and the Joint FAO/WHO Expert Committee on Food Additives and that it appeared in the report of the third session of the Codex Alimentarius Commission. It was further pointed out that paragraph 2 contained information relating to unconditional and conditional zones of acceptability which had been published previously in several reports of the Joint FAO/WHO Expert Committee on Food Additives. Paragraph 3 contained a re-edited version of the method of calculation of food additive intake, published in the 6th report of the Joint FAO/WHO Expert Committee on Food Additives. With regard to paragraph 4. it contained a statement of fact which, in the opinion of the Secretariat, might be useful for incorporation into the Codex Alimentarius but in a re-edited and enlarged form. The Committee agreed that

Annex III of paper CCFA/67/18(4) did not form part of the General Principles of Food Additives.

#### LABELLING OF FOOD ADDITIVES

- 23. The Committee had before it a paper entitled "Labelling of Food Additives" (CCFA/67/24) prepared by the Secretariat and a paper (CCFA/67/24-Add.1) containing matters referred by the Codex Committee on Food Labelling.
- 24. The Committee discussed whether there should be a general standard for the labelling of food additives and whether the General Standard for the Labelling of Pre-packaged Foods would also apply to the labelling of food additives as such. The Committee agreed that a general labelling standard would have to be drawn up for food additives. The Delegation of the <u>United Kingdom undertook to draft a general standard for the labelling of food additives</u> for the next session of this Committee, taking into account any information received from the Delegations, the General Standard for the Labelling of Pre-packaged Foods, and the working paper prepared by the Secretariat.
- 25. The Committee gave consideration to matters referred to it by the Codex Committee on Food Labelling. During the session of the Codex Committee on Food Labelling the Delegate of Japan had asked that the Food Additive Committee give consideration to two groups of compounds, "crystallization inhibitors" and "chemical seasonings". The term "chemical seasonings" was meant to include flavour enhancers such as monosodium glutamate, disodium inosinate and disodium guanylate, The Committee on Food Additives accepted the proposal of the Delegate of Japan to prepare a working paper on these two groups of additives for the next session of this Committee indicating which food additives fall within the above groups.
- 26. The Labelling Committee had also asked the Food Additive Committee to express its views as to the possibility of making a <u>scientific distinction between "natural" and "artificial" colours and flavours.</u> Following a brief discussion the Committee concluded that in most oases where the substance was identical, regardless of its source, it would not be possible to make a scientific distinction. It was also noted that at the third session this Committee had agreed that there should be no discrimination between natural flavouring compounds and identical synthetic compounds.

#### METHODS OF ANALYSIS OF FOOD ADDITIVES IN FOOD

27. The Committee examined a document prepared by the Secretariat entitled "Methods of Analysis of Food Additives in Foods" (CCFA/67/26). It was pointed out in the paper that food additives had been proposed by this Committee for foods which were not being standardized by Codex Commodity Committees or for which no Codex 'Committee had been set up. The Secretariat therefore proposed that this Committee should advise the Codex Committee on Methods of Analysis and Sampling which of these food additives received urgent consideration and in which foods. In this respect, the establishment of methods of analysis for flour-treatment agents appeared to be of some urgency. The Delegation of the United States of America offered to prepare a report on methods of analysis for flour-treatment agents for the next session of this Committee. Delegations and Participants representing interested international organizations were requested to supply information on this subject. Such

information should be sent to the Delegation of the U.S.A with copies to the Secretariat of the Codex Committee on Food Additives and the Chief, Joint FAO/WHO Food Standards Program, FAO, Rome, not later than the end of August 1968. The working paper prepared by the Delegation of the U.S.A. should be sent to the Secretariat of the Codex Committee on Food Additives with copies to the Chief, Joint FAO/WHO Food Standards Program, FAO, Rome, by the end of 1968.

#### GUIDE FOR CONSIDERATION OF FOOD ADDITIVES IN CODEX STANDARDS

28. The Committee reviewed a paper entitled "A guide for consideration of food additives in draft food standards" (CCFA/68/2) prepared by the Secretariat. This paper consolidated the situations in which the Codex Committee on Food Additives endorsed or temporarily endorsed a food additive and where the endorsement of the food additive provision would not be possible. The Guide was intended to facilitate the future work of this Committee. The question was raised in the paper whether or not certain natural colours, natural flavourings and vegetable gums could be endorsed by this Committee, subject to the agreement of the Joint FAO/WHO Expert Committee on Food Additives. After some discussion the Committee adopted the Guide, with slight amendments, as shown in Appendix III.

### CALCULATION OF FOOD ADDITIVE INTAKE FOR ENDORSEMENT OF FOOD ADDITIVE PROVISIONS IN CODEX STANDARDS

- 29. The Committee examined a paper prepared by the Secretariat on the calculation of the intake of food additives in Codex. Standards. This paper outlined a computerized pilot trial for the calculation of the intake of five food additives. The Committee noted the results with interest and agreed that FAO and WHO should continue with such a programme and agreed with the following suggestions in the paper:
  - (a) that Delegations wishing to co-operate with the Secretariat in a computerized programme for the calculation of the intake of food additives should designate, not later than the end of April 1968 an officer with whom the Secretariat can communicate on the matter. The officer in question would send to the Secretariat (Food Standards Branch, FAO, Rome, with copies to the Food Additive Unit, WHO, Geneva) existing food consumption data, especially on processed food items, and any estimated intake figure for those food items in which additives are used and for which no food consumption data are available. The deadline for the receipt of such information would be 31 May 1968. The Secretariat would supplement these data as far as possible and where necessary make further extrapolations on the basis of comparison with countries having similar food patterns, as was done in the pilot trial.
  - (b) that as an initial step, the WHO Secretariat would calculate the "international food additive intake" (taking the highest average food intake figure shown for a food item in a nation's food survey, regardless of the country for which this figure applies, and the maximum level of use listed in the Food Protection Committee's report on chemicals used in food processing and/or levels of use

recommended in Codex Standards.) for all food additives having an ADI and a recommended maximum level of use in Codex Commodity Standards. For those food additives showing an intake, calculated as described above, greater than one third of the unconditional ADI, information on the national legislation would be requested from the designated officer, who would receive a list of such additives not later than 31 July. As it has been found that the provisions in the national legislations of some countries can easily be misinterpreted, the Officer would be requested to provide a list of the food items containing the additives mentioned above and information on the national permitted maximum levels of use for these additives. These data and any further data on food intake should be in the hands of the Secretariat by October 1968.

(c) that the intake of these food additives would then be calculated in a way similar to that in the pilot trial and that the results would be available to the Codex Committee on Food Additives at its next session in 1969. The information on antimicrobials, asked for in the circular letter (CL. 1967-42) sent out by the Secretariat of the Commission on the basis of the decision of the Fourth Session of the Committee would also be needed and taken into consideration by the Secretariat.

#### MATTERS REFERRED BY THE CODEX COMMITTEES

30. The Committee had before it a paper prepared by the Secretariat concerning the food additives proposed by Codex Commodity Committees (CCFA/68/3). There was a full discussion on the questions raised and proposals made by the various Codex Commodity Committees. The decisions of the Committee are shown in Appendix IV.

#### MEAT AND MEAT PRODUCTS (AND PROCESSED MEAT)

#### 31. Nitrate

The Committee did not endorse the tentative proposal of 2000 mg/kg nitrate in Canned Hams, Canned Corned Beef and Canned Luncheon Meat and decided to ask the Codex Committee on Meat and Meat Products to indicate whether a level of 500 mg/kg would be sufficient in good manufacturing practice. The question was also raised whether the higher levels were related to the packaging size of these products or not.

#### 32. Nitrite

The Committee endorsed temporarily the proposal of 200 mg/kg total nitrite, expressed as sodium nitrite, in Canned Hams, Canned Corned Beef and Canned luncheon Meat, pending the endorsement of a figure for nitrate.

33. Ascorbic acid, iso-ascorbic acid and their sodium salts

The Committee endorsed the proposed levels of use of these additives in Canned Hams and Canned Luncheon Meat as there were no toxicological objections against their use. However, a number of delegations were of the opinion that the use of iso-ascorbic acid and its salts created problems in clinical analysis and that there were also <u>nutritional aspects</u> involved. They further felt

that a substance with nutritional value was to be preferred to one which did not have nutritional value. As their point of view created a new principle not covered in the General Principles for the Use of Food Additives, the Committee felt that guidance should be sought from the Executive Committee.

#### 34. Monosodium glutamate

The Committee endorsed the use of monosodium glutamate (not limited) in Canned Hams as proposed by the Commodity Committee. The Delegation of Poland reserved its position because, in its opinion, the use of monosodium glutamate could mask unfavourable changes in the product. Other delegations pointed out that this would not pose a general problem since in the General Principles for the Use of Food Additives such uses would be prohibited because of the provision in paragraph 1(g) (see Appendix II).

#### 35. Sodium and potassium phosphates (mono-, di- and poly-)

The Committee temporarily endorsed the proposal of 3000 mg/kg in Canned Hams and Canned Luncheon Meat. Some delegations expressed the opinion that the use of phosphates in meat products could mask the quality of the product. The Committee proposed that the acceptable daily intake should be reexamined by the Joint FAO/WHO Expert Committee on Food Additives. The Joint Secretariat agreed to place this item on the agenda of the meeting of the Joint Expert Committee which will take place in 1969.

#### 36. Sodium citrate

The Committee endorsed the use of sodium citrate (not limited) in Canned Luncheon Meat as proposed by the Commodity Committee. Some delegations were of the opinion that a maximum level of use should be stipulated and considered that 1000 mg/kg might be a suitable figure. Other delegations were of the opinion that, in view of the ADI not being limited, no such restriction on the level of use should be imposed.

#### 37. Colouring agents approved by the Codex Committee on Food Additives

The Committee agreed that the proposal to use all colouring agents approved by the Joint FAO/WHO Expert Committee on Food Additives was not sufficiently specific and did not endorse the proposal in its present form. The Delegations of Australia, Federal Republic of Germany, New Zealand, Poland, Sweden and Switzerland expressed the view that no colouring agents should be used in Canned Luncheon Meat. The Committee requested the Codex Committee on Meat and Meat Products to state clearly which colouring agents, and at which levels, the colours should be inserted in the Standard concerned so that the proposal could be reconsidered by this Committee.

#### FISH AND FISHERY PRODUCTS

#### 38. Sodium polyphosphate

The Committee requested the Codex Committee on Fish and Fishery Products to state the levels of use they deem necessary for this additive in the Standards concerned.

#### 39. Calcium disodium EDTA

The Committee endorsed the proposal of 250 mg/kg in Canned Shrimps and Prawns with reservations of Switzerland, the Federal Republic of Germany and

Japan, who were of the opinion that, in view of the small ADI set for this additive, it should not be used if it can be replaced by some other additive with a larger ADI. The Committee agreed to draw the attention of the Codex Committee on Fish and Fishery Products to the small ADI and to ask it to reconsider the figure of 250 mg/kg in this light. The Delegation of France pointed out that it was not in the position at present to state its opinion in this matter because it wanted to consult with hygienists in its country.

#### 40. Citric acid

The Committee endorsed the use of citric acid (not limited) in Canned Shrimps and Prawns as proposed by the Codex Committee on Fish and Fishery Products. The Committee wished to be informed concerning the levels used in good manufacturing practice because some delegations considered it necessary to set a maximum level of use for this additive.

#### 41. Orthophosphoric acid

The Committee endorsed temporarily the proposal for 850 mg/kg in Canned Shrimps and Prawns, with the same reservation as made in paragraph 35.

#### 42. Tartaric acid

The Committee decided to refer the proposal for tartaric acid back to the Codex Committee on Fish and Fishery Products with the request that a figure should be set for the maximum level of use. This was found necessary in view of the comparatively small ADI set for this additive. The Committee also wished to be informed as to which isomers were used.

#### QUICK (DEEP) FROZEN FOODS

43. <u>Natural flavourings and their derivatives provided mention is made of the name of the product</u>

The Committee decided to endorse temporarily the use of <u>natural flavourings and their identical synthetic equivalents</u> if this rewording of the proposal is acceptable to the Joint ECS/Codex Alimentarius Group of Experts on Standardization of Quick (Deep) Frozen Foods. The Committee agreed that the level of use is self limited by good manufacturing practice.

#### 44. Blanching residues

It was decided to ask this Group of Experts to state in detail the specific residue levels resulting from good manufacturing practice in the various quick frozen fruits and vegetables.

#### ANTI-CAKIKG AGENTS

45. The Committee had before it compilations of the government comments prepared and introduced by the Secretariat (CCFA/68/4 and CCFA/68/4-Add.1) on the list of anti-caking agents given in Appendix XII of the report of the fourth session of this Committee (ALINORM 68/12). Some countries considered the list too extensive, while some other countries requested the addition of more anti-caking agents to the list.

It was pointed out that only one anti-caking agent, namely magnesium carbonate, had already been toxicologically evaluated by the Joint FAO/WHO Expert Committee on Food Additives.

46. After a discussion whether it would be preferable to refer to the Joint FAO/ WHO Expert Committee on Food Additives a short priority list or the whole list of anticaking agents for toxicological evaluation, it was agreed to refer the whole list so that the Expert Committee could consider the whole group in one meeting.

The new extended list, containing the additional anti-caking agents proposed, is given in Appendix V.

#### **CARRIER SOLVENTS**

- 47. The Delegate of the U.S.A. introduced document CCFA/68/5 entitled Carrier Solvents used in Foods. This list of carrier solvents was a result of government comments on the original list prepared by the Delegation of the U.S.A. for the fourth session of this Committee. The question was raised whether all the substances mentioned in the list were carrier solvents and whether they were all technologically needed.
- 48. It was pointed out by the Secretariat that <u>solvents for food colours</u> were urgently needed. The <u>Swiss Delegation undertook to study this problem</u> and the Delegation of the United Kingdom offered to assist the Swiss Delegation in this task. Governments were requested to send information on this matter to the Delegation of Switzerland before September 1968 and also to <u>comment on the list of carrier solvents given in Appendix VI</u>.

#### FOOD COLOURS

- 49. The Committee had before it a compilation of government comments prepared and introduced by the Secretariat (CCFA/68/6 and CCFA/68/6-Add.1) on the lists of food colours of Category A, and of Category B (and C I) given in Appendix XI of the report of the fourth session of this Committee (ALINORM 68/12). From the comments it appeared that the food colours of Category A, which have been toxicologically evaluated by the Expert Committee, were acceptable to all countries with only a very few exceptions, while the food colours of Category B (and C I) were only partly acceptable. Only Canada appeared to have maximum levels for the use of food colours in its legislation. The Federal Republic of Germany had asked for urgent toxicological evaluation of natural colours, whereas the United Kingdom had drawn the attention of the Committee to the absence of violet, brown and black colours in the list.
- 50. The Committee decided to send the list of food colours of Category A (Appendix VII) to the Commission at Step 5, with the recommendation to omit Steps 6, 7 and 8 of the Procedure for the Elaboration of Codex Standards.
- 51. After a discussion of the proposal of the U.K., supported by some other countries, to delete some colours from the lists of Category B (and C I), the Committee, decided not to do so but to hold this list at Step 4 of the Procedure pending re-appraisal by the Joint FAO/WHO Expert Committee on Food Additives, which would consider the possibility of allocating an ADI or a temporary ADI to colours in this list.
- 52. The Secretariat of the Joint Expert Committee requested the Committee to ask governments to supply all available data on Annatto so that it may be evaluated at the next meeting of the Joint FAO/WHO Expert Committee on Food Additives.
- 53. Regarding a question by the Danish Delegation about the <u>status of Codex Lists</u> <u>of Food Colours</u>, it was pointed out that these lists were at present for the use of

Codex Commodity Committees, from which to select food colours. The Committee agreed that the list, which was submitted to the Commission, should be regarded as an open list to which further colours would be added as they were allocated acceptable daily intakes by the Joint FAO/WHO Expert Committee on Food Additives. It was also recommended that the <a href="Executive Committee should discuss the question of lists of food additives at its next session.">Executive Committee should discuss the question of lists of food additives at its next session.</a>

#### ANTIOXIDANTS IN ESSENTIAL OILS

54. The Committee had before it a paper prepared and introduced by the Delegation of Switzerland. From this paper it appeared that in most countries the use of the following antioxidants are permitted in essential oils, the maximum amount used being 1000 ppm.

ascorbic acid isoascorbic acid ascorbic acid esters of the normal fatty acids lecithin and its components citrio acid  $\alpha$  - or- $\delta$ -tocopherols propyl, octyl, dodecyl gallates butylated hydroxyanisole (BHA) butylated hydroxytoluene (BHT)

55. The Delegations of the United States of America and Canada stated that 3000 to 5000 ppm BHA and/or BHT are needed for citrus oils. It was pointed out that these differences could be explained by the different temperatures in various climates. It was decided that the paper prepared by the Delegation of Switzerland be sent to governments for comments, especially requesting information on intake figures of the essential oils treated with antioxidants.

#### OTHER BUSINESS

56. Mercury level in food, especially Fish

Two delegations drew the Committee's attention to the presence of high levels of mercury in foods, especially in fish. It was pointed out that these levels, at least in some areas, may present a hazard to health. The Committee agreed that this matter be brought to the attention of the Codex Committee on Fish and Fishery Products and requested the Joint FAO/WHO Expert Committee on Food Additives to give high priority to the consideration of this problem. The WHO official pointed out that WHO is collecting data on mercury for the use by the Joint FAO/WHO Expert Committee on Food Additives. The Committee was informed that a more comprehensive collection of relevant information in government files would be achieved if the Director General of WHO would make such a request to the Ministries of Health of Member Governments. The Committee agreed that this matter be brought to the attention of the Director General of WHO.

57. Methods of Analysis of Food Additives as such

The point was raised by the Secretariat whether the <u>methods of analysis</u> contained in <u>food additive standards</u> which had been sent to governments for comment at Step 3 of the Procedure for the Elaboration of Codex Standards should be elaborated as international <u>referee methods or</u> as methods

recommended by the Joint FAO/WHO Expert Committee on Food Additives. The Committee agreed that in principle the elaboration of internationally agreed referee methods was preferable. In view of the magnitude of work which this would represent to the Codex Committee on Methods of Analysis and Sampling the Committee agreed that the opinion of the Executive Committee should be sought.

#### 58. <u>Modified starch</u>

The Secretariat informed the Committee that the Codex Committee on Processed Fruits and Vegetables had proposed the use of modified starch in Canned Green Beans, Sweet Corn, Asparagus, Garden Peas and Mushrooms, without specifying which modified starches were meant. For this reason the Codex Committee on Food Additives had not endorsed these provisions at its fourth session and subsequently the Codex Alimentarius Commission had decided to eliminate modified starch from these Standards. The Committee agreed that the Codex Committee on Processed Fruits and Vegetables should refer the matter again to the Codex Committee on Food Additives, which in turn would refer it to the Joint FAO/WHO Expert Committee on Food Additives for evaluation. The information needed on modified starch would include listing of defined products, including individual types of modified starch, as well as the chemicals used for modifying it. In order to expedite the consideration of modified starches, the Committee agreed that the information supplied by the Codex Committee on Processed Fruits and Vegetables should be made available directly to the Secretariat of the Joint FAO/WHO Expert Committee on Food Additives before being referred to this Committee.

#### 59. Monosodium glutamate

The Secretariat pointed out that at its last session the Codex Committee on Processed Fruits and Vegetables had requested the Codex Committee on Food Additives to indicate whether, in its opinion, monosodium glutamate was to be regarded as a food or a food additive. During the discussion it became evident that in some countries this substance is regarded as an ingredient of food, in others as a food additive, while in some countries a distinction is made on the basis of the quantity used in food. The Committee agreed that monosodium glutamate should be treated as a food additive and requested the Joint FAO/WHO Expert Committee on Food Additives to draw up specifications of identity and purity for this substance. The Committee was of the opinion that there appeared to be no need to establish acceptable daily intake for monosodium glutamate.

60. The Delegation of the Netherlands raised the <u>general point</u> that <u>all ingredients of food</u>, whether or not defined as food additives, <u>should be regulated</u> even if only by establishing specifications of identity and purity. In the opinion of the Netherlands Delegation, such a task should fall within the terms of reference of the Codex Committee on Food Additives. In this connection it was stated that the consideration of such ingredients should have a low priority. The Committee agreed to <u>draw the attention of the Commission to this problem</u> in order to clarify as to which Committee should have the responsibility of dealing with ingredients which do not come under the definition of food additives.

#### 61. Methylethylcellulose

The Committee received a paper from the Organization of Manufacturers of Cellulose Products for Foodstuffs in the EEC, containing information on the levels of use of this food additive. The Committee expressed its appreciation for the valuable information contained in this paper and considered that the information contained in this paper would be particularly useful in the estimation of the intake of methylethylcellulose.

#### 62. Declaration of Food Additives by Class Name

At its last session the Codex Committee on Food Labelling had stated that "when the class name was agreed upon for substances which were subject to endorsement by the Codex Committee on Food Additives or other general Codex Committees, only those ingredients listed within the defined class could be declared in this way". After a short discussion, the Committee endorsed this view.

#### 63. Sulphur dioxide in glucose syrup

The Secretary General of the Comité de Liaison des Fabricants de Glucose de la CEE, in a letter to the Secretariat, drew the Committee's attention to an incorrect statement which appeared in paragraph 14 of the report of the fourth session of this Committee (ALINORM 68/12). The Secretary General pointed out that glucose syrup containing 400 mg/kg sulphur dioxide was not needed for soft drinks and that glucose syrup containing this amount of sulphur dioxide was only used for the manufacture of high-boiled sugar confectionery products.

#### TIME AMD PLACE FOR THE NEXT SESSION

64. The Committee agreed that a suitable time for holding the sixth session of the Codex Committee on Food Additives would be in the Autumn of 1969 and preferably after the meeting of the Joint FAO/WHO Expert Committee on Food Additives and preferably immediately before or after the session of the Codex Committee on Pesticide Residues. The Committee envisaged the possibility of a session of longer than one week duration in view of the heavy workload expected for that session. The Chairman stated that the place for the sixth session of the Committee would be announced in the invitation.

#### APPENDIX I

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#### APPENDIX II

#### **DEFINITIONS**

- 1. For the purpose of the Codex Alimentarius, <u>food additive</u> means any sub stance, including microbial material, not normally consumed as a <u>food</u> by itself, whether or not it has nutritive value, the intended use of which results directly or indirectly in it or its by-products becoming a component of, or otherwise affecting the characteristics of a <u>food</u>. The term includes any substance intended for the use in the production, manufacture, processing, preparing, treating, packing, packaging, transporting or holding of a <u>food</u>. The term does not include either <u>contaminants</u> or pesticide residues <sup>a</sup>
- 2. For the purpose of the Codex Alimentarius, <u>contaminant</u> means any substance not consumed as a <u>food</u> by itself, not being a <u>food additive</u>, some traces of which remain in the finished product as a result of production, manufacture, processing, preparing, treating, packing, packaging, transporting or holding such food.
- 3. For the purpose of the Codex Alimentarius, a <u>process</u> applied to <u>food</u> is any agricultural, technological, manufacturing or distribution practice which affects in any way the characteristics of, or may leave residues in the <u>food</u>, e.g. certain irradiation.
- <sup>a</sup> A definition of <u>pesticide residue</u> can be found in the Report of the Joint Meeting of the FAO Working Party on Pesticide Residues and the WHO Expert Committee on Pesticide Residues, 1967 (CX 4/40.3)

# GENERAL PRINCIPLES FOR THE USE OF FOOD ADDITIVES

- 1. The use of <u>food additives</u> is justified only when it serves one or more of the following purposes:
  - (a) to maintain the nutritional quality of a food;
  - (b) to enhance the keeping quality or stability of a food;
  - (c) to make foods attractive to the consumer;
  - (d) to provide aids in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting or holding food.

#### The use of <u>food additives</u> is not justified:

- (e) if the proposed level of use constitutes a hazard to the health of the consumer;
- (f) when if causes a substantial reduction in the nutritive value of a food;
- (g) when it disguises the faulty qualities of a product or the use of processing and handling techniques which are not permitted;
- (h) when it deceives the consumer;
- (i) when the desired effect can be obtained by food manufacturing practices which are economically feasible.
- Contaminants must not exceed levels that are both safe and technologically feasible.
- 3. The levels of use of <u>food additives</u> should not exceed the level reasonably required to achieve the desired technological effect under good manufacturing practice.
- 4. Food additives should be in conformity with an approved standard of purity.
- 5. (a) All <u>food additives</u> whether actually in use or being proposed for future use, should be subjected to adequate toxicological evaluation.
  - (b) Permitted <u>food additives</u> should be subjected to continuing observation for possible deleterious effects and should be re-appraised whenever necessary in the light of changing conditions of use and new scientific information.
- 6. Approval or temporary approval for the inclusion of a <u>food additive</u> in a permitted list should, as far as possible, be limited to specific foods for specific purposes and under specific conditions.
- 7. When a food containing <u>additives</u> is consumed mainly by some special groups in the community, the approval to use the <u>additives</u> should be based on knowledge of the intake by such special groups concerning the food in question.

#### APPENDIX III

### GUIDE FOR CONSIDERATION OP FOOD ADDITIVES IN DRAFT CODEX STANDARDS

The decision whether or not a food additive should be incorporated in a food standard should be based on the assessment of the technological need for it and the safety of its use. When considering the safety aspect, the Codex Committee on Food Additives may come to one of the following three alternative decisions:

- 1. <u>To endorse</u> the inclusion of the additive in the draft standard at a given level of use.
  - (a) This might be done, for example, in cases where an acceptable daily intake (ADI) has been established by the Joint FAO/WHO Expert Committee on Food Additives and where the estimated daily intake (from the proposed levels of use and the relevant food consumption data) is unlikely to exceed the ADI.
  - (b) The Codex Committee on Food Additives may also endorse food additive provisions where the Joint FAO/WHO Expert Committee on Food Additives did not deem it necessary to set an ADI or where an additive is, in fact, a common food (e.g. starch, etc.).
  - (c) In respect of certain natural colours, natural flavours and vegetable gums, it seems that almost no toxicological work has been done or is likely to be done in the near future, and the drawing-up of chemical specifications will always prove comparatively difficult. There seems no reason, however, in view of their long use, to suppose that these substances will produce a hazard to health. It is, therefore, suggested that, subject to the agreement of the Joint FAO/WHO Expert Committee on Food Additives, it might be possible for the Committee to endorse such substances when they appear in a standard by a phrase such as 'The Codex Committee on Food Additives noted that the Expert Committee had raised no objection at present to the usage of this substance or its inclusion in Codex commodity standards.
- 2. <u>Not to endorse</u> the inclusion of the additive in the draft standard. This might be done in several circumstances, for examples
  - (a) when the food additive has not been considered by the Joint FAO/WHO Expert Committee on Food Additives;
  - (b) when the Joint FAO/WHO Expert Committee on Food Additives has recommended that it should not be used;
  - (c) when no ADI has been established (because of virtual absence of relevant toxicological information) except for cases mentioned in para 1;
  - (d) whenever recent toxicological or technological information cast doubt on its safety or on certain specific uses; in these cases the Codex Committee on Food Additives should refer the matter to the Joint FAO/WHO Expert Committee on Food Additives or the relevant Codex Commodity Committee, as the case may be;

- (e) whenever the estimated daily intake exceeds the ADI. In this case it may be necessary to restrict the use of the additive to those foods in which it is indispensable in order to bring the estimated daily intake below the ADI.
- 3. <u>To endorse temporarily</u> the inclusion of the additive in the draft standard. This might be done, for example:
  - (a) whenever the estimated daily intake slightly exceeds the ADI, pending more precise estimate of the actual intake)
  - (b) whenever a food additive has only been allocated a temporary ADI because of lack of information, pending further toxicological evaluation.

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#### APPENDIX IV

#### Meat and Meat Products

	Additive	Maximum level	<u>Food</u>	Decision	Reference
1.	nitrate	2000 mg/kg expressed as sodium nitrate (tentative proposal)	Canned Hams Canned Corned Beef Canned Luncheon Meat	not endorsed	Paragraph 31
2.	nitrite	200 mg/kg, total nitrite, expressed as sodium nitrite	Canned Hams Canned Corned Beef Canned Luncheon Meat	temporarily endorsed	Paragraph 32
3.	ascorbic acid iso- ascorbic acid and their salts	500 mg/kg, expressed as ascorbic acid	Canned Hams Canned Luncheon Meat	endorsed	Paragraph 33
4.	Mono-sodium glutamate	not limited (a)	Canned Hams	endorsed	Paragraph 34
5.	sodium and potassium phosphates (mono-di-and poly-)	3000 mg/kg expressed as P <sub>2</sub> O <sub>5</sub>	Canned Hams Canned Luncheon Meat	temporarily endorsed pending further toxicological evaluation	Paragraph 35
6.	sodium citrate	not limited (a)	Canned Luncheon Meat	endorsed	Paragraph 36
7.	"colouring agents approved by the Codex Committee on Food Additives"	(no limit stated)	Canned Luncheon Meat	not endorsed	Paragraph 37
Fis	h and Fishery Products				
8.	sodium polyphosphate	to be established	Frozen Fillets of Cod and Haddock	not endorsed	Paragraph 38
9.	calcium disodium EDTA	250 mg/kg	Canned Shrimp and Prawns	endorsed	Paragraph 39

10. citric acid	not limited ( <sup>a</sup> )	Canned Shrimp and Prawns	endorsed	Paragraph 40
11. orthophosphorio acid	850 mg/kg	Canned Shrimp and Prawns	temporarily endorsed pending further toxicological evaluation	Paragraph 41
12. tartaric acid	(no limit stated)	Canned Shrimp and Prawns	not endorsed	Paragraph 42
Quick (Deep) Frozen Foods				
<ol> <li>natural flavourings and their identical synthetic equivalents</li> </ol>	(not limited <sup>b</sup> )	Quick (Deep) Frozen Peas	temporarily endorsed pending toxicological evaluation	Paragraph 43

except by good manufacturing practice self limited by good manufacturing practice

#### APPENDIX V

### Anti-caking agents for consideration by the Joint FAO/WHO Expert Committee on Food Additives a b

Tricalcium phosphate

Calcium silicate

Magnesium carbonate c

Magnesium phosphate

Magnesium trisilicate

Sodium calcium aluminium silicate

Dehydrated silicagel

proposed by the Codex Committees on Sugars

and Cocoa Products and Chocolate

Aluminium silicate monohydrate (pyrophyllite)

Aluminium stearate

Calcium carbonate

Calcium Ferro cyanide

Calcium phosphate (ortho), mono-, di-, tri-

Calcium silico aluminate hydrate

Iron ammonium citrate

Magnesium oxide

Magnesium silicates (Talc)

Magnesium silico aluminate

Potassium ferrocyanide decahydrate

Silicic acid (colloidal)

Silicon dioxide

Sodium ferrocyanide

Sodium palmitate and potassium palmitate

Sodium pyrophosphate

Sodium silico-aluminate hydrate

Fatty acids and their salts

Myristic acid and its sodium and potassium salt

Stearic acid and its sodium, potassium, calcium and magnesium salt

Propylene glycol

Polyethylene glycol

Bone phosphate of food grade

Sterile diatomaceous earth

Terpene resins

- The list is intended to include natural clays such as:

  Bentonite, Sepiolite, Kaolin, which are specially prepared as anti-caking agents for use in food
- b See paragraphs 45-46"
- <sup>c</sup> Already toxicologically evaluated

#### APPENDIX VI

#### List of Carrier Solvents used in Foods a

Benzyl alcohol

Benzyl benzoate

Butylene glycol (1,3) (Butan—1,3-diol)

Butyl acetate

Dibutyl sebacate

Diethyl ether

Diethyl malate

Diethyl sebacate

Diethyl tartrate

Diethylene glycol monoethylether

Ethyl acetate

Ethanol

Ethyl lactate

Ethyl myristate

Ethyl oleate

Glycerol

Glyceryl acetates (mono-, di-, tri-)

Glyceryl monöttleate

Glyceryl monostearate

Glyceryl tributyrate

Isopropylidene glycerol

Isopropyl myristate

Monoethylene glycol

Propanol-1 (Propyl alcohol)

Propanol-2 (Isopropyl alcohol)

Polyethylene glycol (Molecular weight between the limits of 400 and 10,000)

Propylene glycol- (1,2) (Propan-I,2-diol)

Propylene glycol- (1,2) monoacetate

Propylene glycol- (1,2) diacetate

Propylene glycol- (1,2) stearate

Tributyl acetylcitrate

Triethyl citrate

a see paragraphs 47-48

#### APPENDIX VII

## <u>List of food colours</u> <sup>a</sup> <u>submitted to the Codex Alimentarius Commission at Step 5</u>

The following colours have been found acceptable for use in food and have been given acceptable daily intakes for man by the Joint FAO/WHO Expert Committee on Food Additives.

Name of food colour	Colour index
Amaranth	16185
Canthaxanthine	
Beta-apo-8-carotenal	
Beta-carotene	75130
Methyl ester of beta-apo-8-carotenoio acid	
Ethyl ester of beta-apo-8-carotenoic acid	
Sunset yellow FCF	15985
Tartrazine	19140

<sup>&</sup>lt;sup>a</sup> See paragraphs 49-53