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REPORT OF THE SECOND MEETING OF THE CODEX COMMITTEE ON FOOD ADDITIVES

The Hague, 10-14 May 1965

REPORT OF THE SECOND MEETING OF THE JOINT FAO/WHO CODEX

COMMITTEE ON FOOD ADDITIVES

The Hague, 10-14 May, 1965.

1. The Committee met at the Hague, Netherlands from 10-14 May 1965 for the second time. At the Meeting Government experts and advisers from the following thirteen countries were present:

   Australia, Belgium, Canada, Denmark, Federal Republic of Germany, Israel, the Netherlands, Poland, Sweden, Switzerland, Turkey, United Kingdom, United States of America. In addition the following organizations were represented: IUPAC, EEC, International organization for Standardization. A complete list of participants is set out in the Appendix. (Omitted)

2. The name of the Committee was changed to the Codex Committee on Food Additives in accordance with the decision of the Second Session of the Codex Alimentarius Commission.

3. The Terms of Reference of the Committee were changed by the Second Session of the Commission and read now as follows: The main responsibility of the Codex Committee is to establish tolerances for individual food additives in specific food items. A further responsibility is the preparation of lists of food additives for the guidance of the Joint FAO/WHO Expert Committee on Food Additives when the Joint Expert Committee was considering future work.

4. The agenda was adopted, but supplemented with a point 6a, reading: Individual countries to be invited to draw up generally by classes basic lists of food additives which are commonly used. The Committee received a considerable documentation, prepared by the Netherland Technical Secretariat containing information on legal tolerances for the various food additives for a number of countries.

5. Prof. Dr. M.J.L. Dols, (Netherlands) was Chairman of the meeting.

   Dr. O.G. Fitzhugh (USA) was elected Vice-chairman and Dr. S. Hansen (Denmark) Rapporteur.

6. Comments on the First Report of the Committee were received from various countries; these were referred to the corresponding items on the agenda.

   In principle positive lists of permitted food additives should be aimed at, but it was suggested that in certain cases a provisional list of prohibited food additives might be desirable.

7. The tentative tolerances for sulphur dioxide given in the first report of the Committee should be maintained with the exception of wines, for which no tolerances were suggested, pending the technological Justification for specific levels of use. The Committee agreed to ask the Joint FAO/WHO Expert Committee on food Additives to reinvestigate the toxicity of the SO_2 in wines, taking into consideration that the producer was using more SO_2 than the consumer actually received and to also consider all forms in which SO_2 might be present in wine when consumed.

   The Committee asked the member governments to supply figures about the SO_2 content of foods ready for consumption.

8. The Joint FAO/WHO Expert Committee on Food Additives had concluded that hexamethylenetetramin should not be used as a food additive in human foodstuffs. This conclusion was based on lack of sufficient information, particularly on long term studies in animals. As the Joint FAO/WHO Expert Committee on Food Additives did not give acceptable daily intake figures, a tolerance for hexamethylenetetramin could not be given.

The German Government had studied the question, whether the banning of this antimicrobial would endanger the public health because the lack of this antimicrobial might result in spoilt products reaching the consumer and had concluded that there is no such danger.

9. After studying recent reports the FAO/WHO Expert Committee on Food Additives had not altered the acceptable daily intake zones for butylated hydroxytoluene (BHT) that is, 0.5 conditional, and no unconditional level. Although the use of BHT seemed to be important in potato flakes and powder, it was decided to postpone the establishment of tolerances until more information was obtained from the FAO/WHO Expert Committee on Food Additives. The point was raised whether it would be possible to set a low ADI for BHT.

10. With regard to gallates the Joint FAO/WHO Expert Committee on Food Additives had proposed following their study of the Russian Report on propylgallate no change in the conditional acceptable daily intake level for propylgallate.

The Committee proposed a tentative tolerance for propyl-, octyl, and dodecylgallate in edible oils, fats and margarine of 100 ppm.

11. The Joint FAO/WHO Expert Committee on Food Additives had net changed their opinion about nordihydroguaiaretic acid (NDGA). For this reason the Committee would not give tolerances.

12. The Joint FAO/WHO Expert Committee on food Additives had not reevaluated formic acid and the Committee did not discuss the matter further. The substance was included in the list of additives to be dealt with at the 9th Session of the Joint FAO/WHO Expert Committee on Food Additives.

13. With regard to food colours the Joint FAO/WHO Expert Committee on Food Additives had classified some 160 colours according to the available toxicological information.

After consultation with WHO the Chairman has been informed that the report with all explanation and tables will be published in about a months time and will be sent directly from WHO to all the members attending the meeting of the Codex Committee on Food Additives. In view of this fact and to avoid misinterpretation of the significance of the use of colours the Chairman decided to delete the part of this report dealing with food colours.

14. After a full discussion the Committee suggested that the following items be added to the agenda of the 9th Session: Hydroxypropylmethylcellulose and Bleached lecithin. A suggested agenda for the 10th Session was prepared (See addendum CCFA-65-3). The Committee proposed that in the compilation of background material for the meetings of the FAO/WHO Committee on Food Additives equal importance should be given to specifications of food additives from all over the world.

15. The Committee decided to delegate the study of the use, technical need, actual consumption together with other pertinent information technical or otherwise of substances within the different groups of food additives to different parties.

It was agreed to divide the work as follows:

Antimicrobials	Canada	assisted	by Australia
Antioxidants	Switzerland	"	by the Netherlands
Bleaching and Maturing Agents	Netherlands	"	by Sweden
Flavouring agents	USA	"	by United Kingdom
Buffers, Acids, Alkalis and Salts	Belgium	"	by Israel
Emulsifiers, Stabilizers Thickeners	Denmark	"	by United Kingdom + by the Netherlands
Enzymes	Germany	"	by USA
Food Colours	United Kingdom	"	by Germany
Non nutritive sweeteners	USA	"	by United Kingdom

It was agreed that member countries should submit by 1-9-1965 to the country responsible for a particular working party details of the use etc. of substances of that particular class of additive in their own countries. Each working party would then prepare for the Netherlands Secretariat by 31-12-1965 basic lists of substances of that particular class of additive for distribution to member countries in advance and for discussion at the next meeting.

16. The Committee discussed methods of estimating daily-intakes of food additives. Reference was made to the Second Report of the Joint FAO/WHO Expert Committee on Food Additives (Rome 1958) page 7, which reads as follows: - It will be useful to try to define here the daily dietary dose. This is taken to be the amount of the food additive that might be expected to be consumed by an average adult eating a normal diet as determined from some appropriate dietary survey.
It should be assumed in these calculations that all the foods likely to be treated with the additive will contain it at the level proposed. -

Some countries had presented to the meeting figures for food consumption, but nearly all these figures were averages for the whole population. Only the USA had a survey (from one week in the spring 1955) where household consumption was reported and from which it was possible to judge the variation of food intake within the population. On basis of this survey the Household Economics Research Division of the U.S. Department of Agriculture had for some time estimated intakes of food additives used by high consumers. In the United States the ninth decile was adopted, and the Codex Committee was contemplating to follow the same approach. The Committee decided that before adopting this method it should seek the opinion of the Joint FAO/WHO Committee on Food Additives and other authorities. It was appreciated that it would be difficult to define a world wide daily intake of food because diets varied from country to country.

The delegate of Denmark was asked to prepare a survey of the consumption of the main foods with special reference to the various population groups, information would be supplied by contact persons in the different countries.

Emulsifiers and Stabilizers

17. Phosphates and Polyphosphates.

The Committee asked the Working Party on Emulsifiers, Stabilizers and Thickeners to prepare proposals for the next session, the phosphorus content in the natural food also to be taken into consideration.

18. Calcium acetate and Calcium chloride.

The Committee noted that there was no limiting acceptable daily intake proposed by the Joint FAO/WHO Expert Committee on Food Additives for calcium acetate and calcium chloride, and therefore considered that good manufacturing practice was a sufficient restriction. The Working Party on Buffers, Acids, Alkalis and Salts was asked to provide figures about good manufacturing practice.

19. Citric acid and its calcium-, potassium- and sodium salts.

For citric acid the acceptable daily intake zone was given. (6th Report Joint FAO/WHO Expert Committee on Food Additives). It had been pointed out however, in the 7th Report that these limits might be too strict and would need reconsideration by a future Committee.

The Working Party on Buffers, Acids, Alkalis and Salts was asked to provide figures about good manufacturing practice.

20. Tartaric acid and its calcium-, potassium- and sodium salts.

For tartaric acid and its salts the acceptable daily intake zone had been changed by the Joint Expert Committee on Food Additives (unconditional 0-6 mg/kg bodyweight, conditional 6-20 mg/kg).
The Committee suggested that further information on the concentration of tartaric acid in wine and grape juice should be submitted to the Working Party on Buffers, Acids, Alkalis and Salts.

21. Agar.

The Working Party on Emulsifiers, Stabilizers and Thickeners was asked to provide figures for good manufacturing practice.

22. Alginic acid and its salts.

The same remarks as on agar.

23. Methyl cellulose.

The delegate of USA drew the attention to the fact that in USA in many special products methyl cellulose was used. The total daily intake was on average not beyond the unconditional level. However, for dietetic reasons the daily intake of some persons was far beyond the conditional level.

The Working Party on Emulsifiers, Stabilizers and Thickeners was asked to provide figures about actual use.

24. Carboxymethylcellulose and its sodium salt.

The delegate of USA submitted a detailed list of the use in the USA to the Working Party on Emulsifiers, Stabilizers and Thickeners. This Working Party would study this list and the actual consumption in the different countries.

25. Sorbitol.

This substance is often used in dietary foods - food for diabetics and non-cariogenic food in quite high levels.

The matter was referred to the Working Party on Emulsifiers, Stabilizers and Thickeners for detailed information on the actual use... The. Committee further recommended that a special Codex Committee on dietary foods should be formed.

26. 1,2 - Propyleneglyool.

The Committee did not consider this substance as an emulsifier or stabilizer. The acceptable daily intake in the unconditional state was 20 mg/kg body weight, i.e. at 1200 mg per day for a 60 kg person. Calculating with the figures given in USA's high consumption report*and the available data of dosage, it seemed unlikely that this value would be exceeded.

	estimated consumption per day	amount added to the product.	daily intake
	g	ppm	mg
Candies	30	3,200	960
Soft drink	140	0,0700	98
Baked goods	90	0,1300	117
Toppings and icings	10	0,8000	80
Meat products	60	0,0040	2
			1257

* Unpublished paper containing figures on basis of the 1955 Household Consumption Survey.

27. Sorbitan esters of fatty acids.
(sorbitan monopalmitate, sorbitan monostearate, sorbitan tristearate).

The acceptable dally intake in the unconditional state was 25 mg per kg bodyweight, i.e. 1500 mg per day for a 60 kg person. The ADI was not attained with the following products

Product	estimated consumption per day	amount added to the product	daily intake
	g	ppm	mg
Baked goods	20	6000	120
Candies	30	10000	300
Soft drinks	140	500	70
			490

The Working Party on Emulsifiers, Stabilizers and Thickeners was asked to study the consumption in the different countries.

28. Polyoxyethylene (8) stearate.

The acceptable daily intake in the unconditional state was 25 mg per kg bodyweight.

There was lack of information concerninguse and technical need. Only Canada made provision for its use in some unstandardized foods. The Working Party on Emulsifiers, etc. was asked to compile further information.

29. Polyoxyethylene (40) stearate.

The acceptable daily intake in the unconditional state was 25 mg/kg bodyweight. No information was available concerning use and technical need. The Working Party on Emulsifiers, etc. was asked to compile further information.

30. Polyoxyethylene sorbitan esters of fatty acids (polyoxyethylene (20) sorbitan monolaurate; polyoxyethylene (20) sorbitan monooleate; polyoxyethylene (20) sorbitan monopalmitate, polyoxyethylene (20) sorbitan monostearate; polyoxyethylene (20) sorbitan tristearate).

The acceptable daily intake in the unconditional state was 25 mg per kg bodyweight, i.e. at 1500 mg per day for a 60 kg person. The ADI was nog attained with the following products:

	estimated consumption per day	amount added to the product	daily intake
	g	ppm	mg
Ice cream	70	1000	70
Puddings, etc.	20	5000	100
Candies	30	5000	150
Baked goods	90	3000	270
Carbonated beverages			
Soft drinks	140	500	70
Shortenings and oils	50	10000	500
			1160

31. Mono- and diglycerides.

The Committee decided that this additive could be used in an amount not higher than was needed for good manufacturing practice. The Working Party on Emulsifiers, Stabilizers and Thickeners was asked to draw up proposals for tolerances.

32. Lecithin.

As was understood by the Committee the Joint FAO/WHO Expert Committee on Food Additives in its 7th report only referred to commercial (not bleached) lecithin. The acceptable daily intake in the unconditional state was 50 mg per kg bodyweight, giving 3000 mg a day for a 60 kg person. Calculating with the data available this amount is not reached with the following products

	Estimated consumption per day	amount added to the product	daily intake
	g	ppm	mg
Margarine	40	5000	200
Chocolate	30	5000	150
Ice cream	70	10000	700
Baked goods	90	2000	180
Flour	170	2000	340
			1570

In these amounts bleached lecithin is included.

The Committee decided to ask the Joint FAO/WHO Expert Committee on Food Additives to consider bleached lecithin at their 1965 meeting since in the above bleached lecithin is included.

The Danish delegate promised to inform the Joint FAO/WHO Expert Committee on Food Additives about toxicological data on bleached lecithin.

33. Fatty acids and soap.

The Committee was of the opinion that this additive might be used in amounts not exceeding those used in good manufacturing practice, and agreed that the Joint FAO/WHO Expert Committee on Food Additives should be asked to consider these additives at their 1966 meeting.

34 Dextran
Carrageen and its salts
Gelatine (arable, guar, karaya, oat, tragacanth, carob beans, cornhulls, wheat, etc.)
Gums
Pectin
Amylopectin
Gluten
Casein and its salts

The Committee decided not to deal with gelatine, amylopectin, gluten and casein, as these products were considered to be foods in their own right.

The Committee agreed that the Joint FAO/WHO Expert Committee on food Additives should be asked to consider dextran, carrageen and its salts, gums (arabic, guar, karaya, oat, tragacanth, carob beans, cornhulls, wheat, etc.), pectin and the salts of casein on their toxicity at their 1966 meeting.

35. Saponins.

The Committee decided that the Working Party on Emulsifiers, etc. should study this group of substances and that before tolerances could be laid down the Joint FAO/WHO Expert Committee on Food Additives should be asked to consider these compounds at their 1966 meeting.

36. Sucroesters and sucroglycerides.

The Committee considered these food additives which had not so far been studied by the Joint FAO/WHO Expert Committee on Food Additives as they were used only in one or two countries. It was agreed that the FAO/WHO Expert

Committee on Food Additives should be asked to consider them at their 1966 meeting.

37. Enzymes.

The Committee discussed the valuable report of the Delegate of the Federal Republic of Germany "Commercial Enzyme Preparations" and decided that enzyme preparations should be regarded as food additives. The study of these products was referred to the Working Party on Enzymes, asking the Working Party to make proposals for tolerances. The Committee expressed the opinion that it was the task of the Joint FAO/WHO Expert Committee on Food Additives to prepare specifications of identity and purity.

38. Definitions.

The Second Session of the Codex Alimentarius Commission in par. 25 of its report requested the Codex Committee on Food Additives to specify in particular what was meant by "food additives" as no existing definition appeared to be sufficiently accurate.

After a long discussion the Committee agreed on the following definition for food additive. This definition was based on the definition given in the U.S.A. Federal Food, Drug and Cosmetic Act, Title 21, Part 1 and the corresponding Belgian Food Law.

> The term "food additive" means any substance, not being a food per se, the intended use of which results, or may reasonably be expected to result, directly or indirectly, in it or its byproducts becoming a component of, or otherwise affecting the characteristics of a food. The term includes any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and includes any source of radiation intended for any such use.
>
> The Committee did not Judge it necessary to define "a food per se".

For the present the Committee proposed to deal with intentional additives not including food contaminants, which were included in the above definition. The Committee recognized that contaminants and other substances which might unintentionally be present in a food through processing or other means might be important. With the exception of pesticide recidues which were already the responsibility of another Codex Committee, the Codex Committee on Food Additives was prepared to deal with everything falling under the above definition.

39. General principles for the use of food additives.

The Committee discussed appendix G to the report of the First Session of the Joint FAO/WHO Codex Alimentarius Commission, regarding "General Principles for the use of food additives", the text of which was prepared by the Joint FAO/WHO Expert Committee on Food Additives.

After making some alterations, to be given below, the Committee approved the content of this Draft standard with the following amendments.

par. 1. A new definition

par. 2a. Only concerning intentional food additives with the deletion of the word "essential" in (d).

par. 2b. Only concerning unintentional food additives par

6-7-8 Minor alterations.

The Committee suggested the adoption of the amended text, as given in Addendum CCFA-65-5, as a draft provisional standard on "General Principles for the Use of Food Additives".

40. Food Additives in Milk Products.

The Committee discussed items 38-49 (inclusive) of the Report of the 7th Session of the Joint FAO/WHO Committee of Governments Experts on the Code of Principles concerning Milk and Milk Products.

It was agreed that more detailed information was required regarding:

a) the food additives used in milk products;

b) the justification for their use;

c) the required levels of use;

d) information on reasonable daily intake of the various dairy products.

The Committee asked the FAO Secretariat to bring this to the attention of the above mentioned Committee at its next meeting.

ADDENDUM CCFA-65-2

Food Additives which have been considered by the

Joint FAO/WHO Expert Committee on Food Additives [x]

[x] This list includes those additives to be dealt with at the Ninth Session, to be held in Rome in December 1965- Nomenclature to be chequed by IVPAC.

Acids

- Acetic
- Adipic
- Citric
- Fumaric
- Gluconic
- Hydrochloric
- Lactic
- Malic
- Phosphoric
- Tartaric

Bases

- Ammonium hydroxide
- Calcium hydroxide
- Calcium oxide
- Carbonates and bicarbonates of ammonium, magnesium, potassium and sodium
- Magnesium hydroxide
- Magnesium oxide
- Potassium hydroxide
- Sodium hydroxide

Antimicrobial Preservatives

- Benzoic acid
  - calcium benzoate
  - potassium benzoate
  - sodium benzoate
- p-Hydroxybenzoates and their sodium salts
  - butyl
  - ethyl
  - methyl
  - propyl
- Boric acid and borax
- Diethyl pyrocarbonate
- Diphenyl
- Ethylene oxide
- Formic acid
- Hexamethylenetetramine
- Hydrogen peroxide
- Nitrates of sodium and potassium
- Nitrites of sodium and potassium
- Nitrofurazone

o-Phenylphenol and sodium o-phenylphenol

Propionic acid
- calcium propionate
- potassium propionate
- sodium propionate

Propylene oxide
Salicylic acid
Sodium diacetate
Sorbic acid
- calcium sorbate
- potassium sorbate
- sodium sorbate

Sulphur dioxide
- sodium dithionite
- sodium hydrogen sulphite
- sodium metabisulphite
- sodium sulphite
- potassium metabisulphite

Thiodipropionic acid
- dilauryl thiodipropionate
- dlstearyl thiodipropionate

Antioxidants and Synergists

Ascorbic acid
- sodium ascorbate

Isoascorbic acid
- sodium isoascorbate

Ascorbyl palmitate
Butylated hydroxyanisole
Butylated hydroxytoluene
Citric acid
Gallates
- propyl
- octyl
- dodicyl

Gum Guaiac
Isopropyl citrate mixture
Nordihydroguaiaretic acid
Phosphoric acid
Tartaric acid
Tocopherols
- alpha tocopherol
- mixed tocopherols concentrate

2,4,5 Trihydroxybutyrophenone

Bleaching and Maturing Agents

Acetone peroxides
Ammonium persulphate
Azodicarbonamide
Benzoyl peroxide
Calcium peroxide
Calcium stearyl-2-lactylate
Chlorine
Chlorine dioxide
Iodates (Ammonium[1)], calcium, potassium, sodium[1)])
Monocalcium phosphate
Oxides of nitrogen
Potassium bromate
Potassium persulphate

Emulsifiers and Stabilizers

Acetyl tartaric acid esters of mono- and diglycerides
Agar
Alginic acid
- ammonium alginate
- calcium alginate
- potassium alginate
- sodium alginate

Brominated vegetable oils
Calcium acetate
Calcium chloride
Citrates
- calcium
- potassium
- sodium

Ethyl cellulose
Methyl cellulose
Sodium carboxymethylcellulose
Hydroxypropylmethylcellulose
Lecithin (included bleached lecithin[1)])
Mono- and diglycerides
Phosphates
- monosodium monophosphate
- disodium monophosphate
- trisodium monophosphate
- monopotassium monophosphate
- dipotassium monophosphate
- tripotassium monophosphate
- disodium diphosphate
- tetrasodium diphosphate
- pentasodium triphosphate
- sodium polyphosphate

Polyoxyethylene (8) stearate
Polyoxyethylene (40) stearate

Polyoxyethylene (20) sorbitan monolaurate
Polyoxyethylene (20) sorbitan monooleate
Polyoxyethylene (20) sorbitan monostearate
Polyoxyethylene (20) sorbitan tristearate
Propyiene glycol
Propylene glycol alginate
Propyiene glycol monopaltimate
Propylene glycol monostearate
Sorbitan monopaltimate
Sorbitan monostearate
Sorbitan tristearate
Sorbitol
Tannic acid
Tartrates
- sodium tartrate
- potassium sodium tartrate

Sequestering Agents

Calcium disodium ethylenediaminetetraacetate
Disodium ethylenediaminetetraacetate
Stearyl citrate
Stearyl tartrate

Miscellaneous

Tetracyclines[1)]

Colours

At the 8th Meeting of the Joint FAO/WHO Expert Committee on Food Additives, 163 natural and synthetic food colours were considered.

1) The Chairman has been informed bij WHO, that it was impossible at this stage to include these items on the agenda for the 1965 meeting.

ADDENDUM CCFA-65-3

SUGGESTED ITEMS FOR CONSIDERATION AT 10TH SESSION OF JOINT FAO/WHO EXPERT COMMITTEE FOR FOOD ADDITIVES (1966) BY THE CODEX COMMITTEE ON FOOD ADDITIVES

Emulsifiers,

Stabilizers and

Maturing agents

Hydroxylated lecithin
Propyleneglycolether of methylcellulose
Methylethylcellulose
Hydroxymethylcellulose
Sodium celluloseglycolate
Carboxymethylgallactomannan
Carboxymethyl starch
Modified starches
Saccharose esters of fatty acids
Polyvinyl pyrrolidon
Monostearin sodiumsulfoacetate
Mannitol
Taurocholic acid and Na-salt
Furcelleran and its salts
Cholic acid
Desoxycholic acid
Glycocholic acid
Fatty acids and their calcium-, potassium- and soddium salts
Ethyl-hydroxy-ethyl-cellulose
Esters of polyglycerol and polyricinoleic acid
Esters-of polyglycerol and fatty acids
Esters of polyglycerol and dimerized or polymerized fatty acids of soybean oil
Esters of polyglycerol and oxidized soybeam oil
Esters of polysaccharides and fatty acids
Mono- and diglyceride compounds of
(I) citric acid
(II) lastic acid
(III) phosphoric acid
(IV) acetic acid
(V) tartaric acid
Esters of fatty alcohols and hydroxy acids

Miscellaneous

Copper carbonate
Nystatin
Nisin
Formaldehyde

ADDENDUM CCFA-65-5

GENERAL PRINCIPLES FOR THE USE OF FOOD ADDITIVES

(and for establishing permitted lists)

1. The term "food additive" means any substance, not being a food per se, the intended use of which results, or may reasonably be expected to result, directly or indirectly, in it or its by-products becoming a component of, or otherwise affecting the characteristics of a food. The term includes any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and includes any source of radiation intended for any such use.

2a. The use of intentional food additives is justified only when it serves one or more of the following purposes:

(a) the maintenance or the enhancement of the nutritional quality of a food;

(b) the enhancement of keeping quality or stability with resulting reduction in food wastage;

(c) making foods attractive to the consumer in a manner which does nog lead to deception;

(d) providing aids in food processing.

The use of intentional food additives is not justified when it

(a) disguises the use of faulty processing and handling techniques;

(b) deceives the consumer;

(c) results in a substantial reduction in the nutritive value of the food.

2b. The presence of unintentional food additives (to be prepared).

3. If food additives at present in use have not already been subjected to adequate examination to ensure minimum risk in use, this should be done unless existing knowledge indicates that it is unnecessary.

4. All food additives proposed in the future should be subjected to toxicological examination to minimize risk before being accepted for use.

5. Food additives accepted for use should be subjected to continuing observation for possible deleterious effects under changing conditions of use and should be reappraised whenever indicated by advances in knowledge.

6. In general the food additives to be included in the permitted lists to be published in the Codex Alimentarius have been considered by the Joint FAO/WHO Expert Committee on Food Additives which has evaluated the available toxicological data, and established acceptable daily intake levels together with specifications for their identity and purity.

7. Under special circumstances food additives may be included on a provisional basis in the permitted lists, and remain provisionally on such lists until the Joint FAO/WHO Expert Committee has been able to evaluate the available toxicological data and drawn up specifications for their identity and purity.

8. When it is desired to include other food additives in the permitted lists, requests should be sent to FAO/WHO detailing the additional substances suggested, together with published and unpublished data on specifications for identity and purity as well as detailed reports of toxicological and related studies. (See par. 23 of the Report of the 2nd Session Codex Alimentarius Commission).

9. In the permitted lists of food additives in the Codex Alimentarius acceptable daily intake zones are indicated. The acceptable zones represent the limits of intake that can be regarded as presenting no significant hazard to health on the basis of the evidence available. However, the problems that may arise from the introduction of a food additive into the diet may be complex and may sometimes require further study by experts in nutrition or other related fields. This is more likely to occur when high levels of dosage are used or if the food additive is to be used foods mainly consumed by some special group in the community, such as children.

10. Expert opinion will be required whenever higher dosage levels of certain food additives are to be used or when special circumstances arise. The zone of acceptability has therefore been split into two parts in selected cases. The first part has been termed the unconditional zone of acceptability and this represents a level of use that is effective technologically at least for some purposes, and can be safely employed without further expert advice. The second part consists of a conditional zone which is equally acceptable and represents levels of use that can be employed safely but at these levels it is thought desirable that some degree of expert supervision and advice should be readily available. It is, therefore, intended that the unconditional zones of acceptability should be regarded as a guide to developing countries that may not be able to call upon appropriate experts to guide them in the handling of particular problems in this field. The conditional zones of acceptability on the other hand are more likely to be if interest to those countries that have a more elaborate organization for dealing with food policy and the health hazard of the consumer. It must be emphasized that the whole zone of acceptability may be safely employed. It provides for an adequate margin of safety after careful consideration of the evidence available. Added precautions in the unconditional zone of acceptability are only necessary in the special circumstances described.

11. It cannot be too strongly emphasized that food additives should only be used when necessary and that the level of use should not exceed the lowest level that can achieve the desired technological effect under good manufacturing practices.

12. The acceptable daily intake zones indicated in the permitted lists of the Codex Alimentarius should not be used out of their context. Before using them, the relevant report of the Joint FAO/WHO Expert Committee should be consulted.

13. The following procedure illustrates how the information available from daily intake zone figures may be effectively used:

    (a) Decide upon the effective level of the food additive under consideration that would be needed in good technological practice..

    (b) Examine the possible uses and list all the foods in which the food additive might be used.

    (c) Calculate the daily intake level that might occur if the food additive was used in all the foods for which it might be a useful additive, working on the basis of the average intake of the food materials containing the additive. This average intake for appropriate population groups is obtained from

national food consumption surveys. For certain kinds of food, consideration should be given to relatively large variations in consumption between individuals or between special groups of the population.

Such individuals or groups might be exposed to excessive amounts of the additive if the calculation is based on average levels derived from food consumption surveys. Examples of this are beverages and sweets, which may be consumed by children in much larger quantities than the average.

(d) Obtain the necessary information from which to calculate the average body weight of the population group concerned (usually between 50 and 70 kgs.).

(e) From this information calculate the intake of the additive in mg. per kg. of body weight per day.

(f) Check this figure against the acceptable intakes given for the substance in the table. If it falls within the unconditional zone, the situation is satisfactory and the level proposed may be accepted.

If it falls within the conditional intake zone, further scientific advice is required before the level of use proposed is accepted.

Example.

(1) A substance X is proposed as a food additive in several foods at a level of treatment of 100 ppm of the food as it is eaten.

(2) The foods in which it might occur are listed and the amounts of these foods that would be eaten daily on the basis of national food consumption survey are calculated.

(3) The total average intake of treated food of an average man is found to be 500 gs. a day. The daily intake of X is therefore estimated at 50 mgs.

(4) The body weight of an average man in the population under consideration is 70 kgs.

(5) Therefore the intake of X would be 0.7 mg/kg body weight per day.

(6) Prom examination of the table on Appendix A the Acceptable daily intakes for substance X are: unconditional zone: 0-1 mg/kg body weight; conditional zone : 1-7.5 mg/kg body weight. Thus, the suggested use of substance X gives an intake in the unconditional zone. It is therefore acceptable without further advice. (Substance X is an imaginary substance and the figures given here are only illustrative).