CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 2 **CX/FA 12/44/2**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Forty-fourth Session

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MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES AND TASK FORCES

MATTERS ARISING FROM THE 34TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION

Standards and Related Texts adopted by the Commission[1]

1. The Commission adopted the following standards and related texts:

- Food Additives Provisions of the *General Standard for Food Additives* (GSFA)[2] with the following amendments: (i) Deletion of note 16 "For use in glaze, coatings or decorations for fruit, vegetables, meat or fish" in the provision for carotenoids in food category 9.1.1 "Fresh fish" (note 4 "for decoration, stamping, marking or branding the product" associated with the provision was retained); and (ii) Replacement of notes O[1] and P with note P[1] "For use in noodles only" in the provision for beta-carotenes, vegetable in food category 06.4.2 "Dried pastas and noodles and like products;
- Revision of the Food Category System of the GSFA (food categories 05.1, 05.2 and 05.4)[3];
- Amendments to the *International Numbering System for Food Additives*[4]*;*
- Specifications for the Identity and Purity of Food Additives[5];
- Amendments to food additive provisions for antioxidants and preservatives of food category 04.1.2.2 "dried fruits" of the GSFA[6] and revised note 135 to read "Except for use in dried apricots at 2000 mg/kg, bleached raisins at 1500 mg/kg, desiccated coconut at 200 mg/kg and coconut from which oil has been partially extracted at 50 mg/kg";
- Revision of Section 4 "Carry-over of Food Additives" into food of the Preamble to the GSFA[7]; and
- Amendment to "Explanatory notes on the lay-out of the INS" Section 1 of the *Class Names and International Numbering System for Food Additives* (CAC/GL 36-1989)[8].

2. A full record of the discussion of the 34th Session of the Commission on the adoption of the above to texts can be found in REP11/CAC, paras 55-61.

Standards and Related Texts adopted at Step 5 by the Commission[9]

3. The Commission adopted at Step 5 and advanced to Step 6 the draft Revision of the *Standard for Food Grade Salt* (CODEX STAN 150-1985)[10].

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[1] REP11/CAC, paras 55-61 and Appendix III
[2] REP11/FA Appendix III
[3] REP11/FA Appendix VIII
[4] REP11/FA Appendix XII
[5] REP11/FA Appendix XIII
[6] REP11/FA para. 26 and REP11/CAC para. 55-61
[7] REP11/FA Appendix IX
[8] REP11/FA, para. 148
[9] REP11/CAC, para. 116 and Appendix IV

Revocation of existing Codex Standards and Related Texts[11]

4. The Commission approved the revocation from the Codex Alimentarius of food additive provisions of the GSFA as proposed by the 43rd Session of the CCFA[12].

Discontinuation of work[13]

5. The Commission approved the discontinuation of draft and proposed draft food additive provisions for the GSFA as proposed by the 43rd Session of the CCFA[14], with the exception of the provision for carotenoids in food category 02.1.2 that was returned to the CCFA for further consideration.

6. A full record of the discussion of the 34th Session of the Commission on the discontinuation of the draft and proposed draft food additive provisions of the GSFA can be found in REP11/CAC, paras 152-153.

7. The Committee will discuss the provision for carotenoids in food category 02.1.2 under Item 5b.

Amendments to Codex Standards and related texts[15]

8. The Commission agreed to request the CCFA to consider the need to revoke or revise the following texts: *Information on the Use of Food Additives in Foods* (CAC/MISC 1-1989); and *Guidelines for Simple Evaluation of Food Additive Intake* (CAC/GL 03-1989).

9. The Committee **is invited to consider** the request of the 34th Session of the Commission. The texts are attached as Annex I to this document.

Standard for Fish Sauce[16]

10. The Commission adopted the draft Standard for Fish Sauce[17] with editorial corrections to the INS numbers for benzoates and sorbates and noted the reservation expressed by the European Union to the use of caramel III-ammonia caramel (INS 150c) for safety reasons.

11. The Committee will discuss the endorsement of the food additive provisions of the above Standard under Item 4a.

Regional Standard for Halwa Tehenia Regional (Near East)[18]

12. The Commission decided to adopt the proposed draft Regional Standard for Halwa Tehenia at Step 5/8 and to send it for endorsement to CCFA, CCMAS and CCFL.

13. The Committee will discuss the endorsement of the food additive provisions of the regional standard under Item 4a.

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[10] REP11/FA Appendix XI
[11] REP11/CAC para. 120 and Appendix V
[12] REP11/FA paras 83 and 88, Appendix IV
[13] REP11/CAC para. 150, 152-153 and Appendix VII
[14] REP11/FA paras 75 and 83, Appendix V
[15] REP11/CAC para. 129
[16] REP11/CAC para. 67
[17] The 35th CCFFP forwarded the provisions for food additive of the draft Standard for Fish Sauce to the CCFA for endorsement (REP 11/FFP, para. 37)
[18] REP11/CAC para. 86

MATTERS ARISING FROM OTHER COMMITTEES AND TASK FORCES

Executive Committee (CCEXEC)[19]

Critical Review for the elaboration of Codex Standards and Related Texts (Part II – Proposed draft Standards and Related Texts at Step 5)

14. The 65th CCEXEC noted that although the initial target year for the revision of the *Standard for Food Grade Salt* was 2011, further advice was needed from the CCMAS, and encouraged the CCFA to completed the revision in 2012.

Nutrition and Foods for Special Dietary Uses (CCNFSDU)[20]

Food additives provisions in the *Standard for Infant Formulas and Formula for Special Medical Purposes*

15. Taking into account the comments of the 43rd CCFA, the 33rd CCNSFDU agreed that the salts of citric and phosphoric acid, which may be considered as physiological body constituents, should be included in the list of additives. As sodium citrates (331(i) and 331(iii)) and potassium citrates (332(i) and 332(ii)) were already included in the additives section of the standard, the Committee agreed to forward for endorsement the levels for the acidity regulators sodium phosphates (339(i), (ii) and (iii)) and potassium phosphates (340(i), (ii) and (iii)).

16. The Committee will consider the above provisions for endorsement under Item 4a.

Carry-over of food additives into foods

17. In reply to the question of the CCFA concerning the application of the carry-over of food additives in the foods included in food categories 13.1 and 13.2 of the *General Standard for Food Additives* (GSFA), the Committee confirmed that the carry-over was applied consistently with the Preamble of the GSFA, Section 4.3: "*Carry-over of a food additive from a raw material or ingredient is unacceptable for foods belonging to the following food categories, unless a food additive provision in the specified category is listed in Tables 1 and 2 of this standard: a) 13.1- Infant formulae, follow-up formulae, and formulae for special medical purposes for infants; b) 13.2 - Complementary foods for infants and young children.*"

18. In order to ensure consistency in the additive provisions in the standards for foods for infants and young children, the Committee agreed to replace the current section on the carry-over principle in the *Standard for Follow-up Formula and in the Standard for Canned Baby Foods* by the following text at the beginning of the section on food additives:

> *Only the food additives listed in this section may be present in the foods covered by this Standard, as a result of carry-over from a raw material or other ingredient (including food additive) used to produce the food, subject to the following conditions:*
>
> a) *The amount of the food additive in the raw materials or other ingredients (including food additives) does not exceed the maximum level specified; and*
>
> b) *The food into which the food additive is carried over does not contain the food additive in greater quantity than would be introduced by the use of the raw material or ingredients under good manufacturing practice, consistent with the provisions on carry-over in the Preamble of the General Standard for Food Additives* (CODEX/STAN 192-1995).

[19] REP11/EXEC para. 5
[20] REP12/NFSDU paras 5-11

Annex 1

INFORMATION ON THE USE OF FOOD ADDITIVES IN FOOD[1]

CAC/MISC 1-1989

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

The Codex Alimentarius Commission

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

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

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

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

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

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

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

The CCFAC examines the technological need for the use of food additives in food based on nformation supplied by the Codex Commodity Committees. It further applies safety considerations based on the reports of the JECFA. These two sources are combined as CCFAC's contribution to Codex Alimentarius Standards.

[1] In response to requests from several of its Member Governments, the Eighteenth Session of the Codex Alimentarius Commission adopted the attached Statement. The Statement had been prepared by the Commission's Coordinating Committee for Europe and endorsed by the Codex Committee on Food Additives and Contaminants. In adopting the Statement, the Commission agreed that Member Governments would be free to use it and could interpret or modify the text to suit their national legislation.

The discussi ons take pla ce in an ob jective, sci entific climate in which all opinio ns are given full consideration.

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

It is essential for governments, control authorities and, a bove all, the public to know that prior to listing as a substance for authorized use, a given additive has b een evaluated by independen t, respect ed experts who have voiced on this additive a unanimous opinion which can be accepted in full confidence.

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) is co mposed of a small group of experts of int ernational renown in their special fiel ds appointed j ointly by FAO and WHO. The Comm ittee was established after the Joint

FAO/WHO Conference on Food Addit ives, held in 1955. The te rms of reference of this Committee are to evaluate food additives and, where necessary , to est ablish "accep table daily intakes" (ADI) and chem ical specifications. Its recommendations are based on scientific and technical considerations on the safety of food additives. The JECF A is t he principal advisor of the CCF AC in it s work to est ablish a pract ical base for t he determination of toxicological safety and the regulation of food additives in food.

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

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

An ADI without an exp licit indication of the upper li mit of intake ("not limited"), means that on the basis o f the toxicological, biologic al, che mical, and clinical data available, the total daily intake of the substance present as a result of its use or uses in concentrations necessar y to achieve the desired technical effect in food, represents no hazard to health. It is thus cons idered unnecessary to establish a numerical li mit for the ADI of these substances.

ADIs are calculated on the basis of experim ents on an imals and involve a sizeable safety margin taking int o consideration all safety factors. The m ost frequent orde r of magnitude of the com bined safety factors is 100 (10 x 10).Nevertheless, the daily intakes resulting from the use of a food additive seldom tends to exceed the ADI. The JE CFA and the CCFAC treat all additives in the same way and make no distinction between those of "natural" and those of "not of natural"origin.

General Principles for the Use of Food Additives

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

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

b. Only those f ood additives should be used, which sofar as can be judged on the evidenc e presently available, present no hazard to consumer health at the levels of use proposed.

c. All food additives shall be subjected to continuous observation and reevaluated whenever necessary, in the light of changing conditions of use and new scientific information.

d. Food additives shall always conform to an approved specification, for example, the identity and purity specifications recommended by the Codex Alimentarius Commission.

e. The use of food additives is justif ied only where they serve one or m ore of the purposes indicated fro m i) to v) and only where these purposes cannot be achieved by other economically and practically feasible methods at no risk to consumer health;

   i. To preserve the nutritiona l qualities of the fo od; a n intentional reduc tion of the nutritional quality of the food would be justified in the ci rcumstances set in sub-paragraph and also in other cases where the food does not constitute a major item of a normal diet;

ii. to provide t he ingredients or constituents necessary for food products manufactured for consumer groups with specific dietary needs;

iii. to enhance the keeping quality or stabil ity of a food or to im prove its organoleptic propertie s, provided that neither the n ature nor the substance nor the quality of the food are thereby altered in such a way as to deceive the consumer;

iv. to aid in the manufacture, processing, preparation, treatment, packaging, transport or storage of food; provided that the additive is not us ed for the pur pose of mask ing the effects of the use of defective raw materials or of undesirable (inc luding unhygienic) methods or techniques duri ng the course of any of these activities;

v. to maintain the safety of foods by inhibiting the growth of bacteria or other organism s that may cause disease.

f. The approval or pro visional approval o f the incorpo ration of a fo od additive to an advisor y list or in a food standard should: be limited as far as possible to specific foods for specific

i. purposes and under specific conditions;

ii. be at the lowest level of use necessary to achieve the desired effect;

iii. as far as possible take into account any ADI or equivalent

iv. assessment established for the food additive and the probable daily intake of the additive from all sources. Where the food addit ive i s to be used in foods consumed by s pecial groups of consumers, the probable daily intake of this add itive for this t ype of consumer should be taken into account.

Consumer Information

The Codex Committee on Food Labelling, which, like the CCFAC, is a su bsidiary body of the Codex Alimentarius Co mmission, had develo ped a General Standard for the Labelling of Pre-Packaged Foods (CODEX STAN 1-1985). This standard d eals specifically with th e declaration of food ad ditives in food i n such a way that the consumer is made aware of what additives are present in the food, t heir function (e .g. preservative), as well as their specific na me (e.g. potassium so rbate), or the use of an internationally recognized code number.

The reports of the Joint FAO/WHO Expert Committ ee on Food Additi ves, detailed monographs o n the toxicological data evaluated and specifications for th e purity of food-grade additives as well as reports of t he Codex Committee on Food Additi ves and Contam inants ar e freely available to go vernments and interested national and international organizations from FAO.

GUIDELINES FOR SIMPLE EVALUATION OF FOOD ADDITIVE INTAKE[1]

CAC/GL 03-1989

CONTENTS

[1] The text is available on the codex website as follows:
http://www.codexalimentarius.net/download/standards/6/cxg_003e.pdf

1. INTRODUCTION

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

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

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

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

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

2. BACKGROUND

2.1 Acceptable Daily Intake

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

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

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

2.2 Theoretical Maximum Daily Intake

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

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

(a) all foods in which an additive is permitted contain that additive;

(b) the additive is always present at the maximum permitted level;

(c) the foods in question containing the additive are consumed by people each day of their lives at the average per capita level;

(d) the additive does not undergo a decrease in level as a result of cooking or processing techniques;

(e) all foods permitted to contain the additive are ingested and nothing is discarded.

2.3 Estimated Daily Intake

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

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

3. ACCEPTABLE DAILY INTAKE ESTIMATES

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

Groups of animals (e.g. rats) are given daily diets containing different levels of the additive under examination. For example, levels of the additives in the diet could be: 0.1%, 1%, 2%, 5%. If a toxic effect is found at the 2% level and a "no toxic effect" at 1% level, the 1% level (expressed in mg/kg body weight) will be the "no-observed-effect level", and it is from this level that the extrapolation to humans is done. In this case, the no-observed-effect level lies between the 1% and 2% levels, and if no toxicological evaluations are done at intermediary levels (1.25 %, 1.50% , 1 .75%) the choice of the 1% level as the no-observed-effect level introduces already a first safety factor.

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

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

4. DATA AVAILABLE

4.1 Food Consumption and Regulation of Use of food Additives

An excellent review of food consumption data has been presented in the "Guidelines for the Study of Dietary Intakes of Chemical Contaminants" WHO Offset publication NQ 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 in to consideration the regulations in force concerning the additives.

The following three types of regulations will be considered:

(a) The authorisation 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 authorised are only needed.

(b) The additive is authorised 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 authorised 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 authorised according to GMP in all foodstuffs, prohibition of use being indicated for some of them. This legislative situation needs a close collaboration with the food industry and/or a rather complete sampling and analytical evaluation of the levels present in foodstuffs. The financial consequences of this approach will limit its applicability.

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

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

(i) Compliance of the imported food with the legislation of the exporting country;

(ii) Regulation of the exporting country of food additives for the product under consideration.

4 2 Approaches for Determining Food consumption Data

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

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

Table 1

Approaches for Determining Food consumption Data

Assessment	**Method**
Individual	Food Portion diary, weighed intakes, Duplicate Studies, Dietary Recall, Food frequency;
Population	Food recall, disappearance diary, weighed intakes, Dietary Food frequency, Food 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 consu mption by spe cial population groups and use of the additives at home. Correction for wastage is normally not needed for processed food and, since the ADI is established over a lifetime, seasonal variations need not be consider ed. Food cons umption 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	-	food used for seed
into account for	-	food used for non-edible purposes
processed food	-	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 purc hases made during a set ti me period (usual ly one week). Another kit chen invento ry is taken a t the end of that time. The food that has disappeared is assumed to reflect the fo od consumption of the family. The household food disappearanc e data are divided by the num ber of people in the family and the number of day s 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 r eceived as gifts; food consu med away from home; and food consumed by guests.

Food Frequency

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

The food frequenc y form is a list of commonly co nsumed foods to be completed by the individ ual, 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 regi onally. Information regarding the quantity of food cons umed is not usually requested on a food frequenc y form. Data on average serving sizes, obtained from previous diary or recall surveys, are used in connection with the frequency data to produce the desired information on food consumption.

5. SIMPLE APPROACH FOR THE EVALUATION OF FOOD ADDITIVE INTAKE

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

The following priority list can be used to decide for which additives in take evaluation have f irst to be done:

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

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

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

The following stepwise procedure is proposed:

A. Evaluation of the TMDI

A.1 Elaboration of the list of foodstuffs in which the additive is permitted;

A.2 Determination of the levels of use;

A.2.1 Maximum permitted levels according to the regulation;

A.2.2 Actual levels if authorisation is given according to GMP (figures obtained from industry or from analysis);

A.3 Determination of the average consumption of the foodstuffs in which the additive is permitted;

A.3.1 Collection of all available information regarding food habits in the country;

A.3.2 When little information is available, the national food disappearance method should be used as a first step;

A.3.3 Check if, for some foodstuffs, the average consumption of eaters is not much higher than the average consumption of the population. Consumption data for eaters should be used when the special food habits persist for a long period (additive taken daily in the diet during a lifetime: ADI definition);

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

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

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

B. Evaluation of the EDI

B.1 Checking the list of foodstuffs:

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

B.2 Checking the actual levels of use:

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

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

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

C. Use at Home

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

6. SUMMARY

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

Annex 1

Example of Calculation for Benzoic Acid and salts

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

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

TMDI Estimate

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

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

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

IMPROVED TMDI ESTIMATE

Average Intake of Users

Soft Drinks

Average intake of soft drink users: 600 ml

(instead of 144 ml, average intake of the population)

Emulsified Sauces

Average intake of users: 20 gr instead of 3.4 gr

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

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

ANNEX 2

EXAMPLE OF CALCULATION FOR SWEETENERS

Maximum Permitted Quantities of Sweeteners

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

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

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

- The consumption figures are calculated by the national Food Disappearance Method (production + import - export).
- The consumption of table top sweeteners is related to the consumption of cups of coffee and cups of tea, assuming that a cup of coffee is sweetened with one table-top sweetener corresponding to one sugar lump of 4 gram. The sweetening capacity relative to sucrose was considered to be as follows: saccharin 450; cyclamate 35; aspartame 200 and acesulfame 200.
- The model takes care of the consumption by heavy users of the sweetener.
- The assumption is made that the heavy user is only a heavy user of one product and has an average consumption of other products.
- For heavy users of a specific sweetener that particular product is selected which contributes most to the intake of the specific sweetener.
- A correction factor of 3 is used to estimate the heavy users consumption from the average users consumption. This correction factor of 3 is based on information provided in the "Guidelines for the Study of Dietary intakes of Chemical Contaminants", WHO, 1985, which indicates that 95 percentile of the population eats less than 3 times the average consumption.
- A theoretical Maximum Daily Intake (TMDI) is calculated by adding the figure for heavy users to the average consumption figures of other foods and compared with the ADI.
- The Theoretical Maximum Daily Intake (TMDI) should not exceed the ADI.

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

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

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

The results of this exercise are given in Table 2.

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

saccharin	:	135.7 mg
cyclamate	:	659.4 mg
aspartame	:	669.6 mg

acesulfame : 538.6 mg

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

TABLE 1
Maximum Permitted Quantities of Sweetener

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

TABLE 2

Estimation of the possible consumption of some sweeteners (14.11.1988)

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

	consumption product in g per day	**Saccharin**		**Cyclamate**		**Aspartame**		**Acesulfame**	
product		**mg/kg**	**consumption sweetener via product mg**	**mg/kg**	**consumption sweetener via product mg**	**mg/kg**	**consumption sweetener via product mg**	**mg/kg**	**consumption sweetener via product mg**
fruit quark	1.7	150	0.2	250	0.4	300	0.5	-	-
salads	4.9	-	-	-	-	700	3.4	200	1

* Assumes 5 : 1 dilution

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

TABLE 2 (Cont.d)

Estimation of the possible consumption of some sweeteners (14.11.1988)

	Consumption product in g per day	Saccharin		Cyclamate		Aspartame		Acelsufame	
Product		mg/kg	consumption sweetener via product mg	mg/kg	consum ption sweetener via product mg	mg/kg	consum ption sweetener via product mg	mg/kg	consum ption sweetener via product mg
jam products:									
jams and jellies	4	300	1.2	1000	4	-	-	3000	12
sugar reduced jams	0.3	200	0.1	500	0.2	-	-	1500	0.5
fruit nectar	5.8	150	0.9	750	4.4	750	4.4	600	3.5
canned fruits	3.6	380	1.4	1500	5.4	-	-	1000	3.6
coffee (cups)	4.3	2/	26.7	3/	147.4	-	86	-	86
tea (cups)	1.8	2/	11.2	3/	61.7	-	36	-	36
subtotal			82.3		364.6		426.6		344.2
+ 2 x coffee consumption			53.4		294.8		-		-
+ 2 x soft drink consumption							243.0		194.4
Total			135.7		659.4		669.6		538.6

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

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