

GUIDELINES FOR SIMPLE EVALUATION OF FOOD ADDITIVE INTAKE

CAC/GL 03-1989

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1. INTRODUCTION

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

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

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

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

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

2. BACKGROUND

2.1 Acceptable Daily Intake

The Acceptable Daily Intake (ADI) is an estimate by JECFA of the amount of a food additive, expressed on a body weight basis, that can be ingested daily over a lifetime without appreciable health risk (standard man - 60 Kg) (WHO Environmental Health Criteria document N° 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 into 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

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

These approaches are described in detail in WHO Offset publication No 87 referred to above.

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

National Food disappearance Method

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

national food balance	=	food production
	+	food imported
	+	food taken from stocks
	-	food added to stocks
	-	food exported
generally not taken	-	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 purchases made during a set time period (usually one week). Another kitchen inventory is taken at the end of that time. The food that has

disappeared is assumed to reflect the food consumption of the family. The household food disappearance data are divided by the number of people in the family and the number of days of the time period to estimate the consumption per person per day.

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

Food Frequency

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

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

5. SIMPLE APPROACH FOR THE EVALUATION OF FOOD ADDITIVE INTAKE

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

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

1. additives 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 they are used as additives according to good manufacturing practice.

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

The following stepwise procedure is proposed:

A. Evaluation of the TMDI

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

A.2 Determination of the levels of use;

A.2.1 Maximum permitted levels according to the regulation;

A.2.2 Actual levels if 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. Condiments	
7.1 Mustard	250
7.2 Emulsified sauces (from egg-yolk)	1000
Others	

TMDI Estimate

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

		Daily Food Intake Consumption	Daily Intake of Additive mg/person
		_____	_____
1.	Meat products		
1.1	Croquettes of meat, poultry, game	negligible	-
2.	Fish products		
2.1	Caviar and other roe	17 mg	negligible
2.2	Semi-preserved 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 ESTIMATEAverage Intake of UsersSoft 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 SWEETENERSMaximum 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
syrops (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	-	-

	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
others	24.4	50	1.2	250	6.1	750	18.3	200	4.9
fruit quark	1.7	150	0.2	250	0.4	300	0.5	-	-
salads	4.9	-	-	-	-	700	3.4	200	1

* 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)

Product	Consumption product in g per day	Saccharin		Cyclamate		Aspartame		Acelsufame	
		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
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.