Food additives

Guidelines for the preparation of working papers on intake of food additives for the Joint FAO/WHO Expert Committee on Food Additives

Geneva, January 2001

PREFACE

This is the first edition of guidelines for the preparation of working papers on the intake of food additives for the Joint FAO/WHO Expert Committee on Food Additives (JECFA). They are intended primarily for WHO Temporary Advisers, FAO Consultants, and Members who prepare working papers on intake for the Committee.

Traditionally, JECFA has evaluated the toxicological data on food additives and, when considered to be appropriate, has established acceptable daily intakes (ADIs) on them. Specifications for identity and purity are also developed (a) to identify the substance that has been biologically tested; (b) to ensure that the substance is of the quality required for safe use in food; and (c) to reflect and encourage good manufacturing practice. With the advent of more formalized risk analysis procedures, intake is now assessed whenever food additives are evaluated. When intake does not exceed the upper bound of the ADI the Committee concludes that there is no appreciable risk. Further details on the role of JECFA in the risk analysis process is provided in section 2.2 of the report of the fifty-third meeting of JECFA (WHO Technical Report Series No. 896, to be published in early 2001; in the meantime it is available in the summary report available at the WHO web site, *http://www.who.int/pcs/jecfa/jecfa.htm*).

When assessing exposure through food JECFA uses the term *intake*, for a number of reasons. One is that it is a similar term to the one to which it is being compared against, the acceptable daily *intake* for food additives and the provisional tolerable weekly *intake*, provisional maximum tolerable daily *intake*, etc for contaminants. Another reason is that it is a more specific term and eliminates ambiguity that may be associated with the more general term, *exposure*. Its use in this context, which is associated with oral ingestion, is consistent with its definition in section 1.2 of Environmental Health Criteria No. 214 (Human Exposure Assessment, 2000). If other routes of exposure exist, they should, of course, be considered as well.

This is our first attempt at producing guidelines for the preparation of working papers on the intake of food additives, and we envision that they will be modified based upon comments and experience. These and other JECFA guidelines, including guidelines for the preparation of toxicological working papers, the working paper (monograph) format for flavouring agents, and guidelines for the preparation of working papers on contaminants, are available from the WHO Joint Secretary, Joint FAO/WHO Expert Committee on Food Additives, International Programme on Chemical Safety, World Health Organization, 1211 Geneva 27, Switzerland; fax: (+41 22)791 4848; herrmanj@who.int. Comments on these guidelines and suggestions for future editions are gladly accepted.

GUIDELINES FOR THE PREPARATION OF WORKING PAPERS ON THE INTAKE OF FOOD ADDITIVES FOR THE JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES

1. Introduction

These notes are designed to guide authors in the preparation of working papers on the intake of food additives for the Joint FAO/WHO Expert Committee on Food Additives (JECFA). Such working papers summarize the available information on food consumption and levels of food additives in processed foods and provide estimates of intake on the basis of this information.

Intake is assessed whenever food additives are evaluated toxicologically. Safety assessments that are published in the *WHO Technical Report Series* include information on intake based on the working papers. Although working papers on toxicology and intake are developed separately they are combined and published together as monographs in the *WHO Food Additives Series*. Sometimes only intake is considered on the basis of a request from the Codex Committee on Food Additives and Contaminants (CCFAC), in which case considerations relating to intake become a separate item in the report and are published as a separate monograph.

Members invited by WHO are assigned as peer reviewers on specific substances and in this capacity are responsible for proposing evaluations before the meeting based on the draft working papers. In the past this has been done only with toxicological working papers, but the Secretariat encourages authors of working papers on intake to be part of this process as well. The ideal situation would be one in which authors of working papers on both toxicology and intake work together and with the Member to prepare a consolidated working paper that includes information on toxicology and intake and the proposed evaluation. Such a consolidated working paper should be submitted to the Secretariat in sufficient time before the meeting for reproduction and distribution to the participants.

Most working papers are published after meetings of the Expert Committee as monographs in the *WHO Food Additives Series*. To facilitate their editing and to avoid delays in their publication, the Secretariat would appreciate close adherence by authors to the standard style described in these guidelines.

Working papers should be submitted in ***single spacing***. They should be provided in electronic format on diskette at the time of the meeting. If a Macintosh computer is used, the file should be converted to PC format before submitting it to the Secretariat.

Working papers prepared on food additives for which intake assessments only or toxicological and intake re-assessments have been requested by CCFAC or governments may contain more information than working papers prepared on food additives that are being assessed for the first time because they relate to food additives that have a history of use, while first-time assessments often are performed on relatively new food additives. Governments and trade associations usually commit themselves to providing information requested by CCFAC, while the manufacturer generally provides data on food additives that are being evaluated toxicologically. When a food additive is evaluated for the first time only predictions of intake can be made. Therefore, these instructions are divided into two sections to account for these two scenarios. The guidelines should not be used rigidly, however, as elements of both scenarios should sometimes be incorporated into the working paper.

2. Working paper structure and content for assessments of intake requested by CCFAC

This section summarizes the types of information that are usually included in working papers on intake and the way that this information should be organized. The studies that are listed do not comprise a checklist of required studies, and information under some headings may be missing. Rather, they are included to provide guidance on ways the usual types of data should be summarized and organized (see Appendix A).

Information for screening food additives to identify those of potential concern should be presented first, followed by data for assessing intake.

2.1 Title - The main title should be the name usually given to the food additive.

2.2 Table of contents - A table of contents consisting of section headings and page numbers should be included on the first page of the working paper.

2.3 Introduction – The background to the assessment, including the reason that the food additive is on the agenda, the types of foods in which it is used, and the ADI that has been allocated should be provided. Previous evaluations should be referenced by number using the standardized reference list of JECFA publications, which may be found in Annex 1 of recent reports (WHO Technical Report Series) and evaluations (WHO Food Additives Series). Thus, the report of the forty-ninth meeting would be referenced as (Annex 1, reference 131) and a toxicological monograph prepared at the forty-ninth meeting would be referenced as (Annex 1, reference 132). Reference to previous Committees should be made by number spelled out (such as the forty-sixth meeting of the Committee), rather than by year, because in some cases the report has not been published in the same year as the meeting and in many years two meetings have been held, which would create confusion if meetings were referenced by year.

Sources of data for the assessment and the general type of information that was provided should be identified. This information is usually provided by countries based on 'data request sheets' (Appendix B). It may be useful to tabulate the information as shown in Table 1 using benzoates as an example.

Table 1. Summary of submissions on benzoates

Country	'Poundage data'	FBS/HES/ sales data	Model diets	Individual dietary records
Aus-NZ[a]			v	v
China	v		v	
Finland	v			
France		v		v
Japan			v	
Spain	v	v		
United Kingdom			v	v
United States	v		v	

Aus-NZ, Australia-New Zealand; FBS, food balance sheet; HES, household economic survey; sales, retail stores

[a]Australia and New Zealand submitted a combined assessment of intake for the two countries.

2.4 Screening by the budget method – This procedure is used to estimate a theoretical maximum food additive level in the proportion of the food and/or beverage supply likely to contain

the food additive that would not result in the ADI being exceeded by the population[1]. When the permitted level of use of the food additive exceeds the calculated maximum theoretical level, an intake assessment is required. Because food additives with high intakes usually are referred to the Committee intake assessments will be required in most cases.

In the past, governments were requested to submit assessments by the budget method. However, such information is no longer requested and the budget method should be undertaken by the Member as part of the assessment. Information for use in the budget method may be derived from government submissions and from the Codex draft General Standard for Food Additives (GSFA) as follows: (1) maximum levels permitted in national food standards and the draft GSFA for solid foods and beverages; (2) distribution of use in the food supply between solid foods and beverages (sum of use in solid foods and beverages = 100%) in the draft GSFA; and (3) the percentage of solid foods and/or beverages that are likely to contain the additive. Theoretical maximum levels in mg/kg are then calculated using the following equations:

For solid foods

$$\text{Theoretical maximum level} = \frac{\text{proportion of additive use in solid foods X 40 X ADI}}{\text{proportion of solid foods containing the additive}}$$

For beverages

$$\text{Theoretical maximum level} = \frac{\text{proportion of additive use in beverages X 10 X ADI}}{\text{proportion of beverages containing the additive}}$$

These factors are based on physiological energy requirements and the energy density of food. The paper by Hansen (1979) should be consulted for details. When the food additive is used in both solid foods and beverages, but the proportion in each category is unknown, it should be assumed that 50% of the additive is used in solid foods and 50% is used in beverages.

Example

ADI: 40 mg/kg bw
Maximum level permitted in national food standard for solid foods: 4000 mg/kg
Maximum level permitted in national food standard for beverages: 900 mg/kg

It is assumed that 50% of the food additive is used in solid foods and 50% in beverages.

It is assumed that the food additive is used in 25% of solid foods and 25% of beverages.

For solid foods,

$$\text{Theoretical maximum level} = \frac{0.5 \text{ X } 40 \text{ X } 40}{0.25} = 3200 \text{ mg/kg food}$$

For beverages,

$$\text{Theoretical maximum level} = \frac{0.5 \text{ X } 10 \text{ X } 40}{0.25} = 800 \text{ mg/kg beverages}$$

[1] Hansen, S.C. (1979) Conditions for use of food additives based on a budget method for an acceptable daily intake. *Journal of Food Protection*, **42**, 429-434.

In this example, the theoretical maximum use levels are less than the maximum levels permitted in the national food standards for solid foods and beverages.

The information described in this example plus other information provided relating to national standards and the draft GSFA should be tabulated as shown in Table 2.

Table 2. Estimates of theoretical maximum level of food additive by the budget method[a]

Distribution of use in the food supply	% of solid foods or beverage supply containing BHA	Theoretical maximum level (mg/kg)	National maximum level[b] (mg/kg)	GSFA maximum level[c] (mg/kg)
50% solid foods	25%	3200	4000	5000
50% beverages	25%	800	900	1000

[a]JECFA ADI, 0-40 mg/kg bw
[b]Highest level for solid foods and/or beverage category derived from government submissions. Alternatively, the highest levels for individual countries may be tabulated.
[c]Highest level for solid food and/or beverage category derived from the draft GSFA.

In this case the theoretical maximum levels were less than either the national maximum levels or GSFA maximum levels based on the percent of the solid food or beverage supply derived from the draft GSFA, so intake assessments in solid foods and beverages were required.

2.5 Assessments of intake – These should be placed in increasing order of accuracy. Information will not always be available on all types of assessment, in which case the heading should not be included. These assessments are based on information provided on food consumption in individual countries, so they are evaluations of national assessments of intake. Intake estimates are based on three types of concentration data: maximum levels of use from the draft GSFA, national standards, and measured levels, when available. Because processed foods are being considered, it usually is not appropriate to use food consumption data derived from GEMS/Food regional diets, which provide information on the apparent consumption of raw agricultural commodities, unless data are provided on the proportion of the raw commodity that is processed and the proportion of processed foods that may contain the food additive.

General considerations to keep in mind are the following:

- Estimates of chronic (long-term) intake should generally be derived for the general population.
- Additional assessments of intake for a specific population group can be undertaken when the Committee has identified the groups that are potentially susceptible or at risk on the basis of the toxicological evaluation.
- The estimate of chronic intake is adjusted for body weight and then compared with the ADI. Estimates of intake for high consumers derived from short-term (24-h) surveys tend to overestimate habitual food consumption and food additive intake and should be treated with caution for estimating chronic intake.
- Estimates of acute (short-term) intake can be derived when considered necessary because of potential acute adverse effects on health.
- When a number of food additives are included in a group ADI, the intake assessment should cover the whole group of substances.
- An adult body weight of 60 kg is used for intake assessments unless alternative body weights are provided by countries for use with national data.
- Intake assessments based on national data on food consumption and maximum levels of use specified in the draft GSFA should state whether all the food categories proposed for use in the draft GSFA have been considered or only those food categories permitted in national standards.

- Food consumption data reported on an "as consumed" basis should be grouped according to the food classification system used in the draft GSFA (Appendix C).

It is important to distinguish between the relative contributions of variability and uncertainty to the accuracy and precision of intake estimates. When using the various methods itemized in this section for assessing intake, it is important to note that the data may not be strictly comparable even among countries using a particular method due to the following differences:

- duration of the survey;
- number of individuals surveyed;
- population groups selected, such as age/sex groupings;
- average body weights;
- definition of "high-intake" consumers, e.g. 90th percentile consumers;
- chemical levels (depending on whether the maximum levels specified in the draft GSFA are used, or levels are measured); and
- the use of certain methods for collecting data, combining data sets, and estimating consumption of food and/or food additive levels may result in different estimates of food additive intake (see section 2.3 of the report of the fifty-first meeting of JECFA (WHO Technical Report Series No. 891, 2000) for further information).

2.5.1 Assessments based on 'poundage' (disappearance) data

This procedure estimates the amount of a food additive available per capita for use in food manufacturing in a country during a period of time, usually over one year. When appropriate, estimates can take into account the import or export of the food additives and of foods containing the food additive and non-food uses. Estimates may be adjusted to the proportion of the population likely to consume the food additive, as is done in the Procedure for the Safety Evaluation of Flavouring Agents (outlined in recent reports of JECFA at which the Procedure has been used and in Annex 5 of WHO Food Additives Series No. 35, 1996). If this adjustment is not made, the intake of a food additive by individuals actually consuming the food additive may be underestimated.

Relevant information that should be included in this section are the proportion of the population that is assumed to consume the food additive, the year(s) in which the data were collected, assumptions used, estimated intake of the food additive, and percent of the ADI. It is recommended that this information be tabulated as illustrated for sulfites in Table 3.

Table 3. Estimates of intake of sulfites based on 'poundage' data

Country	Date	Assumptions	Estimated intake of sulfites (mg/kg bw per day)	% ADI[a]
Finland	1994	Population, 5.1 million	0.067[b]	10
Spain	NR	Not consumed by 15% of population <3 years	0.48	70
United Kingdom	1984-86	Population, 56 million	1.6	230
United States	1987	Population, 244 million	Mean, 0.38	50
			90th percentile, 0.77	110

NR, not reported

[a]JECFA ADI, 0-0.7 mg/kg bw

[b]The report indicates that data on use in potatoes is missing; the effect of the exclusion is unknown.

2.5.2 Assessments based on data from food balance sheets, household economic surveys, and/or retail sales surveys

Food balance sheet data (population-based method) and household economic surveys and retail sales surveys (both household-based methods) result in improved estimates of daily per capita

intake of food additives, compared to estimates based on 'poundage' data. However, none of them account for household wastage, which would tend to overestimate intake. On the other hand, they may underestimate intake for individuals with high intakes of food additives. The type of survey, year(s) in which it was conducted, assumptions used, estimated intake, and comparison with the ADI should be specified. Table 4 provides an example of tabulation of such information for BHA.

Table 4. Estimates of intake of BHA based on household economic surveys and sales data

Country	Source and year of data	Assumptions	Estimated intake (mg/kg bw per day)	% ADI[a]
Brazil	Sales data, 1992-96	Maximum national use levels for all foods, except chewing gum	0.08	16
		Maximum national use levels, including chewing gum, at GSFA level	0.13	26
	Sales data, 1984-94	Maximum national use levels for all foods, except chewing gum	0.09	18
		Maximum national use levels, including chewing gum, at GSFA level	0.14	28
France	Sales data, year not reported	Maximum European Union levels of use; mean corrected for foods that never contain BHA in France (fats/oils)	0.02 (corrected)	4
			0.08 (uncorrected)	16
		Adjustment for catering outside the home:		
		90th percentile consumers	0.16 (uncorrected)	32
		95th percentile consumers	0.2 (uncorrected)	40
Spain	Household survey, 1993	All foods in permitted groups contain BHA; consumption inside and outside the home; no distinction for subgroups or rural/urban groups	0.25	50

[a]JECFA ADI, 0-0.5 mg/kg bw

2.5.3 Assessments based on model diets

Model diets are constructed from available information on food consumption and are designed to represent a typical diet for the general population or for a specified population group with high intakes of foods containing the food additive. They can be extremely useful in estimating the intake of food additives, but they are only as good as the underlying data and assumptions, which should be stated for each model. The type of survey and year in which it was conducted, assumptions used, type of model, estimated intake, and comparison with the ADI should be specified. The information should be presented as shown in Table 5 for benzoates.

Table 5. Estimates of intake of benzoates based on model diets

Country	Survey (year)	Assumptions	Type of model	Intake (mg/kg bw per day)	% ADI[a]
Aus-NZ	National, 24-h recall; adults, 25-64 yrs; sample size, 6254 (1983)	Two models: Aus-NZ and GSFA - Max. levels (Aus-NZ or GSFA) - modified GSFA classification system - corrections for premixes/drink bases	High consumer[b], Aus-NZ permissions	44	880
			GSFA permissions	11	220
United Kingdom	National; 7-day weighted record (1986-87)	Two models: UK and GSFA - max. levels in the UK - unit quantity diet - GSFA classification system	High consumer[b], UK permissions/adult	32	640
			UK permissions/child	93	1900
			GSFA permissions/adult	43	860
United States	14-day menu obtained from MRCA food frequency data (1982-87) combined with portion sizes from USDA/NFCS; =2 years (1987-88)	Two models: US and GSFA - max. levels in the US or GSFA - GSFA classification system (except FSDU) - corrections for premixes/drink bases	Long-term consumer, GSFA permissions/ mean	27	540
			GSFA permissions, 90th percentile	35	700
			US permissions:		
			Entire population		
			Per capita mean	2.3	46
			Per capita 90th	6.4	130
			Eaters only mean	2.8	
			Eaters only 90th	7.3	150
			Children, 3-11 yrs		
			Per capita mean	3.4	68
			Per capita 90th	8.5	170
			Eaters only mean	3.9	78
			Eaters only 90th	9.3	190

Aus-NZ, Australia-New Zealand; GSFA, General Standard for Food Additives; EU, European Union; MRCA, Market Research Corporation of America; USDA/NFCS, US Department of Agriculture/National Food Consumption Survey; FSDU, foods for special dietary uses

[a]JECFA ADI, 0-5 mg/kg bw

[b]Assumed to consume one food with potentially highest benzoate level from two major food groups at the 95th percentile (Aus-NZ) or 97.5th percentile (United Kingdom) and one food with potentially highest benzoate level from each of the other major food groups at a mean level for all correspondents

2.5.4 Assessments based on individual dietary records

Estimates are based on records of food consumption by individuals within a population. The intake of food additives can be adjusted to individual body weights, if available, before deriving population statistics. The duration of the survey can influence intake estimates, especially for assessments of chronic intake. Such data, assumptions, and conclusions may be summarized as shown in Table 6 for BHA.

Table 6. Estimates of intake of BHA based on individual dietary records

Country	Survey (year)	Assumptions	Model	BHA intake (mg/kg bw per day	% ADI[a]
Aus-NZ	National, 24-h recall; adults, 25-64 yrs; sample size, 6254 (1983)	- max. additive levels (Aus-NZ or GSFA) - modified GSFA classification system - max. additive level within any one group - corrections for premixes/drink bases - reports 95th percentile consumption - adjusted for individual body weight - all respondents were consumers	Mean Aus-NZ Mean GSFA 95th Aus-NZ 95th GSFA	0.39 0.91 1.3 2.5	80 180 260 500
France	National, 5-75 yrs; sample size, 1116 (1993-94)	- max. additive levels (EU) but corrected for foods that never contain BHA in France (fats/oils) - adjusted for catering outside the home - adjusted for individual body weight - reports 90th and 95th percentile consumption - reports by age group	Mean EU Corrected mean EU 90th EU 95th EU	0.07 0.03 0.14 0.16	14 6 28 32
United Kingdom	National; 7-day weighted record; adults, 16-64 yrs (1986-87)	- max. additive levels (EU) - reports 97.5th percentile - GSFA classification system - Assumes average body weight of 60 kg	Mean EU 97.5th EU	0.19 0.45	38 90

Aus-NZ, Australia-New Zealand; GSFA, General Standard for Food Additives; EU, Eureopean Union
[a]JECFA ADI, 0-0.5 mg/kg bw

2.6 Evaluation of estimates of intake

Results of screening by the budget method should be presented first, after which national assessments should be evaluated. The various methods of intake assessment based both on maximum limits in national standards and in the GSFA should be compared, and reasons for differences among countries and methods should be provided. This section would ordinarily go into the report as well as the monograph, so its preparation before the meeting will serve as a draft report item at the meeting. An example of this section is provided in Appendix D.

2.7 Conclusions and recommendations

This section, which will go into the report as well as the monograph, provides the basic conclusions of the evaluation of national assessments based on both maximum limits in national standards and in the GSFA, with recommendations to the Codex as to which food categories in the GSFA contribute the most to intake when the ADI is exceeded. When appropriate, this section should be subdivided into assessments based on national maximum limits, maximum limits in the GSFA, and recommendations to the Codex. An example of this section is provided in Appendix D.

In its recommendations to Codex, the Committee has generally recommended that CCFAC review food additive levels proposed in the draft GSFA for given food categories, based on information provided in national submissions. For example, the maximum level specified for a particular food category may be a major contributor to intake or the maximum level specified in the draft GSFA may be considerably higher than any reported national use.

2.8 References

2.8.1 Citations in the text - References in the text should be in parenthesis following the relevant summaries (e.g. Williams, 1987a; Dalidowicz & Babbitt, 1986; Dalidowicz et al., 1986; Dalidowicz, 1987).

When a report has more than two authors, the first author is followed by "et al.". It should be noted that "et al." is not underlined or italicized, "&" replaces "and", the punctuation must be correct, and several references to the same statement (including more than one by the same author(s)) are placed in chronological order.

When more than one article by the same author(s) in any one year is cited, the year should be followed by the lower-case letters "a", "b", "c", etc.

The names of authors are not always provided. In this case, the name of the organization associated with the generation of the data, followed by the year, should be cited, for example, (IARC, 1983) or (BIBRA, 1976).

Personal communications should be cited only in the text; they should not be included in the reference list. The name of the author, the recipient, and the date should be given. If the original recipient was not the World Health Organization, the submitter of the communication to WHO should be included.

Examples:
(Personal communication from Prof. R. Truhaut, Director, Toxicological Research Centre, Department of Pharmaceutical and Biological Sciences, René Descartes University, Paris, France, to WHO, 1975).

(Personal communication with attachments from R. Patterson, Northwestern University, Evanston, IL, USA, to S.A. Anderson, Federation of American Societies for Experimental Biology (FASEB), Bethesda, MD, USA; submitted to WHO by FASEB).

2.8.2 Reference list at the end of the working paper - The layout indicated below should be used. The order in which the information is presented is particularly important.

References should be listed in alphabetical order. All authors' names and initials should be listed, the name of the first author establishing the placement in the list of references. When more than one article by the same author(s) is cited, they should be placed in chronological order and, as indicated above, the lower-case letters "a", "b", "c", etc., should be used when more than one article by the same author(s) in any one year is cited. Only initial letters are capitalized.

When the name of an author is not available, the organization associated with the generation of the data should be given first in the citation (do not use the word "anonymous").

Translated titles appear in square brackets and the original language in parentheses. Titles of articles originally in French should remain in French.

2.8.2.1 Published studies - References should include authors (if provided), the year of publication, the title of the article, the journal and volume number, and inclusive page numbers. Names of journals should be abbreviated according to the ISDS (International Serials Data System) List of Serial Title Word Abbreviations or otherwise given in full. The initial letter of each abbreviation is capitalized. The volume number is indicated in bold print and is followed by the issue number (if any) in parentheses. First and last page numbers must be given.

Examples:

Dean, I., Jackson, F. & Greenough, R.J. (1996) Chronic (1-year) oral toxicity of erythritol in dogs. *Regul. Toxicol. Pharmacol*., **24**, S254-S260.

IARC (1983) IARC (International Agency for Research on Cancer) monographs on the evaluation of the carcinogenic risk of chemicals to humans: Miscellaneous pesticides, **30**, 329-344.

Laubstein VH & Niedegesass G (1970) [Examination of human sensitivities to nitrofurans]. *Derm Mschr*, **156**, 1-8 (in German).

2.8.2.2 Unpublished studies - The essential elements of unpublished studies that should be included are:

- The name of the author(s) who performed the research work, if provided.
- The year in which the experimental work was completed.
- The title of the experimental study; if the title is in a language other than English, translation of the title into English is preferred (except titles in French).
- Study number, if provided.
- An indication that the study is unpublished.
- The name of the institution at which the experimental study was performed.
- The name of the institution that submitted the report to the World Health Organization.

Examples - These examples provide guidance on the appropriate format to use under varying conditions, including when the names of authors are not provided, when the institution submitting the study to WHO did not perform the study, and when the institution submitting the study to WHO did perform the study.

Baker RC, Mastri CW, Kinoshita FK & Keplinger ML (1976) Acute irritation tests with a sample coded N252-C10406, Lot No. BL7668, in albino rabbits. Unpublished report No. 8530-08861 from Industrial Bio-Test Laboratories, Inc., Northbrook, IL, USA. Submitted to WHO by Uniroyal Inc., Bethany, CT, USA (validated by the Canadian Health Protection Branch).

Bailman JJ & Barber ED (1985) Evaluation of mono-t-butylhydroquine in the CHO/HGPRT forward mutation assay. Unpublished report No. 85-0061 from Health and Environment Laboratories, Eastman Kodak Co., Rochester, NY, USA. Submitted to WHO by Eastman Kodak Co., Kingsport, TN, USA.

BIBRA (1976) A study of the haematological effects of caramel in human volunteers. Unpublished report No. 1/172/76 from the British Industrial Biological Research Association, Carshalton, Surrey, England. Submitted to WHO by International Technical Caramel Association.

Herken, H. (1961) [Pharmacological expertise on tolerance to natural and synthetic menthol.] Unpublished report from Pharmakologischen Institut der Freien Universität, Berlin. Submitted to WHO by Schering AG, Berlin, Germany (in German).

2.8.2.3 Conference proceedings - The following elements are necessary: Name(s) and initial(s) of author(s), the year of publication, title of paper, the word "In:" the editors of the proceedings; the full title of the conference (not abbreviated); the place and date of the conference; the place of publication; the publisher; the volume number (if any) and the page numbers.

Example:

Wassermann M (1984) L'étude de la toxicologie des pesticides en climat tropical In: Smith JH ed. Proceedings of the 14th international Congress of Occupational Health, Madrid, 16-21 May 1983. Amsterdam, Excerpta Medica, vol 3, 1728-1733.

2.8.2.4 Books

Examples:

Windholz M ed. (1983) The Merck Index: an encyclopedia of chemicals, drugs, and biologicals, 10th ed. Rahway, New Jersey, Merck and Co., Inc.

Reference to a chapter in a book should be given as follows:

Rall TW (1990) Oxytocin, prostaglandins, ergot alkaloids, and other drugs; tocolytic agents. In: Gilman AG, Rall TW, Nies AS & Taylor P eds. the pharmacological basis of therapeutics, eighth edition. New York, Pergamon Press, pp 933-953.

2.8.2.5 Agency reports

Example:

US EPA (1984) Mercury health effects update: health issue assessment. Washington, DC, US Environmental Protection Agency (EPA-60018-84-019F).

2.8.3 Order of entries in the list

The following rules are applied:

a) Several papers by different authors with the same surname are listed alphabetically according to their initials.
b) Several papers by one author are listed chronologically.
c) Several papers by the author plus a co-author are listed alphabetically.
d) Several papers by the author plus two or more coauthors are listed chronologically.

Examples:

Smith DE (1985)
Smith JH (1983)
Smith JH (1984)
Smith JH & Barns MP (1986)
Smith JH & Jones TD (1979)
Smith JH, Jones TD, & Barnes MP (1981)
Smith JH, Barnes MP, & Jones TD (1983)

3. Working papers prepared in conjunction with toxicological evaluations

Elements of the structure outlined in section 2 can be used for food additives with a long history of use. For food additives that have been introduced to the market recently, only predictions of intake can be made based on proposed uses, proposed maximum use levels, and food consumption patterns. Therefore, the structure and content of such working papers will vary a great deal from one food additive to another. Appendix E provides an example of a working paper on a new food additive.

Appendix A

Working paper pattern

This appendix provides the format that should be used in preparing working papers on intake of food additives with a long history of use for the Joint FAO/WHO Expert Committee on Food Additives. Close adherence to this pattern will facilitate the editing of those working papers that are subsequently published as monographs.

Please adhere to the heading hierarchy shown in this appendix. The headings are indented here to clearly show the hierarchy, but they should not be indented in the text. The headings should be indented as shown in this appendix in the table of contents at the beginning of the working paper. Boldfacing should be used with all titles.

TITLE

Table of contents

Appendix B

Data request sheets

The information in this appendix was developed to provide guidance to countries submitting their national assessments of intake. It is included in the guidelines so that authors of working papers will understand the basis for the submissions.

There are four approaches to estimating food additive intake that can be used at a national level if the screening process has indicated a need for further intake assessments. The approach(es) you use in your country will depend on the food consumption data and data on use of the food additive that you have available. All countries are requested to use the maximum food additive levels in the draft Codex General Standard for Food Additives (GSFA). Additional calculations using national additive usage data, are also requested when such data are available.

In all cases, each country should state clearly in their report to JECFA the maximum food additive use levels and the foods/food groups used in each intake assessment.

'Poundage' data: combines the amount of food additive available for use in processed foods with total population figures (see information sheet 1).

Food balance sheet data/household survey data: combines food available for use per capita from food balance sheets or household economic/consumption surveys with food additive usage data from GSFA or national data (see information sheet 2).

Model diets: combines a model diet, usually for specific population subgroups, constructed from information on food consumption with food additive usage data from GSFA or national data (see information sheet 3).

Individual dietary records: combines food consumption data for individuals from representative national surveys with food additive usage from GSFA or national data (see information sheet 4).

A fifth approach to intake assessments using *duplicate diet surveys* may also be undertaken where a problem has been identified for specific additives in a specific region or population subgroup. Duplicate diet surveys are not generally suitable for use in making national assessments of food additive intake. There is no information sheet for this method.

National intake assessments using 'poundage data'

'Poundage' data are based on the amount of the food additive that is available for use in food manufacturing in the country. Data from food additive manufacturers are required for this calculation. Preferably data should be a yearly average over a 5-year period, particularly when the food additive is not manufactured every year.

The amount of the food additive available for use = the amount manufactured in the country + imports - exports - non-food uses.

To calculate the amount of food additive available per person in the population, the total amount of food additive available per year is divided by the total population figure and adjusted to a daily intake.

$$\text{Amount of food additive/person per day} = \frac{\text{Amount of food additive available for use per year}}{\text{Total population figure} \times 365}$$

Data can be expressed per kilogram body weight, assuming an average body weight of 60 kg.

$$\text{Amount of food additive/kg bw per day} = \frac{\text{Amount of food additive/person per day}}{60}$$

Additional factors may be used to account for the degree of under-reporting of food additive manufactured, the percent of the population consuming the foods likely to contain the additive, and for high consumers of foods likely to contain the additive. If an additive is known to be consumed only by a specific population subgroup, or by a low percentage of the population, factors to account for the number of consumers should be used in the calculations.

Information sheet 1

Country:
Name of respondent: **Contact address and e-mail**:

Name of food additive:
JECFA ADI:
National ADI (use in calculations if different from JECFA ADI):

(a) Amount of food additive produced =
(b) Amount of food additive exported =
(c) Amount of food additive imported =
(d) Amount of food additive not used in food =

Total food additive available for use = a + c - b - d =

Other factors accounted for in poundage data calculations:

Type of factor	Factor used	How was factor derived?
Under-reporting		
Consumers only		
High consumers		

Estimated food additive intake/person per day =
Potential range of food additive intake/person per day =

National intake assessments using food balance sheets or household surveys

Food balance sheet/household survey data are combined with food additive usage data to give an estimate of food additive intakes. For an estimation of food additive intake, additional information is required to be able to use food balance sheet data: the percentage of the commodity available for use that is processed and is likely to contain the additive.

Household economic or consumption surveys may provide information on the processed food available at a household level for consumption.

Food balance sheet (FBS) data are based on food available for consumption (as raw commodities), not food actually consumed. The food available for consumption is estimated by taking into account food production (commercial and estimated home production), food imports, exports and estimated non-food use and waste. Household waste is not taken into account. National FBS data, FAO standardized Food Balance Sheets, or GEMS/FOOD regional diets can be used. Total population figures are used to derive the amount of commodities available per capita/year, and can be presented as the amount of commodity available per capita/day.

The amount of raw commodity available for consumption = amount of raw commodity produced in the country + imports - exports - non-food uses and wastage.

Amount of commodity available for consumption/person per day =

$$\frac{\text{total amount of commodity available for consumption}}{\text{total population} \times 365}$$

To assess food additive intake, the percentage of the commodity that has been processed and is likely to contain the food additive should be taken into account.

Amount of commodity likely to contain food additives/person per day = amount of commodity available/person per day
x % total commodity which is processed
x % processed food likely to contain the additive.

Food additive data used in calculations can be derived from national food standards, or where appropriate, from Codex standards or from food manufacturers. Maximum levels of use are those permitted in food standards. If available, data on manufacturers' level of use of the additive can be used in the calculations. Where food additives are listed as used at GMP (good manufacturing practice) levels, it should be noted what numerical value has been assigned to the food/food groups for the food additive level in the intake assessment.

Food additive intake estimates are derived by combining adjusted per capita food balance sheet data or household consumption data with food additive usage levels for each food/food group and summing across the whole diet.

Information sheet 2

Country:
Name of respondent: **Contact address and e-mail**:

Name of food additive:
JECFA ADI:
National ADI (use in calculations if different from JECFA ADI):

Food consumption data

Source of data	Date of survey	Comments
National food balance sheet **or** Regional food balance sheets **or** Household survey	GEMS/FOODS	

For food balance sheet data:

Commodity	% total food supply which is processed	% processed food likely to contain the additive

NOTE: it would be useful to use the codes and names for commodities used in GEMS/Food data sets if possible

Household economic/consumption surveys: it would be useful to list the food groups for which data was collected, as for the food balance sheet data.

Food additive usage data

Food/food group	Maximum level of use	Manufacturers level of use

NOTE: Food additive standards usually refer to processed food and not raw commodities, therefore some adjustments may have to be made to present data from food balance sheets or household consumption surveys according to the food groups used in additive food standards.

Estimated food additive intake/person per day =
Potential range of food additive intake/person per day =

National intake assessments using model diets

Model diets can be constructed from available information on food consumption to represent a typical diet of a specified population subgroup, for example young children or high consumers of foods containing the food additive. Food consumption data from the model diet are then combined with food additive usage data to estimate total food additive intakes. The values that are chosen to represent food consumption and food additive usage levels will depend on the purpose of the model.

In the model diet approach to intake assessments a range of assumptions are made in constructing the model diet and in combining the diet with food additive data. These assumptions should always be listed with the intake assessment. For example, a food additive permission may be given for cheese only but it may have been assumed that the additive is used in all dairy products, not just in cheese. Where food additives are listed as used at GMP (good manufacturing practice) levels, it should be noted what numerical value has been assigned to the food/food groups for the food additive level in the intake assessment. The food consumption level for high

consumers which has been assumed in the model diet should also be listed, for example, the 90th percentile consumption level for consumers only.

When a food classification system has been used (food consumed is grouped into specified food groups), details of the system should be listed. It is very important that food classification information is listed and that any assumptions used in constructing the model diet and in the intake assessment are listed, because this information is crucial for interpreting the results of the intake assessment.

Information sheet 3

Country:
Name of respondent: **Contact address and e-mail**:

Name of food additive:
JECFA ADI:
National ADI (use in calculations if different from JECFA ADI):

Model diet used:

Population subgroup:
Source of food consumption data:
name of survey:
date of survey:
type of survey:
sample size:
If data from another source, please give details:

Food group	**Amount of food consumed (g/day)**

NOTE: it would be useful to use the food group names from the Codex classification system for food additives if possible

Food additive usage data

Food/food group	Maximum level of use	Manufacturers level of use

NOTE: it would be useful to use the food group names from the Codex classification system for food additives if possible

Food classification system used in intake assessment:
Assumptions made in calculations:

Estimated food additive intake/day =
Range of potential food additive intakes/day =

National intake assessments using individual dietary records

This approach should only be used when representative national dietary surveys are available. Intake estimates are derived by combining, for each individual, records of food consumed which are likely to contain the additive with food additive usage data. The information derived on food additive intakes for the population surveyed can be reported in a variety of ways, depending on the purpose of the assessment. Typically, results are reported as:

Whole population	mean food additive intakes median food additive intakes
Consumers only	mean food additive intakes median food additive intakes (50th percentile) high-percentile food additive intakes (90th, 95th, 97.5th)

This approach provides the best estimate of food additive intakes and estimates can be further improved by using market-share data to better represent the food additive levels used in specific foods. Special surveys that record food consumption data by brand name will also provide better estimates of food additive intakes.

In intake assessments using individual dietary records a range of assumptions are made in describing food consumption by food or food group, in assigning food additive levels to foods/food groups and in combining the two data sets. These assumptions should always be listed with the intake assessment. For example, a food additive permission may be given for cheese only but it may have been assumed that the additive is used in all dairy products, not just in cheese. Where additives are listed as used at GMP (good manufacturing practice) levels, it should be noted what numerical value has been assigned to the food/food groups for the food additive level in the intake assessment. The food consumption level for high consumers which has been assumed in the intake assessment should also be listed, for example, the 90th percentile consumption level for consumers only. It is very important that any such assumptions are listed because this information is crucial for interpreting the results of the intake assessment.

Information sheet 4

Country:
Name of respondent: **Contact address and e-mail**:

Name of food additive:
JECFA ADI:
National ADI (use in calculations if different from JECFA ADI):

Food consumption data

name of survey:
date of survey:
type of survey:
sample size:

Food additive usage data

Food/food group	Maximum level of use	Manufacturers level of use

NOTE: it would be useful to use the food group names from the Codex classification system for food additives if possible

Food classification system used in intake assessment:
Assumptions made in calculations:

Additional factors used (for example, market share data):

Estimated food additive intakes =
Range of potential food additive intakes/day =

Appendix C

Food categorization system for the General Standard for Food Additives[2]

1. Dairy products, excluding products of category 2
   - 1.1 Milk and dairy-based drinks
     - 1.1.1 Milk and buttermilk
       - 1.1.1.1 Milk, including sterilized and UHT goats' milk
       - 1.1.1.2 Buttermilk (plain)
     - 1.1.2 Dairy-based drinks, flavoured and/or fermented (e.g. chocolate milk, cocoa, egg-nog)
   - 1.2 Fermented and renneted milk products (plain), excluding drinks
     - 1.2.1 Fermented milks (plain)
       - 1.2.1.1 Fermented milks (plain), not heat-treated after fermentation
       - 1.2.1.2 Fermented milks (plain), heat-treated after fermentation
     - 1.2.2 Renneted milk
   - 1.3 Condensed milk (plain) and analogues
     - 1.3.1 Condensed milk (plain)
     - 1.3.2 Beverage whiteners
   - 1.4 Cream (plain) and similar products
     - 1.4.1 Pasteurized cream
     - 1.4.2 Sterilized, UHT, whipping or whipped and reduced-fat creams
     - 1.4.3 Clotted cream
     - 1.4.4 Cream analogues
   - 1.5 Milk and cream powders (plain)
     - 1.5.1 Milk and cream powders
     - 1.5.2 Milk and cream powder analogues
   - 1.6 Cheese
     - 1.6.1 Unripened cheese
     - 1.6.2 Ripened cheese
       - 1.6.2.1 Total ripened cheese, including rind
       - 1.6.2.2 Rind of ripened cheese
       - 1.6.2.3 Cheese powder (for reconstitution, e.g. for cheese sauces)
     - 1.6.3 Whey cheese
     - 1.6.4 Processed cheese
     - 1.6.5 Cheese analogues
   - 1.7 Dairy-based desserts (e.g, ice cream, ice milk, pudding, fruit or flavoured yoghurt)
   - 1.8 Whey and whey products, excluding whey cheese

2. Fats and oils and fat emulsions (type water-in-oil)
   - 2.1 Fats and oils essentially free from water
     - 2.1.1 Butter oil, anhydrous milk fat, ghee
     - 2.1.2 Vegetable oils and fats
     - 2.1.3 Lard, tallow, fish oil and other animal fats

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[2] Reproduced, with minor editorial corrections, from *Draft Codex General Standard for Food Additives* (Rome, Food and Agriculture Organization of the United Nations, 1999; unpublished document FX/FAC 99/6) by permission of the publisher.

2.2 Fat emulsions mainly of type water-in-oil
- 2.2.1 Emulsions containing at least 80% fat
  - 2.2.1.1 Butter and concentrated butter
  - 2.2.1.2 Margarine and similar products (e.g. butter-margarine blends)
- 2.2.2 Emulsions containing less than 80% fat (e.g. margarine)

2 3 Fat emulsions other than 2.2, including mixed and/or flavoured products based on fat emulsions

2.4 Fat-based desserts (excluding dairy-based desserts)

3 Edible ices, including sherbet and sorbet

4 Fruits and vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes) and nuts and seeds
- 4.1 Fruit
  - 4.1.1 Fresh fruit
    - 4.1.1.1 Untreated fruit
    - 4.1.1.2 Surface-treated fruit
    - 4.1.1.3 Peeled or cut fruit
  - 4.1.2 Processed fruit
    - 4.1.2.1 Frozen fruit
    - 4.1.2.2 Dried fruit
    - 4.1.2.3 Fruit in vinegar, oil or brine
    - 4.1.2.4 Canned or bottled (pasteurized) fruit
    - 4.1.2.5 Jams, jellies and marmalades
    - 4.1.2.6 Fruit-based spreads other than 4.1.2.5 (e.g. chutney)
    - 4.1.2.7 Candied fruit
    - 4.1.2.8 Fruit preparations, including pulp and fruit toppings
    - 4.1.2.9 Fruit-based desserts, including fruit-flavoured water-based desserts
    - 4.1.2.10 Fermented fruit products
    - 4.1.2.11 Fruit fillings for pastries
    - 4.1.2.12 Cooked or fried fruit
- 4.2 Vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes) and nuts and seeds
  - 4.2.1 Fresh vegetables
    - 4.2.1.1 Untreated vegetables
    - 4.2.1.2 Surface treated vegetables
    - 4.2.1.3 Peeled or cut vegetables
  - 4.2.2 Processed vegetables and nuts and seeds
    - 4.2.2.1 Frozen vegetables
    - 4.2.2.2 Dried vegetables
    - 4.2.2.3 Vegetables in vinegar, oil or brine
    - 4.2.2.4 Canned or bottled (pasteurized) vegetables
    - 4.2.2.5 Vegetable, nut and seed purees and spreads (e.g. peanut butter)
    - 4.2.2.6 Vegetable, nut and seed pulps and preparations other than 4.2.2.5
    - 4.2.2.7 Fermented vegetable products
    - 4.2.2.8 Cooked or fried vegetables

5 Confectionery
- 5 1 Cocoa products and chocolate products, including imitations and chocolate substitutes
  - 5.1.1 Cocoa mixes (powders and syrups)
  - 5.1.2 Cocoa-based spreads, including fillings
  - 5.1.3 Cocoa and chocolate products other than 5.1.1, 5.1.2 and 5.1.4 (e.g. milk chocolate bars, chocolate flakes, white chocolate)
  - 5.1.4 Imitation chocolate and chocolate substitute products
- 5.2 Sugar-based confectionery other than 5.1, 5.3 and 5.4, including hard and soft candy and nougats
- 5.3 Chewing gum
- 5.4 Decorations (e.g. for fine bakery wares), toppings (non-fruit) and sweet sauces

6 Cereals and cereal products, including flours and starches from roots and tubers, and pulses and legumes, excluding bakery wares
- 6.1 Whole, broken or flaked grain, including rice
- 6.2 Flours and starches
- 6.3 Breakfast cereals, including rolled oats
- 6.4 Pastas and noodles
- 6.5 Cereal and starch-based desserts (e.g. rice pudding, tapioca pudding)
- 6.6 Batters (e.g. for fish or poultry)

7 Bakery wares
- 7.1 Bread and ordinary bakery wares
  - 7.1.1 Breads and rolls
  - 7.1.2 Crackers, excluding sweet crackers
  - 7,1.3 Other ordinary bakery products (e.g. bagels, pitta, English muffins)
  - 7.1.4 Bread-type products, including bread stuffing and breadcrumbs
- 7.2 Fine bakery wares
  - 7.2.1 Cakes, cookies and pies (e.g. fruit-filled or custard types)
  - 7.2.2 Other fine bakery products (e.g. doughnuts, sweet rolls, scones and muffins)
  - 7.2.3 Mixes for fine bakery wares (e.g. cakes, pancakes)

8 Meat and meat products, including poultry and game
- 8.1 Fresh meat, poultry and game
  - 8.1.1 Fresh meat, poultry and game, whole pieces or cuts
  - 8.1.2 Fresh meat, poultry and game, comminuted
- 8.2 Processed meat, poultry and game products in whole pieces or cuts
  - 8.2.1 Non-heat-treated processed meat, poultry and game products in whole pieces or cuts
    - 8.2.1.1 Cured (including salted) non-heat-treated processed meat, poultry and game products in whole pieces or cuts
    - 8.2.1.2 Cured (including salted) and dried non-heat-treated processed meat, poultry and game products in whole pieces or cuts
    - 8.2.1.3 Fermented non-heat-treated processed meat, poultry and game products in whole pieces or cuts
  - 8.2.2 Heat-treated processed meat, poultry and game products in whole pieces or cuts
  - 8.2.3 Frozen processed meat, poultry and game products in whole pieces or cuts

- 8.3 Processed comminuted meat, poultry and game products
  - 8.3.1 Non-heat-treated processed comminuted meat, poultry and game products
    - 8.3 1.1 Cured (including salted) non-heat-treated processed comminuted meat, poultry and game products
    - 8.3.1.2 Cured (including salted) and dried non-heat-treated processed comminuted meat, poultry and game products
    - 8 3.1.3 Fermented non-heat-treated processed comminuted meat, poultry and game products
  - 8.3.2 Heat-treated processed comminuted meat, poultry and game products
  - 8.3.3 Frozen processed comminuted meat, poultry and game products
- 8.4 Edible casings (e.g. sausage casings)

9 Fish and fish products, including molluscs, crustaceans and echinoderms
- 9.1 Fresh fish and fish products, including molluscs, crustaceans and echinoderms
  - 9.1.1 Fresh fish
  - 9.1.2 Fresh molluscs, crustaceans and echinoderms
- 9.2 Processed fish and fish products, including molluscs, crustaceans and echinoderms
  - 9.2.1 Frozen fish, fish fillets and fish products, including molluscs, crustaceans and echinoderms
  - 9.2.2 Frozen battered fish, fish fillets and fish products, including molluscs, crustaceans and echinoderms
  - 9.2.3 Frozen minced and creamed fish products, including molluscs, crustaceans and echinoderms
  - 9.2.4 Cooked and/or fried fish and fish products, including molluscs, crustaceans and echinoderms
    - 9 2.4.1 Cooked fish
    - 9.2.4.2 Cooked molluscs, crustaceans and echinoderms
    - 9 2.4.3 Fried fish and fish products, including molluscs, crustaceans and echinoderms
  - 9.2.5 Smoked, dried, fermented and/or salted fish and fish products, including molluscs, crustaceans and echinoderms
- 9.3 Semi-preserved fish and fish products, including molluscs, crustaceans and echinoderms
  - 9.3.1 Fish and fish products, including molluscs, crustaceans and echinoderms, marinated and/or in jelly
  - 9 3.2 Fish and fish products, including molluscs, crustaceans and echinoderms, pickled and/or in brine
  - 9 3.3 Salmon substitutes, caviar and other fish roe products
  - 9.3.4 Semi-preserved fish and fish products, including molluscs, crustaceans and echinoderms other than 9.3,1-9.3,3
- 9.4 Fully preserved (including canned or fermented) fish and fish products, including molluscs, crustaceans and echinoderms

10 Eggs and egg products
- 10.1 Fresh eggs
- 10.2 Egg products
  - 10.2.1 Liquid egg products
  - 10.2.2 Frozen egg products
  - 10.2.3 Dried and/or heat-coagulated egg products
- 10 3 Preserved eggs, including alkaline. salted and canned eggs
- 10.4 Egg-based desserts (e.g. custard)

11 Sweeteners, including honey
- 11.1 White and semi-white sugar (sucrose or saccharose), fructose, glucose (dextrose), xylose, sugar solutions and syrups, and (partially) inverted sugars, including molasses, treacle and sugar toppings
- 11.2 Other sugars and syrups (e.g. brown sugar, rnaple syrup)
- 11.3 Honey
- 11.4 Table-top sweeteners, including those containing high-intensity sweeteners, other than 11.1-11.3

12 Salts, spices, soups, sauces, salads, protein products, etc.
- 12.1 Salt
- *12.2* Herbs, spices, seasonings (including salt substitutes) and condiments
- 12.3 Vinegars
- 12.4 Mustards
- 12.5 Soups and broths
  - 12.5.1 Ready-to-eat soups and broths, including canned, bottled and frozen
  - 12.5.2 Mixes for soups and broths
- 12.6 Sauces and similar products
  - 12.6.1 Emulsified sauces (e.g. mayonnaise, salad dressing)
  - 12.6.2 Non-emulsified sauces (e.g. ketchup, cheese sauce, cream sauce, brown gravy)
  - 12.6.3 Mixes for sauces and gravies
- 12.7 Salads (e.g. macaroni salad, potato salad) and sandwich spreads (excluding cocoa- and nut-based spreads)
- 12.8 Yeast
- 12.9 Protein products

13 Foodstuffs intended for particular nutritional uses
- 13.1 Infant formulae and follow-on formulae
- 13.2 Foods for young children (weaning foods)
- 13.3 Dietetic foods intended for special medical purposes
- 13.4 Dietetic formulae for slimming purposes and weight reduction
- 13.5 Dietetic foods other than 13.1-13.4
- 13.6 Food supplements

14 Beverages, excluding dairy products
- 14.1 Non-alcoholic ("soft") beverages
  - 14.1.1 Waters
    - 14.1.1.1 Natural mineral waters and source waters
    - 14.1.1.2 Table waters and soda waters
  - 14.1.2 Fruit and vegetable juices
    - 14.1.2.1 Canned or bottled (pasteurized) fruit juice
    - 14.1.2.2 Canned or bottled (pasteurized) vegetable juice
    - 14.1.2 3 Concentrates (liquid or solid) for fruit juice
    - 14.1.2.4 Concentrates (liquid or solid) for vegetable juice
  - 14 1.3 Fruit and vegetable nectars
    - 14.1.3.1 Canned or bottled (pasteurized) fruit nectar
    - 14 1.3.2 Canned or bottled (pasteurized) vegetable nectar
    - 14.1.3.3 Concentrates (liquid or solid) for fruit nectar
    - 14.1.3.4 Concentrates (liquid or solid) for vegetable nectar

- 14.1.4 Water-based flavoured drinks, including "sport" or “electrolyte” drinks
  - 14.1.4.1 Carbonated drinks
  - 14.1.4.2 Non-carbonated drinks, including punches and ades
  - 14.1.4.3 Concentrates (liquid or solid) for drinks
- 14.1.5 Coffee. coffee substitutes, tea, herbal infusions and other hot cereal beverages, excluding cocoa

14.2 Alcoholic beverages, including alcohol-free and low-alcoholic counterparts

- 14.2.1 Beer and malt beverages
- 14.2.2 Cider and perry
- 14.2.3 Wines
  - 14.2.3.1 Still wine
  - 14.2.3.2 Sparkling and semi-sparkling wines
  - 14.2.3.3 Fortified wine and liquor wine
  - 14.2.3.4 Aromatized wine
- 14 2.4 Fruit wine
- 14.2.5 Mead
- 14.2.6 Spirituous beverages
  - 14.2.6.1 Spirituous beverages containing at least 15% alcohol
  - 14.2.6.2 Spirituous beverages containing less than 15% alcohol

15 Ready-to-eat savouries

- 15.1 Snacks, potato-, cereal-, flour- or starch-based (from roots and tubers, pulses and legumes)
- 15.2 Processed nuts, including coated nuts and nut mixtures (with e.g. dried fruit)

16 Composite foods (e.g. casseroles, meat pies, mincemeat) – foods that could not be placed in categories 1-15

Appendix D

Sample evaluation and conclusion and recommendation sections

EVALUATION OF ESTIMATES OF INTAKE OF BHT

Screening of BHT by the budget method indicated that use of BHT as a food additive requires further assessment. Inclusion of national proportions of the food supply that may contain BHT in the budget method of screening did not change this decision.

Estimates of the intake of BHT were submitted by 10 countries. All of the estimates based on model diets or individual consumption data combined with GSFA levels of use show that the ADI is consistently exceeded. The mean intake was estimated to be between 0.70 and 0.99 mg/kg bw (230 and 240% of the ADI for China and the United States), and the intake of high consumers was estimated to be 2.0-6.0 mg/kg bw (690-2000% of the ADI).

Intake estimates based on national levels of use were consistently below the ADI, ranging from 0 to 0.11 mg/kg bw per day (0-30% of the ADI) on the basis of 'poundage', 0.052-0.1 mg/kg bw per day (20-40% of the ADI) on the basis of household surveys or sales data, 0.02-0.09 mg/kg bw per day (10-30% of the ADI) on the basis of model diets and national levels of use (except for the United States), and 0.02-0.1 mg/kg bw per day (0.1-30% of the ADI) on the basis of indi-vidual consumption data.

Two exceptions must be noted. The first is estimates for mean and high consumption based on a model diet and authorized levels of use in the United States (0.39 and 0.78 mg/kg bw per day and 130 and 260% of the ADI, respectively). This result can be explained by the high levels of BHT authorized in that country. The second is the low estimate (0.00089 mg/kg bw per day or 0.003% of the ADI) in the study provided by Japan, which was based on the concentrations of BHT found in a total diet survey.

CONCLUSIONS AND RECOMMENDATIONS

The Committee concluded that the ADI for BHT is unlikely to be exceeded on the basis of the estimated intakes in the 10 countries for which data were available but that it might be exceeded when the proposed maximum limits in the GSFA are assumed.

The Committee recognized that BHT is likely to be used in conjunction with other antioxidants, such as TBHQ and BHA, which act synergistically with BHT. Consequently, the amount of BHT used in practice will be lower and it will be used in fewer foods than assumed in the estimates. All of the estimates except those from Japan are based on the assumption that BHT is the only antioxidant in foods where use is permitted and that all such foods contain it at maximum permitted levels. The actual intake of BHT will depend on the relative proportions of antioxidants used in foods and on the proportion of foods in any one category that contains the additive.

Recommendations to the Codex Committee on Food Additives and Contaminants

The Committee identified certain food groups that could potentially contribute to a high intake of BHT. The Codex Committee may wish to review the appropriate levels of BHT in the following food groups: category 2.1, 'fats and oils essentially free from water'; category 5.3, 'chewing gum'; and category 9.2, 'processed fish and fish products'.

Appendix E

Sample working paper for food additive for which Intake is predicted

ESTIMATE OF DIETARY INTAKE

?-Cyclodextrin can be used as a carrier for flavours, sweeteners, and colours, and it has been proposed for use in this manner in dry mixes for beverages, soups, dressings, gravies, sauces, puddings, gelatines, and fillings and also in instant coffee and instant tea, coffee whiteners, compressed sweets, chewing gum, breakfast cereals, savoury snacks, crackers, and spices and seasonings. It is also proposed for use as a carrier for vitamins and polyunsaturated fatty acids in dry food mixes and in dietary supplements, as a flavour modifier in soya milk, and as a stabilizer in bread spreads, frozen dairy desserts, baked goods, bread, fruit-based fillings, fat-based fillings, processed cheese, and dairy desserts.

The estimated daily intake of ?-cyclodextrin in the United States from its use in food has been calculated by the dietary survey approach (Amann et al., 1998), which is based on food consumption data from the 1989-91 Continuing Survey of Food Intakes by Individuals, in which data were collected from a representative sample of individuals residing in households in the United States. Each individual was surveyed over three successive one-day periods, and the foods consumed were coded into one of about 6000 different categories. For the purposes of the calculation, it was assumed that each food (or food component) contains ?-cyclodextrin at the highest feasible concentration. When ?-cyclodextrin was used as a component of the food, the intake of ?-cyclodextrin was calculated from data on food consumption. The estimated daily intake was calculated for each food in which ?-cyclodextrin may be used from data on one- and three-day average food intake. Intakes were calculated both *per capita* and per user. Users were defined as individuals who consumed a food of at least one of the categories concerned on at least one occasion.

The largest amounts of ?-cyclodextrin are consumed with soya milk and dairy desserts. Relatively high intakes (> 2 g/day) also result from its use in bread spreads and fruit-based fillings. The mean one-day intake of ?-cyclodextrin from all its food uses was estimated to be 4.1 g. The 90th percentile user was estimated to ingest about 8.8 g on any one day. The three-day average intakes are 4 g for the average consumer and 7.5 g for the 90^{th} percentile consumer. The intake of ?-cyclodextrin from chewing gum was estimated from a separate survey on chewing-gum intake in the United States, and the average consumer was estimated to ingest about 0.07 g ?-cyclodextrin per day. These data represent a 'worst-case' scenario and are based on the assumption that ?-cyclodextrin is used simultaneously in all possible applications and at the highest feasible concentrations. The realistic average daily intake of ?-cyclodextrin would therefore be lower than the levels indicated above.