CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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CODEX COMMITTEE ON FOOD ADDITIVES

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DISCUSSION PAPER ON THE REVISION OF THE *GUIDELINES FOR THE SIMPLE EVALUATION OF FOOD ADDITIVE INTAKE* (CAC/GL 3-1989)

Prepared by an electronic Working Group led by Brazil, with the assistance of Belgium, European Union, Indonesia, Japan, Iran, Italy, Malaysia, Netherlands, Paraguay, Thailand, United Kingdom, United States of America, CCC, IACM, ICGMA, NATCOL and WHO/JECFA Secretariat.

BACKGROUND

1. At its 34th Session, the Commission agreed to request the Codex Committee on Food Additives (CCFA) to consider the need to revoke or revise the following texts: Information on the Use of Food Additives in Foods (CAC/MISC 1-1989); and Guidelines for Simple Evaluation of Food Additive Intake (CAC/GL 03-1989).

2. The 44th Session of the CCFA, that took place in Hangzhou - China, from 12th to 16th of March 2012, agreed to recommend the 35th Session of the Commission to revoke the Information on the Use of Food Additives in Foods (CAC/MISC 1-1989), as its content was already included in the Preamble of the General Standard for Food Additives (GSFA). It further agreed to establish an electronic Working Group, led by Brazil and open to all interested Members and Observers and working in English only, to prepare a project document for new work in the revision of the Guidelines for the Simple Evaluation of Food Additive Intakes (CAC/GL 3-1989) and possibly including an outline of the revised Guidelines, for consideration at its next Session[1].

3. The Committee was of the view that the Guidelines for the Simple Evaluation of Food Additive Intake (CAC/GL 3-1989) contained useful guidance for countries to assess food additive intakes and that it should be revised taking into account the FAO/WHO Principles and Methods for the Risk Assessment of Chemicals in Foods (EHC 240).

INTRODUCTION

4. Exposure assessment is defined within the Codex Alimentarius as "the qualitative and/or quantitative evaluation of the likely intake of biological, chemical, and physical agents via food as well as exposures from other sources if relevant"[2]. It is an essential element for quantifying risk and important to prevent that food additives intake exceeds Acceptable Daily Intakes (ADI).

5. The role of dietary exposure assessment has been central to the work of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) in performing risk assessments on chemicals in foods.

6. In summary, dietary exposure assessment combines food consumption data with data on the concentration of chemicals in food. The resulting dietary exposure estimate may then be compared with the relevant health based guidance value for the food additive of concern, if available, as part of the risk characterization.

[1] REP 12/FA, para. 13

[2] Procedural Manual 20th edition, Section IV: Risk Analysis, p. 113

7. In regard to the work of CCFA, the Codex General Standard for Food Additives – GSFA (Codex Stan 192-1995) states that "the inclusion of a food additive in this Standard shall have taken into account any ADI, or equivalent safety assessment established for the additive by JECFA and its probable daily intake from all food sources. Where the food additive is to be used in foods eaten by special groups of consumers (e.g., diabetics, those on special medical diets, sick individuals on formulated liquid diets), *account shall be taken of the probable daily intake of the food additive by those consumers*". Information regarding the probable daily intake is therefore needed, especially in the case of food additives with low ADI, food additives added in high levels into highly consumed foods, and/or food additives added to foods consumed by special population groups.

8. Some approaches for the estimation of the dietary exposure may be very expensive and time consuming, and countries may therefore have difficulties in undertaking these studies at national level. The Guidelines for the Simple Evaluation of Food Additive Intakes (CAC/GL 3-1989) were then elaborated in order to provide simple guidance to facilitate the dietary exposure assessments of food additives.

9. However, since the adoption of CAC/GL 3-1989, updated references on the subject were made available, including the "Principles and Methods for The Risk Assessment of Chemicals in Food - Environmental Health Criteria (EHC) 240"[3]. In Chapter 6 of the EHC 240, a summary of approaches to estimating dietary exposure (intake) is provided, with consideration of the concentration and food consumption data sets that may be used to derive these estimates.

DISCUSSION BY THE eWG

10. Two drafts were circulated for comments within the electronic Working Group, based on the FAO/WHO Principles and Methods for the Risk Assessment of Chemicals in Foods (EHC 240), as agreed by 44th meeting of CCFA.

11. For the first draft, the eWG was also invited to address and comment the following questions:

- Are there other updated scientific references on food additive exposure assessment that may be taken into account for the revision of CAC/GL 3-1989?
- Is the simple approach for the evaluation of food additive intake proposed in the document (Theoretical Maximum Daily Intake - TMDI and Estimated Daily Intake - EDI) still appropriate? Please provide detailed information on other possible approaches for the simple evaluation of food additives intake.
- Is it appropriate to review the examples presented in the document (benzoic acid and sweeteners)? If yes, please send proposal(s) or example(s) of food additive dietary exposure assessment.

12. In regard to other scientific references, the eWG provided relevant updated information, but agreed that the discussion should be based on the EHC 240.

13. The eWG considered that approaches of TMDI and EDI were appropriate for the simple evaluation of dietary exposure to food additives, and agreed to retain them in the document.

14. There was general support for the revision of the examples of calculation in the document (benzoic acid and sweeteners). Most participants considered that it would be useful to have some examples as part of the guidelines, but no updated proposal was presented for discussion by this eWG.

15. The second draft also raised the following specific subjects for discussion by the eWG:

- A proposal to delete reference to food additive provisions in Commodity Standards and keep a reference to the GSFA only – this proposal was agreed by the eWG;
- A proposal to change TMDI to "TADMI - Theoretical Added Maximum Daily Intake" – this proposal was not agreed by the eWG;
- Appropriate and practical ways to implement the proposal made by the WHO JECFA Secretariat to base the TMDI on broad food categories (e.g. categories 1 to 16 of the CCFA classification) rather than on foodstuff or food group as mentioned in the text – this proposal was generally supported by the eWG, however, some participants expressed their concerns on the extent of possible overestimation of food additive dietary exposure;

[3] The Food and Agriculture Organization of the United Nations and the World Health Organization, 2009.

- Appropriate and practical ways to implement the proposal made by the WHO JECFA Secretariat regarding a simple modeling of high consumers (EHC 240, page 6-56) for Estimated Daily Intake (EDI): to add up potential dietary exposure to a food chemical at the 97.5th percentile of consumers of the two food categories that lead to the highest dietary exposure (high consumption multiplied by mean actual concentration) with the mean potential exposure for all other food categories (mean consumption for the whole population multiplied by mean actual concentration) – this proposal was generally supported by the eWG; however, further discussion on the methodology is needed;
- The relevance of keeping the note about the Global Environment Monitoring System (GEMS)/Food Consumption Cluster Diets, which is not applicable to assessments of food additives – the eWG agreed to delete the note;
- A proposal to delete reference to the "use at home" of food additives, since it is covered by the GSFA food category system – this proposal was agreed by the eWG.

16. Moreover, major comments referred to the need of standardized format and terminology, in order to ensure consistent application and understanding. The eWG considered appropriate that "consumption" be used to refer to the amount of food consumed and "dietary exposure" to the amount of food additive ingested via food. The term "dietary exposure" is used synonymously with the term "dietary intake", depending upon existing regulatory frameworks or other related considerations[4].

17. For clarity and consistency with the EHC 240 document and the Principles of Risk Analysis, the title of CAC/GL 3-1989 was changed to GUIDELINES FOR SIMPLE EVALUATION OF DIETARY EXPOSURE TO FOOD ADDITIVES. The whole text was revised accordingly in order to incorporate such terminology (see Appendixes II and III).

18. The eWG also agreed that the evaluation of dietary exposure to food additives should be considered in the context of the Risk Analysis Principles, as part of the risk assessment process.

RECOMMENDATION

19. The eWG recommends the Committee to forward the project document presented as Appendix I, on the revision of the *Guidelines for the Simple Evaluation of Food Additive Intakes* (CAC/GL 3-1989), for approval as new work by the Commission.

20. The proposed outline of the revised text, based on the comments sent by the participants, is presented in two versions as Appendixes II and III: one contains a comparison with the original version of CAC/GL 3-1989, with the revisions presented in **bold** font (addition) and ~~strikethrough~~ font (deletion); the other is a "clean version", to facilitate the reading.

21. Recommended topics for further discussions:

- Adaptation of the TMDI method to work as a "screening tool". If the TMDI > ADI then a refined approach should be performed, combining a refined concentration with a high consumption.
- Development of simple approaches to assess the food additives exposure of high consumers, considering the proposed methodologies (TMDI and EDI);
- Development of ways to implement the TMDI assessment based on the broad food categories;
- Clarification on the basis for the establishment of 0-5mg/kg body weight as a "low ADI". This ADI range is included in CAC/GL 3-1989 current text as a prioritization criteria for the simple evaluation of dietary exposure to food additives, although no other reference was found in regard to this assumption
- Revision and update the examples of calculation of simple evaluation of dietary exposure to food additives.

[4] EHC 240. Food and Agriculture Organization of the United Nations and the World Health Organization, 2009, Chapter 6, p. 3.

Appendix I

PROJECT DOCUMENT – PROPOSAL FOR NEW WORK ON THE REVISION OF THE GUIDELINES FOR THE SIMPLE EVALUATION OF FOOD ADDITIVE INTAKE

(CAC/GL 3-1989)

1. Purpose and scope of the proposed new work

The proposal to revise CAC/GL 3-1989 is based on the need to update terminologies, methodologies and examples to the currently adopted text, based on the FAO/WHO Principles and Methods for the Risk Assessment of Chemicals in Foods (EHC 240).

2. Its relevance and timeliness

Considering the request of the 34th Session of the Commission for the CCFA to consider the need to revoke or revise the Guidelines for Simple Evaluation of Food Additive Intake (CAC/GL 03-1989), the Committee has agreed that it contains useful guidance to facilitate the dietary exposure assessments of food additives at national level, and the text needs to be revised according to FAO/WHO updated references, such as the Principles and Methods for the Risk Assessment of Chemicals in Foods (EHC 240), more specifically.

3. Main aspects to be covered

In summary, the revised document should cover the following subjects:

- Dietary Exposure Assessment: Theoretical Maximum Daily Intake (TMDI) and Estimated Daily Intake (EDI);
- Data Available: concentration of food additives in food, regulation of use of food additives, food consumption data and body weight;
- Simple approach for the evaluation of dietary exposure to food additives: criteria for prioritization of evaluation of dietary exposure to food additives and proposed method for a simple evaluation of dietary exposure to additives;
- Examples of calculation.

4. An assessment against the Criteria for the Establishment of Work priorities

The proposal is consistent with the criteria applicable to general subjects:

(a) Diversification of national legislations and apparent resultant or potential impediments to international trade.

Different methodologies may be applied for the estimation of the dietary exposure to food additives. The proposal is to revise the existing document in order to provide updated guidelines for countries to perform simplified assessments.

(b) Scope of work and establishment of priorities between the various sections of the work.

In summary, dietary exposure assessment combines food consumption data with data on the concentration of chemicals in food. The resulting dietary exposure estimate may then be compared with the relevant health based guidance value for the food additive of concern, if available, as part of the risk characterization. The work constitutes of two parts, equally important and useful: the guidelines and the examples of calculation, both need to be revised according to updated data.

(c) Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies).

The proposal mainly rely on the FAO/WHO “Principles and Methods for The Risk Assessment of Chemicals in Food - Environmental Health Criteria (EHC) 240” and the Risk Analysis Principles.

(d) Amenability of the subject of the proposal to standardization.

According to the Codex General Standard for Food Additives – GSFA (CODEX STAN 192-1995), "the inclusion of a food additive in this Standard shall have taken into account any ADI, or equivalent safety assessment established for the additive by JECFA and its probable daily intake from all food sources. Where the food additive is to be used in foods eaten by special groups of consumers (e.g., diabetics, those on special medical diets, sick individuals on formulated liquid diets), account shall be taken of the probable daily intake of the food additive by those consumers". Information regarding the probable daily intake is therefore needed.

(e) Consideration of the global magnitude of the problem or issue.

Some approaches for the estimation of the dietary exposure to food additives may be very expensive and time consuming, and countries may therefore have difficulties in undertaking these studies at national level. The *Guidelines for the Simple Evaluation of Food Additive Intakes* (CAC/GL 3-1989) provide simple guidance to facilitate the assessment.

5. Relevance to codex strategic objectives

The proposal for new work is relevant to Goal 2 of the Codex Alimentarius Commission Strategic Plan 2008-2013 - Promoting Widest and Consistent Application of Scientific Principles and Risk Analysis, with regard to the integration of existing scientific advice from FAO and WHO. The standard also covers the needs of developing countries, allowing them to generate and submit relevant data to Codex and working to ensure that GSFA is applicable globally.

6. Information on the relation between the proposal and other existing Codex documents

The proposal relates to: Preamble to the Codex *General Standard for Food Additives* (GSFA; CODEX STAN 192-1995); Procedural Manual (20th Ed.) Section IV: Risk Analysis; and the "Risk Analysis Principles Applied by the Codex Committee on Food Additives", which was revised by the 44th CCFA and adopted by the 35th CAC (REP 12/FA, para. 21 and Appendix II).

7. Identification of any requirement for and availability of expert scientific advice

FAO/WHO updated references on the subject are available, including the "Principles and Methods for The Risk Assessment of Chemicals in Food - Environmental Health Criteria (EHC) 240"[5]. Moreover, the following Codex texts also provide relevant guidance: Preamble to the Codex General Standard for Food Additives (GSFA; CODEX STAN 192-1995); Procedural Manual (20th Ed.) Section IV: Risk Analysis; and the "Risk Analysis Principles Applied by the Codex Committee on Food Additives".

8. Identification of any need for technical input to the standard from external bodies so that this can be planned for

It is recommended that the Joint FAO/WHO Expert Committee on Food Additives - JECFA participates on the whole revision of the document, since it is the subsidiary scientific body responsible for performing the risk assessments of food additives within Codex, including the evaluation of dietary exposure. Specific questions may be addressed to JECFA during the proposed work.

9. The proposed timeline for completion of the new work

The proposed timeline for completing of the work on the revision is up to two years, after approval by the Commission. If the new work is approved in 2013, the CCFA could start the work in 2014, based on the outline of the proposed revised text presented as Appendix II and III, which was prepared by an Electronic Working Group opened to all Codex Members and Observers. The revised document should be forwarded for adoption by the Commission in 2015.

[5] The Food and Agriculture Organization of the United Nations and the World Health Organization, 2009.

Appendix II

*Proposed revisions are presented in **bold font** (addition) and ~~strikethrough~~ font (deletion)*

GUIDELINES FOR SIMPLE EVALUATION OF ~~FOOD ADDITIVE INTAKE~~ OF DIETARY EXPOSURE TO FOOD ADDITIVES

CAC/GL 03-1989

CONTENTS

1. INTRODUCTION

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

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

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

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

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

The use of food additives is justified only when such use has an advantage, does not present an appreciable health risk to consumers, does not mislead the consumer, and serves one or more technological functions. The quantity of a food additive added to food is the lowest level necessary to achieve the intended technological function[6].

In regard to protecting the health of the consumers, principles for risk analysis have been applied in the framework of the Codex Alimentarius. Risk analysis has been defined by the Codex Alimentarius Commission (CAC) as "a process consisting of three components: risk assessment, risk management and risk communication"[7]. Risk assessment is defined as a scientifically based process consisting of the following steps: 1) hazard identification, 2) hazard characterization, 3) exposure assessment and 4) risk characterization[8].

Risk assessments should be based on realistic exposure scenarios, with consideration of different situations being defined by risk assessment policy. They should include consideration of susceptible and high-risk population groups. Acute, chronic (including long-term), cumulative and/or combined adverse health effects should be taken into account in carrying out risk assessment, where relevant[9].

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) is primarily responsible for performing the risk assessments upon which Codex Committee on Food Additives (CCFA) and ultimately the CAC base their risk management decision[10].

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[6] Preamble to the Codex General Standard for Food Additives (GSFA; CODEX STAN 192-1995, available at www.codexalimentarius.org/codex-home/en/ under the "Standards" menu.

[7] Codex Alimentarius Commission Procedural Manual (20th Ed.) Section IV: Risk Analysis, Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius, p. 105.

[8] Codex Alimentarius Commission Procedural Manual (20th Ed.) Section IV: Risk Analysis, Definitions of Risk Analysis Terms Related to Food Safety, p. 112.

[9] Codex Alimentarius Commission procedural manual, 20th ed. Rome, Food and Agriculture Organization of the United Nations, Codex Alimentarius Commission, p. 115.

[10] Codex Alimentarius Commission Procedural Manual (20th Ed.) Section IV: Risk Analysis, Risk Analysis Principles Applied by the Codex Committee on Food Additives and the Codex Committee on Contaminants in Foods, p. 117. *[NOTE: this text will be superseded by the "Risk Analysis Principles Applied by the Codex Committee on Food Additives" that was forwarded by the 44th CCFA to the 35th CAC for adoption (REP 12/FA, para. 21 and Appendix II). This reference should be updated when the new text is incorporated in the 21st Ed. of the Procedural Manual.]*

The first step on international level in the consideration of the safety assessment of food additives is an evaluation by JECFA, including the establishment of an Acceptable Daily Intake (ADI), and the elaboration of identity and purity criteria. The ADI is an estimate of the amount of a food additive in food or beverages expressed on a body weight basis that can be ingested daily over a lifetime without appreciable health risk to the consumer[11]. It is derived on the basis of all the known facts at the time of the evaluation. The ADI is expressed in milligrams of the chemical per kilogram of body weight[12].

In the second step, proposals for the permitted use of an additive in different foods are made by the responsible national authorities or by the Codex Commodity Committees to the CCFA. The endorsement of the proposed use in a food is done in accordance with the Codex General Standard for Food Additives (GSFA; CODEX STAN 192-1995) which states in its Preamble that "the inclusion of a food additive in this Standard shall have taken into account any ADI, or equivalent safety assessment established for the additive by JECFA and its probable daily intake from all food sources. Where the food additive is to be used in foods eaten by special groups of consumers (e.g., diabetics, those on special medical diets, sick individuals on formulated liquid diets), account shall be taken of the probable daily intake of the food additive by those consumers".

Information regarding the probable daily dietary exposure to food additives is therefore needed, especially in the case of food additives with assigned a low ADI, food additives used at high levels in commonly consumed foods, foods consumed in large quantities and/or food additives used in foods consumed by special population groups.

Different approaches exist regarding the estimation of the probable daily dietary exposure to food additives. Some of these approaches are very expensive and time consuming and may pose difficulties to some countries in initiating such dietary exposure assessments for food additives. Therefore, the present guidelines are intended for a simple evaluation of food additive intake, in order to facilitate the dietary exposure assessments.

~~**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.~~

DIETARY EXPOSURE ASSESSMENT

Dietary exposure assessment[13] combines food consumption data and the concentration of the food additive in food. The resulting dietary exposure estimate may then be compared with the ADI value for the considered food additive, if available, as part of the risk characterization.

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[11] 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 (Preamble to the GSFA).

[12] The methods used to establish health-based guidance value such as an ADI are described in chapter 5 of the publication Principles and Methods for the Risk Assessment of Chemicals in Food - Environmental Health Criteria 240 (EHC 240; Food and Agriculture Organization of the United Nations and the World Health Organization, 2009; www.who.int/foodsafety/chem/principles/en/index1.html), Chapter 5..

[13] The use of standard terminology is recommended to ensure consistent application and understanding. It is recommended that "consumption" be used to refer to the amount of food consumed and "dietary exposure" to the amount of food additive ingested via food. The term "dietary exposure" is used synonymously with the term "dietary intake", depending upon existing regulatory frameworks or other related considerations. Food also includes beverages, drinking-water and food supplements (EHC 240, Chapter 6, p. 3).

Three elements must be taken into account in assessing the dietary exposure to a food additive: (1) concentration of food additive in food; (2) amount of food consumed; and (3) average body weight of the population (kg). The general equation for dietary exposure is:

$$\text{Dietary exposure} = \frac{\Sigma\ (\text{Concentration of food additive in food} \times \text{Food consumption})}{\text{Body weight (kg)}}$$

Different methods exist for estimating probable dietary intake[14]. The method used should be appropriate for the purpose, clearly stated and reproducible. Information about the model and data sources used, assumptions, limitations and uncertainties should also be documented. National or regional data should be used whenever possible.

International dietary exposure assessments should provide exposure estimates that are equal to or greater than the estimates carried out at the national level. It is assumed that the international estimate covers potential dietary exposure in countries for which no data were available.

A stepwise approach is recommended, in which screening methods based on conservative assumptions can be applied to identify, among the large number of food additives that may be present, those of no safety concern, using minimal resources in the shortest possible time. If no safety concerns are identified[15], no additional exposure assessment is required. Where potential safety concerns are identified, the subsequent steps of the framework provide methods that incorporate increasingly specific and refined data (as they also require more resources).

The screening methods are conservative deterministic or point estimates[16] with the aim of identifying the food additives for which a more comprehensive dietary exposure assessment is necessary. Examples of these methods are poundage data, budget method, model diets, as theoretical added maximum daily intakes (TAMDI) and single portion exposure technique (SPET) model diets for flavourings, and theoretical maximum daily intake (TMDI).

The screening methods do not yield true dietary exposure estimates. They should overestimate dietary exposure of high consumers by using conservative assumptions for food consumption and food additive concentration. This overestimation will avoid situations where the dietary exposure estimated by the screening process would erroneously indicate no safety concern (i.e. underestimate exposure). However, in order to effectively screen food additives and establish risk assessment priorities, the first steps of the procedure should not consider unsustainable diets, or the results will be too unrealistic to be useful. At a minimum, physiological limits of food consumption should be taken into account[17].

Further steps to refine the dietary exposure assessment should be designed in such a way that potential high dietary exposure to a food additive is not underestimated. Point estimate modeling may also be appropriate as a second step in a tiered approach. The methodologies should take into consideration non-average individuals, such as those who consume large portions of specific food items (highly exposed consumers, e.g., 90th, 95th, or 97.5th percentiles of food consumption data)[18]. Some consumers who may also be loyal to those foods or brands of food containing the highest concentrations of the food additive or may occasionally consume foods with very high concentrations of the food additive should also be taken into account.

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[14] For more detailed information on the dietary exposure assessment methods, see EHC 240, Chapter 6

[15] For this purpose, there is no safety concern if the estimated dietary exposure to a food additive does not exceed its ADI value.

[16] A deterministic or point estimate of dietary exposure is simply a single value that describes some parameter of consumer exposure. Deterministic models use a single point estimate for each model parameter. For food additive concentration data, the mean, the median, a high percentile of all observed values, or even the maximum use level proposed by national or international food authorities may be used. These food additive concentrations can be further refined using other data (e.g., analytically determined levels of a food additive in food), as appropriate. For food consumption data, consumption at the mean and at a high percentile (e.g., 90th, 95th, 97.5th) for a food is considered for each population of interest (EHC 240, Chapter 6, pp. 45 -66).

[17] EHC 240, Chapter 6, p. 45.

[18] EHC 240, Chapter 6, p. 6.

If the existence of a safety concern cannot be ruled out on the basis of dietary exposure assessed at the initial steps, more refined assessments of dietary exposure may be needed. Refinements to a point estimate would include less conservative assumptions based on more specific information about the foods consumed. For example, the use of market share data to identify specific types or brands of food to refine the amount of food consumed; the use of actual levels of additive in foods obtained from laboratorial analysis to refine the concentration of the food additive in food; and consider the impact of processing and food preparation. More complex exposure assessment models can also be employed to allow a more realistic simulation of consumer food consumption practices. Thereby, a probabilistic analysis of exposure variability may be necessary.

The fundamental difference between a probabilistic analysis and a deterministic or point estimate methods is that in a probabilistic analysis at least one variable is represented by a distribution function instead of a single value. Conceptually, population exposure must be thought of as a range of values, rather than a single value, because individual members of the population experience different levels of exposure. The model sample from each distribution is a distribution of potential dietary exposures generated using several thousand iterations.

In a simple probabilistic assessment only one variable is represented by a distribution function. In this case, the exposure distribution assessment of a food additive is determined by the multiplication of a point estimate to represent the concentration of the food additive in the food products with the points of a distribution of food consumption, or conversely. In more complex probabilistic methods both the concentration and consumption data are presented as distributions from which samples are randomly drawn and multiplied (Monte Carlo simulation). It should be noted that probabilistic methods require significant amounts of data in order to have a robust distribution from which to sample.[19]

Considering the aim of this guideline, two deterministic methods have been proposed for a simple evaluation of dietary exposure to food additives: Theoretical Maximum Daily Intake (TMDI) and Estimated Daily Intake (EDI).

~~2.2~~ **2.1** Theoretical Maximum Daily Intake **(TMDI)**

The Theoretical Maximum Daily Intake (TMDI) is calculated by multiplying the average per capita[20] 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~~. **food by the maximum use level of the food additive contained in the GSFA or by national regulations and by summing the resulting values.**

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

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

(b) the **food** 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 **amount of food** additive does not ~~undergo a~~ decrease ~~in level~~ as a result of cooking or processing techniques;

2.2 Estimated Daily Intake (EDI)

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) **the use of food additive** 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 ~~3~~ **4** and ~~4~~ **5**.

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[19] See EHC 240, Chapter 6, pp. 61-67 for a discussion of probabilistic modeling.

[20] The per capita food consumption data represents the food intake by the entire population of a country. For most foods, only a certain percentage of the population will consume that food. Therefore, the per capita food consumption includes “eaters” as well as “non-eaters” of that food. As such, the amount of food consumed on a per capita basis will generally be lower than the “eaters-only” amount (i.e., the amount of food consumed only by those individuals who actually consumed the food). In the case where the entire population consumes the food, the per capita and “eaters-only” food consumption amount will be the same.

~~**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 a-s 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.~~ 3. 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

Assessment	**Method**
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 into account for processed food	-	food used for seed
	-	food used for non-edible purposes
	-	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.~~

The first step is to identify and collect all data available in the country and check if these data can provide sufficient information (i.e., concentration of the food additive in food, food consumption data and average body weights of the population) to assess the dietary exposure to the food additive.

It is recommended to use national data on food additive concentrations, food consumption, body weight, and international toxicological reference values[21].

3.1 Concentration of the food additive in food

The type of data required for assessing dietary exposure for food additives is determined by the objective of the assessment. Dietary exposure can be assessed for a food additive before it has been approved for use (pre-regulation) or after it has been in the food supply for years (post-regulation). In a pre-regulation exposure assessment, food additive concentration data are available from or estimated by the manufacturer or food processor.

Maximum use levels (MLs) established for food additives by national authorities can also be used in pre-regulation dietary exposure assessments. In absence of a national regulation for the use of the food additive, the assessment can be conducted using the MLs in the GSFA[22]. It is recognized that the use of these maximum use levels will overestimate the dietary exposure to a food additive because it is not typical that a person would consume foods containing the food additive at the corresponding maximum use level.

In a post-regulation exposure assessment, in addition to all pre-regulation data sources, information on the specific foods containing the food additive at the market and the actual use levels of the food additives in those foods may be obtained from food manufacturers or food processors. Analytical data on the concentrations of the food additive in food are needed to more realistically estimate the levels of the food additive likely to be found in the diet as consumed. These data can be derived from monitoring and surveillance data on food. When using data provided by national authorities as well as other sources in international exposure assessments, it is important, whenever possible, to have detailed information on the data source, survey type or design, sampling procedures, sample preparation, analytical method, limit of detection (LOD) or limit of quantification (LOQ), and quality assurance procedures, as applicable to the assessment methodology.

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[21] EHC 240, Chapter 6, pp. 4-5.

[22] The use of the maximum use levels established in the GSFA will necessarily overestimate the exposure to a food additive from its use in a given food. The maximum use levels in the GSFA are *acceptable* maximum use levels that "... will not usually correspond to the optimum, recommended, or typical level of use. Under GMP, the optimum, recommended, or typical use level will differ for each application of an additive and is dependent on the intended technical effect and the specific food in which the additive would be used, taking into account the type of raw material, food processing and post-manufacture storage, transport and handling by distributors, retailers, and consumers."(Preamble to the GSFA; CODEX STAN 192-1995).

3.1.1 Regulation of use of food additives

The use of national or international standards of food additives for dietary exposure assessments should be made taking into consideration the regulations in force concerning the additives.

The following three types of regulations will be considered:

(a) Authorization for using the food additive is given according to a specific use and thereby there is a positive list. That is, for each additive there is a list of foods in which the additive may be used with an indication of the maximum level of use. Here data on consumption of foods in which the additive is specifically authorized are needed.

(b) The food additive is authorized for use in specified foods, but according to GMP. Here also, as in (a), consumption data are needed for the specified foods. However, numerical use levels representing current GMP need to be provided. The food industry can provide actual levels for the additive in different foods. Foods in which the use of the additive is authorized may be sampled, if necessary, and analyzed to determine the levels of the additive present in foods, as long as the financial impact of this approach is not too great.

(c) The food additive is authorized according to GMP in all foods, but the use in certain foods is specifically prohibited. This legislative situation requires close collaboration with the food industry and/or a rather complete sampling and analytical evaluation of the levels present in food. 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.

In the case of imported food, the following information may be provided by exporters:

(i) Compliance with the legislation of the importing country, exporting country, and/or the GSFA;

(ii) Relevant food additive regulations of the importing country, exporting country, and/or the GSFA.

It should be noted that distinguishing the imported food products from those produced domestically is not simple. Consumers may not realize that a product has been imported (e.g., in household-based food consumption surveys), or may not report it as such. However, data on the amount of imported food may be available from food disappearance data (see section 3.2), depending on the reporting requirements.

3.2 Food consumption data

Food consumption data reflect what individuals or groups consume in terms of solid foods, beverages (including drinking-water), and dietary supplements. Food consumption can be estimated through surveys at an individual or household level or approximated through food production statistics.

There are two general approaches in order to obtain information on the dietary habits: (i) involving the collection of inferred data on the movement and disappearance of food 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 generally used methods is given in Table 1.

Table 1: Approaches for Determining Food Consumption Data

Approaches	Method	Characteristics
Population-based methods	**food balance sheets; food disappearance data**	**Represent the total annual amount of a commodity available for domestic consumption per year. The amount consumed daily by an individual may be estimated by dividing the total annual amount by 365 and by the national population. The major limitation is that they reflect food availability rather than food consumption. Losses due to cooking, processing, spoilage and other sources of waste and additions from subsistence practices cannot be easily assessed. Because consumption is expressed in terms of raw and semi-processed commodities, these data are not generally useful for estimating dietary exposure to food additives,**

Approaches	Method	Characteristics
		which are primarily used in processed foods.
Household-based methods	**data on food purchased by a household; follow-up of consumed foods or changes in food stocks**	**Useful for comparing food availability among different communities, geographic areas and socioeconomic groups and for tracking dietary changes in the total population. However, these data do not provide information on the distribution of food consumption among individual members of the household.**
Individual-based methods	**food record; 24 h dietary recall; food frequency questionnaires (FFQs); diet history survey; food habit questionnaire**	**Provide detailed information on food consumption patterns. However, individuals may tend to overestimate consumption of foods perceived as "good" foods and underestimate consumption of foods perceived as "bad" foods.**

When examining existing food consumption data, the possible variation of food habits within subgroups of the population should be kept in mind. The methodologies should take into consideration non-average individuals. Some subgroups within the population will show patterns of food consumption that are differ widely from those of the population as a whole and include, for example, ethnic and cultural minority groups within a community; and individuals consuming large portions of specific food items. Some consumers may also be loyal to those foods or brands of food containing the highest concentrations of the food additive or may occasionally consume foods with very high concentrations of the food additive. In this regard, individual-based methods are the most useful. Populations that consume large quantities of food in general, or of specific food items may be taken into account by considering higher percentiles of food consumption data (e.g., 90th, 95th or 97.5th), and these methods typically contain data for different sex, age, ethnic, economic, and regional populations.

3.3 Body weight

For the purposes of dietary exposure estimates, an average body weight of 60 kg for adults and 15 kg for children are assumed for most populations in the world. However, for certain regions, the average body weight of the adult population may differ significantly from 60 kg. For example, an average body weight of 55 kg is assumed for the adult Asian population[23].

Nevertheless, it is important that the average body weight used is representative of the individuals in the country or region as much as possible. For food consumption data collected using individual-based methods, it is recommended that the actual body weights of the survey participants be used. If the default 60 kg adult body weight underestimates the actual individual body weights, the dietary exposure estimate on a per kg body weight basis will be overestimated. Similarly, if the default 60 kg adult body weight overestimates the actual individual body weights, the dietary exposure estimate on a per kg body weight basis will be underestimated.

~~5.~~ 4. SIMPLE APPROACH FOR THE EVALUATION ~~OF FOOD ADDITIVE INTAKE~~ DIETARY EXPOSURE TO FOOD ADDITIVES

Estimates of dietary exposure may be sequentially calculated starting with the simplest TMDI and proceeding to more refined EDI if necessary. If available, data on consumption of specific foods should be used. When such data do not exist, suitable approximations can be adequate to support a safe use. An estimate based upon a highly conservative approach, such as the TMDI, can give adequate assurance of safe use if the estimated exposure is lower than the ADI. However, if the ADI is exceeded using this approach, data that approximate the actual intake would need to be available. The TMDI can be refined by taking into account food consumption by appropriate population subgroups.

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

4.1 Criteria for prioritization of evaluation of dietary exposure to food additives:

The following ~~priority list can~~ **criteria may** be used to ~~decide~~ **prioritize those foods** for which ~~additives intake evaluation have first to be done:~~ **a dietary exposure assessment is applicable:**

[23] **EHC 240, Chapter 6, p. 42.**

1. additives authorized for use at high level ~~in highly consumed foodstuffs,~~ **in foods consumed in large quantities or by a significant percentage of the population,**
2. additives authorized ~~in highly consumed foodstuffs~~ **foods consumed in large quantities or by a significant percentage of the population,**
3. additives ~~having received~~ **assigned** a low ADI (0-5 mg/kg of body weight),
4. **additives consumed by potentially-at-risk subgroups (e.g. children, diabetics, pregnant women, elderly), as appropriate.**

A low priority can be given to additives that have ~~a non specified~~ **been assigned an ADI of "not specified"** when they are used ~~as additives~~ according ~~to good manufacturing practice~~ to ~~good manufacturing practice~~ **GMP[24].**

~~5.2~~ **4.2** Proposed method for a simple evaluation ~~of the intake of an~~ **dietary exposure to food** additive**s**

The following stepwise procedure is proposed:

A. Evaluation of the TMDI

A.1 Elaboration of the list of ~~foodstuffs~~ **foods** in which the additive is permitted. **Assume that the additive is used in all of the foods in which it is regulated for use;**

A.2 Determination of the levels of use;

A.2.1 Maximum permitted levels according to the regulation;

A.2.2 Actual levels if authorization is given according to GMP (levels obtained from industry or from analysis of foods);

A.3 Determination of the average consumption of the ~~foodstuffs~~ **food** 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~~ **population-based method (i.e., per capita estimate)** should be used as a first step;

A.3.3 Check ~~if, for some foodstuffs,~~ **whether** the average consumption of eaters is not much higher than the average consumption of ~~**population**~~ **some foods by the individuals consuming of those foods ("eaters") is comparable to the average consumption by the total 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);~~ **eaters" consume greater quantities of the food than the total population over long periods;**

A.3.4 Obtain a better estimate of food consumption by replacing average values obtained from the national ~~population-based method~~ **population-based method** by average consumption for eater**s** (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 considered to be lower than the ADI (overestimations in A.1 and A.2).

If the TMDI > ADI, the EDI approach should be followed.

B. Evaluation of the EDI

B.1 Checking the list of food~~stuffs:~~

[24] **According to JECFA, an ADI of "not specified" is a term applicable to a food additive of very low toxicity that, on the basis of the available chemical, biochemical and toxicological data, as well as the total dietary exposure of the additive (from its use at the levels necessary to achieve the desired effect and from its acceptable background in food), does not represent a hazard to health. For that reason, the establishment of an ADI expressed in numerical form is not necessary. An additive meeting this criterion must be used in accordance with GMP: that is, it should be technologically efficacious and should be used at the lowest level necessary to achieve this effect, it should not conceal inferior food quality or adulteration, and it should not create a nutritional imbalance**. (**EHC 240, Annex 1 – Glossary of Terms, p. 2)**

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

B.2 Checking the actual levels of use:

- **Determine whether the** ~~is the~~ additive used at the maximum authorized level for all the food~~stuffs~~, or only for some of them~~?~~. **Use actual use levels of the additive obtained from the food industry or determined from the analysis of foods, as appropriate.**

B.3 ~~Introduction of~~ **Introducing** these more ~~accurate figures~~ **representative data** in the TMDI calculation.

If the EDI < ADI ~~and when there is "no use at home" of the additive, one can consider,~~ the actual intake is **considered to be** lower than the ADI. If the EDI > ADI, discussion should be ~~started~~ **initiated** with the food industry to ~~discuss levels of use~~ **review the use levels of the additive and the foods in which it is used.**

~~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.~~

5. 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~~ **estimate exposure to additives to check whether an ADI is likely to be exceeded.**

ANNEX 1

Example of Calculation for Benzoic Acid and Salts - SUBJECT TO FUTURE REVISION

ADI	0-5 mg/kg b.w	
For person weighing ~~50~~ **55** kg:	5 x 55=	275 mg/person
For person weighing 60 kg:	5 x 60=	300 mg/person
For child weighing 15 kg:	**5 x 15 =**	**75 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-preserves 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 ESTIMATES

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

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

Sources:

National Institute of Statistics
Federation of Fisheries Federation of Soft Drinks

IMPROVED TMDI ESTIMATE

Average Intake of Users

Soft Drinks

Average intake of soft drink users: 600 ml

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

Emulsified Sauces

Average intake of users: 20 gr instead of 3.4 gr

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

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

ANNEX 2

EXAMPLE OF CALCULATION FOR SWEETENERS - SUBJECT TO FUTURE REVISION

Maximum Permitted Quantities of Sweeteners

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

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

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

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

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

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

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

The results of this exercise are given in Table 2.

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

saccharin:	135.7 mg
cyclamate:	659.4 mg
aspartame:	669.6 mg
acesulfame:	538.6 mg

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

TABLE 1

Maximum Permitted Quantities of Sweetener

Foodstuff or beverages	Sweetener			
	Saccharin mg/kg	Cyclamate mg/kg	Aspartame mg/kg	Acesulfame mg/kg
soft drinks	125	400	750	600
syrups (ready to drink)	125	400	750	600
sugar confectionery	1000	4000	2500	2500
pudding powder	50	250	750	1000
pickles	400	1100	0	0
pickles herring	50	0	140	200
flour confectionery	0	0	1500	500
chocolate	300	900	5000	3000
chocolate spread	300	900	0	3000
edible ice	150	1500	1000	1000
desserts	0	0	1000	0
special beer	60	0	0	0
chewing gum	2000	3000	5500	2000
liquid milk products:				
fruit yoghurt	150	250	300	0
others	50	250	750	200
fruit quark	150	250	300	0
salads	0	0	700	200
jam products: jam and jellies sugar	300	1000	0	3000
reduced jams fruit	200	500	0	1500
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 products									
fruit yoghurt	1.0	150	0.1	250	0.2	300	0.3	-	-
others	24.4	50	1.2	250	6.1	750	18.3	200	4.9
fruit quark	1.7	150	0.2	250	0.4	300	0.5	-	-
salads	4.9	-	-	-	-	700	3.4	200	1
jam products:									
jam and jellies	4	300	1.2	1000	4	-	-	3000	12
sugar reduced jams	0.3	200	0.1	500	0.2	-	-	3000	12
fruit nectars	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**
+ 2x coffee consumption			53.4		294.8		-		-
+ 2x soft drink consumption							243.0		194.4
Total			**135.7**		**659.4**		**669.6**	**538.6**	

* Assumes 5: 1 dilution

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

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

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

Appendix III

GUIDELINES FOR THE SIMPLE EVALUATION OF DIETARY EXPOSURE TO FOOD ADDITIVES

CAC/GL 03-1989

CONTENTS

1. INTRODUCTION

The use of food additives is justified only when such use has an advantage, does not present an appreciable health risk to consumers, does not mislead the consumer, and serves one or more technological functions. The quantity of a food additive added to food is the lowest level necessary to achieve the intended technological function[1].

In regard to protecting the health of the consumers, principles for risk analysis have been applied in the framework of the Codex Alimentarius. Risk analysis has been defined by the Codex Alimentarius Commission (CAC) as "a process consisting of three components: risk assessment, risk management and risk communication"[2]. Risk assessment is defined as a scientifically based process consisting of the following steps: 1) hazard identification, 2) hazard characterization, 3) exposure assessment and 4) risk characterization[3].

Risk assessments should be based on realistic exposure scenarios, with consideration of different situations being defined by risk assessment policy. They should include consideration of susceptible and high-risk population groups. Acute, chronic (including long-term), cumulative and/or combined adverse health effects should be taken into account in carrying out risk assessment, where relevant[4].

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) is primarily responsible for performing the risk assessments upon which Codex Committee on Food Additives (CCFA) and ultimately the CAC base their risk management decision[5].

The first step on international level in the consideration of the safety assessment of food additives is an evaluation by JECFA, including the establishment of an Acceptable Daily Intake (ADI), and the elaboration of identity and purity criteria. The ADI is an estimate of the amount of a food additive in food or beverages expressed on a body weight basis that can be ingested daily over a lifetime without appreciable health risk to the consumer[6]. It is derived on the basis of all the known facts at the time of the evaluation. The ADI is expressed in milligrams of the chemical per kilogram of body weight[7].

In the second step, proposals for the permitted use of an additive in different foods are made by the responsible national authorities or by the Codex Commodity Committees to the CCFA. The endorsement of the proposed use in a food is done in accordance with the Codex *General Standard for Food Additives* (GSFA; CODEX STAN 192-1995) which states in its Preamble that "the inclusion of a food additive in this Standard shall have taken into account any ADI, or equivalent safety assessment established for the additive by JECFA and its probable daily intake from all food sources. Where the food additive is to be used in foods eaten by special groups of consumers (e.g., diabetics, those on special medical diets, sick individuals on formulated liquid diets), account shall be taken of the probable daily intake of the food additive by those consumers".

Information regarding the probable daily dietary exposure to food additives is therefore needed, especially in the case of food additives with assigned a low ADI, food additives used at high levels in commonly consumed foods, foods consumed in large quantities and/or food additives used in foods consumed by special population groups.

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[1] Preamble to the Codex *General Standard for Food Additives* (GSFA; CODEX STAN 192-1995, available at www.codexalimentarius.org/codex-home/en/ under the "Standards" menu.

[2] Codex Alimentarius Commission Procedural Manual (20th Ed.) Section IV: Risk Analysis, Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius, p. 105.

[3] Codex Alimentarius Commission Procedural Manual (20th Ed.) Section IV: Risk Analysis, Definitions of Risk Analysis Terms Related to Food Safety, p. 112.

[4] Codex Alimentarius Commission procedural manual, 20th ed. Rome, Food and Agriculture Organization of the United Nations, Codex Alimentarius Commission, p. 115.

[5] Codex Alimentarius Commission Procedural Manual (20th Ed.) Section IV: Risk Analysis, Risk Analysis Principles Applied by the Codex Committee on Food Additives and the Codex Committee on Contaminants in Foods, p. 117. *[NOTE: this text will be superseded by the "Risk Analysis Principles Applied by the Codex Committee on Food Additives" that was forwarded by the 44th CCFA to the 35th CAC for adoption (REP 12/FA, para. 21 and Appendix II). This reference should be updated when the new text is incorporated in the 21st Ed. of the Procedural Manual.]*

[6] 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 (Preamble to the GSFA).

[7] The methods used to establish health-based guidance value such as an ADI are described in chapter 5 of the publication Principles and Methods for the Risk Assessment of Chemicals in Food - Environmental Health Criteria 240 (EHC 240; Food and Agriculture Organization of the United Nations and the World Health Organization, 2009; www.who.int/foodsafety/chem/principles/en/index1.html), Chapter 5.

Different approaches exist regarding the estimation of the probable daily dietary exposure to food additives. Some of these approaches are very expensive and time consuming and may pose difficulties to some countries in initiating such dietary exposure assessments for food additives. Therefore, the present guidelines are intended for a simple evaluation of food additive intake, in order to facilitate the dietary exposure assessments.

2. DIETARY EXPOSURE ASSESSMENT

Dietary exposure assessment[8] combines food consumption data and the concentration of the food additive in food. The resulting dietary exposure estimate may then be compared with the ADI value for the food additive, if available, as part of the risk characterization.

Three elements must be taken into account in assessing the dietary exposure to a food additive: (1) concentration of considered food additive in food; (2) amount of food consumed; and (3) average body weight of the population (kg). The general equation for dietary exposure is:

$$\text{Dietary exposure} = \frac{\Sigma\ (\text{Concentration of food additive in food} \times \text{Food consumption})}{\text{Body weight (kg)}}$$

Different methods exist for estimating probable dietary intake[9]. The method used should be appropriate for the purpose, clearly stated and reproducible. Information about the model and data sources used, assumptions, limitations and uncertainties should also be documented. National or regional data should be used whenever possible.

International dietary exposure assessments should provide exposure estimates that are equal to or greater than the estimates carried out at the national level. It is assumed that the international estimate covers potential dietary exposure in countries for which no data were available.

A stepwise approach is recommended, in which screening methods based on conservative assumptions can be applied to identify, among the large number of food additives that may be present, those of no safety concern, using minimal resources in the shortest possible time. If no safety concerns are identified[10], no additional exposure assessment is required. Where potential safety concerns are identified, the subsequent steps of the framework provide methods that incorporate increasingly specific and refined data (as they also require more resources).

The screening methods are conservative deterministic or point estimates[11] with the aim of identifying the food additives for which a more comprehensive dietary exposure assessment is necessary. Examples of these methods are poundage data, budget method, model diets, as theoretical added maximum daily intakes (TAMDI) and single portion exposure technique (SPET) model diets for flavourings, and theoretical maximum daily intake (TMDI).

The screening methods do not yield true dietary exposure estimates. They should overestimate dietary exposure of high consumers by using conservative assumptions for food consumption and food additive concentration. This overestimation will avoid situations where the dietary exposure estimated by the screening process would erroneously indicate no safety concern (i.e. underestimate exposure). However, in order to effectively screen food additives and establish risk assessment priorities, the first steps of the procedure should not consider unsustainable diets, or the results will be too unrealistic to be useful. At a minimum, physiological limits of food consumption should be taken into account[12].

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[8] The use of standard terminology is recommended to ensure consistent application and understanding. It is recommended that “consumption” be used to refer to the amount of food consumed and “dietary exposure” to the amount of food additive ingested via food. The term “dietary exposure” is used synonymously with the term “dietary intake”, depending upon existing regulatory frameworks or other related considerations. Food also includes beverages, drinking-water and food supplements (EHC 240, Chapter 6, p. 3).

[9] For more detailed information on the dietary exposure assessment methods, see EHC 240, Chapter 6

[10] For this purpose, there is no safety concern if the estimated dietary exposure to a food additive does not exceed its ADI value.

[11] A deterministic or point estimate of dietary exposure is simply a single value that describes some parameter of consumer exposure. Deterministic models use a single point estimate for each model parameter. For food additive concentration data, the mean, the median, a high percentile of all observed values, or even the maximum use level proposed by national or international food authorities may be used. These food additive concentrations can be further refined using other data (e.g., analytically determined levels of a food additive in food), as appropriate. For food consumption data, consumption at the mean and at a high percentile (e.g., 90th, 95th, 97.5th) for a food is considered for each population of interest (EHC 240, Chapter 6, pp. 45 -66).

[12] EHC 240, Chapter 6, p. 45.

Further steps to refine the dietary exposure assessment should be designed in such a way that potential high dietary exposure to a food additive is not underestimated. Point estimate modeling may also be appropriate as a second step in a tiered approach. The methodologies should take into consideration non-average individuals, such as those who consume large portions of specific food items (highly exposed consumers, e.g., 90th, 95th, or 97.5th percentiles of food consumption data)[13]. Some consumers who may also be loyal to those foods or brands of food containing the highest concentrations of the food additive or may occasionally consume foods with very high concentrations of the food additive should also be taken into account.

If the existence of a safety concern cannot be ruled out on the basis of dietary exposure assessed at the initial steps, more refined assessments of dietary exposure may be needed. Refinements to a point estimate would include less conservative assumptions based on more specific information about the foods consumed. For example, the use of market share data to identify specific types or brands of food to refine the amount of food consumed; the use of actual levels of additive in foods obtained from laboratorial analysis to refine the concentration of the food additive in food; and consider the impact of processing and food preparation. More complex exposure assessment models can also be employed to allow a more realistic simulation of consumer food consumption practices. Thereby, a probabilistic analysis of exposure variability may be necessary.

The fundamental difference between a probabilistic analysis and a deterministic or point estimate methods is that in a probabilistic analysis at least one variable is represented by a distribution function instead of a single value. Conceptually, population exposure must be thought of as a range of values, rather than a single value, because individual members of the population experience different levels of exposure. The model sample from each distribution is a distribution of potential dietary exposures generated using several thousand iterations.

In a simple probabilistic assessment only one variable is represented by a distribution function. In this case, the exposure distribution assessment of a food additive is determined by the multiplication of a point estimate to represent the concentration of the food additive in the food products with the points of a distribution of food consumption, or conversely. In more complex probabilistic methods both the concentration and consumption data are presented as distributions from which samples are randomly drawn and multiplied (Monte Carlo simulation). It should be noted that probabilistic methods require significant amounts of data in order to have a robust distribution from which to sample.[14]

Considering the aim of this guideline, two deterministic methods have been proposed for a simple evaluation of dietary exposure to food additives: Theoretical Maximum Daily Intake (TMDI) and Estimated Daily Intake (EDI).

2.1 Theoretical Maximum Daily Intake (TMDI)

The Theoretical Maximum Daily Intake (TMDI) is calculated by multiplying the average per capita[15] daily food consumption for each food by the maximum use level of the food additive contained in the GSFA or by national regulations and by summing the resulting values.

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

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

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

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

(d) the amount of food additive does not decrease as a result of cooking or processing techniques;

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

2.2 Estimated Daily Intake (EDI)

[13] EHC 240, Chapter 6, p. 6.
[14] See EHC 240, Chapter 6, pp. 61-67 for a discussion of probabilistic modeling.
[15] The per capita food consumption data represents the food intake by the entire population of a country. For most foods, only a certain percentage of the population will consume that food. Therefore, the per capita food consumption includes “eaters” as well as “non-eaters” of that food. As such, the amount of food consumed on a per capita basis will generally be lower than the “eaters-only” amount (i.e., the amount of food consumed only by those individuals who actually consumed the food). In the case where the entire population consumes the food, the per capita and “eaters-only” food consumption amount will be the same.

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) the use of food additive 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 3 and 4.

3. DATA AVAILABLE

The first step is to identify and collect all data available in the country and check if these data can provide sufficient information (i.e., concentration of the food additive in food, food consumption data and average body weights of the population) to assess the dietary exposure to the food additive.

It is recommended to use national data on food additive concentrations, food consumption, body weight, and international toxicological reference values[16].

3.1 Concentration of the food additives in food

The type of data required for assessing dietary exposure for food additives is determined by the objective of the assessment. Dietary exposure can be assessed for a food additive before it has been approved for use (pre-regulation) or after it has been in the food supply for years (post-regulation). In a pre-regulation exposure assessment, food additive concentration data are available from or estimated by the manufacturer or food processor.

Maximum use levels (MLs) established for food additives by national authorities can also be used in pre-regulation dietary exposure assessments. In absence of a national regulation for the use of the food additive, the assessment can be conducted using the MLs in the GSFA[17]. It is recognized that the use of these maximum use levels will overestimate the dietary exposure to a food additive because it is not typical that a person would consume foods containing the food additive at the corresponding maximum use level.

In a post-regulation exposure assessment, in addition to all pre-regulation data sources, information on the specific foods containing the food additive at the market and the actual use levels of the food additives in those foods may be obtained from food manufacturers or food processors. Analytical data on the concentrations of the food additive in food are needed to more realistically estimate the levels of the food additive likely to be found in the diet as consumed. These data can be derived from monitoring and surveillance data on food. When using data provided by national authorities as well as other sources in international exposure assessments, it is important, whenever possible, to have detailed information on the data source, survey type or design, sampling procedures, sample preparation, analytical method, limit of detection (LOD) or limit of quantification (LOQ), and quality assurance procedures, as applicable to the assessment methodology.

3.1.1 Regulation of use of food additives

The use of national or international standards of food additives for dietary exposure assessments should be made taking into consideration the regulations in force concerning the additives.

The following three types of regulations will be considered:

(a) Authorization for using the food additive is given according to a specific use and thereby there is a positive list. That is, for each additive there is a list of foods in which the additive may be used with an indication of the maximum level of use. Here data on consumption of foods in which the additive is specifically authorized are needed.

[16] EHC 240, Chapter 6, pp. 4-5.

[17] The use of the maximum use levels established in the GSFA will necessarily overestimate the exposure to a food additive from its use in a given food. The maximum use levels in the GSFA are *acceptable* maximum use levels that "... will not usually correspond to the optimum, recommended, or typical level of use. Under GMP, the optimum, recommended, or typical use level will differ for each application of an additive and is dependent on the intended technical effect and the specific food in which the additive would be used, taking into account the type of raw material, food processing and post-manufacture storage, transport and handling by distributors, retailers, and consumers."(Preamble to the GSFA; CODEX STAN 192-1995).

(b) The food additive is authorized for use in specified foods, but according to GMP. Here also, as in (a), consumption data are needed for the specified foods. However, numerical use levels representing current GMP need to be provided. The food industry can provide actual levels for the additive in different foods. Foods in which the use of the additive is authorized may be sampled and analyzed to determine the levels of the additive present in foods, as long as the financial impact of this approach is not too great.

(c) The food additive is authorized according to GMP in all foods, but the use in certain foods is specifically prohibited. This legislative situation requires close collaboration with the food industry and/or a rather complete sampling and analytical evaluation of the levels present in food. 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.

In the case of imported food, the following information may be provided by exporters:

(i) Compliance with the legislation of the importing country, exporting country, and/or the GSFA;

(ii) Relevant food additive regulations of the importing country, exporting country, and/or the GSFA.

It should be noted that distinguishing the imported food products from those produced domestically is not simple. Consumers may not realize that a product has been imported (e.g., in household-based food consumption surveys), or may not report it as such. However, data on the amount of imported food may be available from food disappearance data (see section 3.2), depending on the reporting requirements.

3.2 Food consumption data

Food consumption data reflect what individuals or groups consume in terms of solid foods, beverages (including drinking-water), and dietary supplements. Food consumption can be estimated through surveys at an individual or household level or approximated through food production statistics.

There are two general approaches in order to obtain information on the dietary habits: (i) involving the collection of inferred data on the movement and disappearance of food 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 generally used methods is given in Table 1.

Table 1: Approaches for Determining Food Consumption Data

Approaches	Method	Characteristics
Population-based methods	food balance sheets; food disappearance data	Represent the total annual amount of a commodity available for domestic consumption per year. The amount consumed daily by an individual may be estimated by dividing the total annual amount by 365 and by the national population. The major limitation is that they reflect food availability rather than food consumption. Losses due to cooking, processing, spoilage and other sources of waste and additions from subsistence practices cannot be easily assessed. Because consumption is expressed in terms of raw and semi-processed commodities, these data are not generally useful for estimating dietary exposure to food additives, which are primarily used in processed foods.
Household-based methods	data on food purchased by a household; follow-up of consumed foods or changes in food stocks	Useful for comparing food availability among different communities, geographic areas and socioeconomic groups and for tracking dietary changes in the total population. However, these data do not provide information on the distribution of food consumption among individual members of the household.
Individual-based methods	food record; 24 h dietary recall; food frequency questionnaires (FFQs); diet history survey; food habit questionnaire	Provide detailed information on food consumption patterns. However, individuals may tend to overestimate consumption of foods perceived as “good” foods and underestimate consumption of foods perceived as “bad” foods.

When examining existing food consumption data, the possible variation of food habits within subgroups of the population should considered. The methodologies should take into consideration non-average individuals. Some subgroups within the population will show patterns of food consumption that are differ widely from those of the population as a whole and include, for example, ethnic and cultural minority groups within a community; and individuals consuming large portions of specific food items. Some consumers may also be loyal to those foods or brands of food containing the highest concentrations of the food additive or may occasionally consume foods with very high concentrations of the food additive. In this regard, individual-based methods are the most useful. Populations that consume large quantities of food in general, or of specific food items may be taken into account by considering higher percentiles of food consumption data (e.g., 90^{th}, 95^{th} or 97.5^{th}), and these methods typically contain data for different sex, age, ethnic, economic, and regional populations.

3.3 Body weight

For the purposes of dietary exposure estimates, an average body weight of 60 kg for adults and 15 kg for children are assumed for most populations in the world. However, for certain regions, the average body weight of the adult population may differ significantly from 60 kg. For example, an average body weight of 55 kg is assumed for the adult Asian population[18].

Nevertheless, it is important that the average body weight used is representative of the individuals in the country or region as much as possible. For food consumption data collected using individual-based methods, it is recommended that the actual body weights of the survey participants be used. If the default 60 kg adult body weight underestimates the actual individual body weights, the dietary exposure estimate on a per kg body weight basis will be overestimated. Similarly, if the default 60 kg adult body weight overestimates the actual individual body weights, the dietary exposure estimate on a per kg body weight basis will be underestimated.

4. SIMPLE APPROACH FOR THE EVALUATION OF DIETARY EXPOSURE TO FOOD ADDITIVES

Estimates of dietary exposure may be sequentially calculated starting with the simplest TMDI and proceeding to more refined EDI if necessary. If available, data on consumption of specific foods should be used. When such data do not exist, suitable approximations can be adequate to support a safe use. An estimate based upon a highly conservative approach, such as the TMDI, can give adequate assurance of safe use if the estimated exposure is lower than the ADI. However, if the ADI is exceeded using this approach, data that approximate the actual intake would need to be available. The TMDI can be refined by taking into account food consumption by appropriate population subgroups.

4.1 Criteria for prioritization of evaluation of dietary exposure to food additives:

The following criteria may be used to prioritize those food additives for which a dietary exposure assessment is applicable:

1. additives authorized for use at high level in foods consumed in large quantities or by a significant percentage of the population,
2. additives authorized in foods consumed in large quantities or by a significant percentage of the population,
3. additives assigned a low ADI (0-5 mg/kg of body weight),
4. additives consumed by potentially-at-risk subgroups (e.g. children, diabetics, pregnant women, elderly), as appropriate.

A low priority can be given to additives that have been assigned an ADI of “not specified” when they are used according to GMP[19].

[18] EHC 240, Chapter 6, p. 42.

[19] According to JECFA, an ADI of “not specified” is a term applicable to a food additive of very low toxicity that, on the basis of the available chemical, biochemical and toxicological data, as well as the total dietary exposure of the additive (from its use at the levels necessary to achieve the desired effect and from its acceptable background in food), does not represent a hazard to health. For that reason, the establishment of an ADI expressed in numerical form is not necessary. An additive meeting this criterion must be used in accordance with GMP: that is, it should be technologically efficacious and should be used at the lowest level necessary to achieve this effect, it should not conceal inferior food quality or adulteration, and it should not create a nutritional imbalance. (EHC 240, Annex 1 – Glossary of Terms, p. 2)

4.2 Proposed method for a simple evaluation of the dietary exposure to food additives

The following stepwise procedure is proposed:

A. Evaluation of the TMDI

A.1 Elaboration of the list of foods in which the additive is permitted. Assume that the additive is used in all of the foods in which it is regulated for use;

A.2 Determination of the levels of use;

A.2.1 Maximum permitted levels according to the regulation;

A.2.2 Actual levels if authorization is given according to GMP (levels obtained from industry or from analysis of foods);

A.3 Determination of the average consumption of the food 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 population-based method (i.e., per capita estimate) should be used as a first step;

A.3.3 Check whether the average consumption of eaters is not much higher than the average consumption of some foods by the individuals consuming of those foods ("eaters") is comparable to the average consumption by the total population. Consumption data for eaters should be used when "eaters" consume greater quantities of the food than the total population over long periods;

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

If the TMDI < ADI, the actual intake is considered to be lower than the ADI (overestimations in A.1 and A.2).

If the TMDI > ADI, the EDI approach should be followed.

B. Evaluation of the EDI

B.1 Checking the list of food:

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

B.2 Checking the actual levels of use:

Determine whether the additive used at the maximum authorized level for all the foods, or only for some of them. Use actual use levels of the additive obtained from the food industry or determined from the analysis of foods, as appropriate.

B.3 Introducing these more representative data in the TMDI calculation.

If the EDI < ADI, the actual intake is considered to be lower than the ADI. If the EDI > ADI, discussion should be initiated with the food industry to review the use levels of the additive and the foods in which it is used.

5. SUMMARY

This document describes a stepwise approach to estimate exposure to additives to check whether an ADI is likely to be exceeded.

ANNEX 1

Example of Calculation for Benzoic Acid and Salts - SUBJECT TO FUTURE REVISION

ADI	0-5 mg/kg b.w	
For person weighing ~~50~~ **55** kg:	5 x 55=	275 mg/person
For person weighing 60 kg:	5 x 60=	300 mg/person
For child weighing 15 kg:	**5 x 15 =**	**75 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-preserves 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 ESTIMATES

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

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

Sources:

National Institute of Statistics Federation of Fisheries Federation of Soft Drinks

IMPROVED TMDI ESTIMATE

Average Intake of Users

Soft Drinks

Average intake of soft drink users: 600 ml

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

Emulsified Sauces

Average intake of users: 20 gr instead of 3.4 gr

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

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

ANNEX 2

EXAMPLE OF CALCULATION FOR SWEETENERS - SUBJECT TO FUTURE REVISION

Maximum Permitted Quantities of Sweeteners

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

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

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

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

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

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

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

The results of this exercise are given in Table 2.

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

saccharin:	135.7 mg
cyclamate:	659.4 mg
aspartame:	669.6 mg
acesulfame:	538.6 mg

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

TABLE 1

Maximum Permitted Quantities of Sweetener

Foodstuff or beverages	Sweetener			
	Saccharin mg/kg	Cyclamate mg/kg	Aspartame mg/kg	Acesulfame mg/kg
soft drinks	125	400	750	600
syrups (ready to drink)	125	400	750	600
sugar confectionery	1000	4000	2500	2500
pudding powder	50	250	750	1000
pickles	400	1100	0	0
pickles herring	50	0	140	200
flour confectionery	0	0	1500	500
chocolate	300	900	5000	3000
chocolate spread	300	900	0	3000
edible ice	150	1500	1000	1000
desserts	0	0	1000	0
special beer	60	0	0	0
chewing gum	2000	3000	5500	2000
liquid milk products:				
fruit yoghurt	150	250	300	0
others	50	250	750	200
fruit quark	150	250	300	0
salads	0	0	700	200
jam products: jam and jellies sugar	300	1000	0	3000
reduced jams fruit	200	500	0	1500
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 products									
fruit yoghurt	1.0	150	0.1	250	0.2	300	0.3	-	-
others	24.4	50	1.2	250	6.1	750	18.3	200	4.9
fruit quark	1.7	150	0.2	250	0.4	300	0.5	-	-
salads	4.9	-	-	-	-	700	3.4	200	1
jam products:									
jam and jellies	4	300	1.2	1000	4	-	-	3000	12
sugar reduced jams	0.3	200	0.1	500	0.2	-	-	3000	12
fruit nectars	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**
+ 2x coffee consumption			53.4		294.8		-		-
+ 2x soft drink consumption							243.0		194.4
Total			**135.7**		**659.4**		**669.6**	**538.6**	

* Assumes 5: 1 dilution

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

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

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