CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

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Hong Kong, China, 17-21 March 2014

REVISION OF THE *GUIDELINES FOR THE SIMPLE EVALUATION OF FOOD ADDITIVE INTAKES* (CAC/GL 3-1989) (N08-2013)

Prepared by an electronic Working Group led by Brazil, with the assistance of Argentina, Australia, Belgium, Chile, China, European Union, Ghana, Greece, Indonesia, Iran, Japan, Malaysia, Mexico, Norway, Peru, Philippines, Poland, Russia, South Africa, Spain, USA, Calorie Control Council (CCC), European Chemical Industry Council (CEFIC), Federation of European Specialty Food Ingredients (ELC), Institute of Food Technologists (IFT), International Alliance of Dietary/Food Supplement Associations (IADSA), International Aluminium Institute (IAI), International Council of Grocery Manufacturer Associations (ICGMA), International Food Additives Council (IFAC), International Organization of Vine and Wine (OIV), the Natural Food Colours Association (NATCOL), World Association of Seaweed Processors (Marinalg International) and WHO/JECFA Secretariat.

Governments and international organizations in Observer status with the Codex Alimentarius Commission wishing to submit comments at Step 3 on the proposed draft Revised Guidelines (Annex 1) are invited to do so no later than **31 January 2014** as follows: Secretariat, Codex Committee on Food Additives, China National Center for Food Safety Risk Assessment (CFSA), Building 2, No. 37 Guangqu Road, Chaoyang District, Beijing 100022, China, (E-mail: secretariat@ccfa.cc), with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Viale delle Terme di Caracalla, 00153 Rome, Italy (E-mail: Codex@fao.org).

Format for submitting comments: In order to facilitate the compilation of comments and prepare a more useful comments document, Members and Observers, which are not yet doing so, are requested to provide their comments in the format outlined in the Annex II to this document.

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 agreed to recommend 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). The Committee was of the view that the *Guidelines for the Simple Evaluation of Food Additive Intake* (CAC/GL 3-1989) contained useful and simple guidance to facilitate the dietary exposure assessments of food additives, since 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.

3. 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”.

4. The CCFA then 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].

[1] REP 12/FA, para. 13

5. The report of the eWG and the project document was presented to the 45th Session of the CCFA. It was agreed to start new work on the revision of the Guidelines and to forward the project document to the Commission for approval as new work. The Committee further agreed to reestablish the electronic Working Group, led by Brazil, open to all members and observers and working in English only, to prepare proposed draft revised Guidelines for circulation for comments at Step 3 and consideration at its next Session, subject to approval of new work by the 36th Session of the Commission[2].

6. The revision of the Guidelines for the Simple Evaluation of Food Additive Intakes (CAC/GL 3-1989) was then approved as new work by the 36th Session of the Codex Alimentarius Commission[3].

DISCUSSION BY THE eWG

7. Two drafts were circulated for comments within the eWG, based on the EHC 240. As a starting point, the eWG considered the outline of the revised text prepared by the previous eWG in Appendixes II and III of CX/FA 13/45/6 and the outcomes of the 45th Session of the CCFA.

8. Following the previous discussions, the TMDI (Theoretical Maximum Daily Intake) and EDI (Estimated Daily Intake) were considered the appropriate approaches for the simple evaluation of dietary exposure to food additives, and both should be retained in the document.

9. It had been agreed that reference to other screening methods should not be included, as this might lead to the application of methodologies of different levels of complexity. The GSFA already contains guidance to screen proposals for development of maximum levels for use of food additive with numerical acceptable daily intakes i.e. the Budget method. Reference to modelling of high consumers should not be included either, since guidance for this particular situation was already made available on the FAO/WHO document EHC 240[4].

10. For clarity and consistency with the EHC 240 document and the Principles of Risk Analysis, the title of the document 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.

11. 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. As the chair of the eWG, Brazil presented examples of calculation for benzoic acid, using its national data. The existing example for sweeteners was removed, since the new example addresses both the TMDI and the EDI approaches. No other updated proposal was presented for discussion.

12. Participants were also invited to address and comment the following topics:

- The need to consider food additives authorized in food ingredients on the exposure assessments included in these guidelines;
- The proposal to remove the information about high percentiles of food consumption data from the document;
- The proposal to maintain “additives assigned a low ADI (0-5 mg/kg of body weight)” on the criteria to prioritize food additives for the exposure assessment.

13. There was general agreement not to consider the food additives authorized in food ingredients on the exposure assessments included in these guidelines, in order to keep the simple approach.

14. There was strong support to keep the reference on high percentiles of food consumption, since an exposure assessment generally addresses both the “average” and “high” consumer to determine the range of potential exposure. It was considered that, despite the fact that TMDI works with average consumption data, the guidelines should draw attention to high consumers. Moreover, the EHC 240 includes a discussion of approaches for estimating exposure for “high” consumers[5].

15. There was also strong support to maintain “low ADI” as a criterion for prioritization of food additives for the exposure assessment, as it is in the CAC/GL 3-1989 current text. On the other hand, there is no definition for “low ADI” in Codex documents and EHC 240. “Additives assigned a low ADI” was then kept amongst the criteria, with a recommendation to the Committee to ask JECFA to define “low ADI”, in order to prevent from different interpretations.

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[2] REP 13/FA, para. 63-64
[3] REP 13/CAC, Appendix VI
[4] REP 13/FA, para. 55-59
[5] Food and Agriculture Organization of the United Nations and the World Health Organization, 2009. Principles and Methods for the Risk Assessment of Chemicals in Food - Environmental Health Criteria - EHC 240; Chapter 6, pp. 56-57.

RECOMMENDATIONS

16. The eWG recommends the CCFA:

- To consider the revised renamed GUIDELINES FOR SIMPLE EVALUATION OF DIETARY EXPOSURE TO FOOD ADDITIVES presented in Annex 1; and
- To discuss the possibility to request JECFA to define “additives assigned a low ADI”.

ANNEX 1

PROPOSED DRAFT GUIDELINES FOR SIMPLE EVALUATION OF DIETARY EXPOSURE TO FOOD ADDITIVES

CAC/GL 3-1989

(at Step 3)

1. INTRODUCTION
2. DIETARY EXPOSURE ASSESSMENT
   - 2.1 Theoretical Maximum Daily Intake (TMDI)
   - 2.2 Estimated Daily Intake (EDI)
3. DATA AVAILABLE
   - 3.1 Concentration of food additives in food
     - 3.1.1 Regulation of use of food additives
   - 3.2 Food consumption data
   - 3.3 Body weight
4. SIMPLE APPROACH FOR THE EVALUATION OF DIETARY EXPOSURE TO FOOD ADDITIVES
   - 4.1 Criteria for prioritization of evaluation of dietary exposure to food additives
   - 4.2 Proposed method for a simple evaluation of dietary exposure to food additives
5. SUMMARY

ANNEX Example of calculation for benzoic acid

1. INTRODUCTION

1. The Codex General Standard for Food Additives (GSFA) states in its Preamble that 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 shall be limited to the lowest level necessary to achieve the intended technical effect[1], according to the basic principle of the Good Manufacture Practice (GMP).

2. 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 closely linked 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].

3. 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[4].

4. On an international level, the first step in the consideration of the safety assessment of food additives is an evaluation by JECFA, including the establishment of an Acceptable Daily Intake (ADI), where relevant, and the elaboration of their 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 (bw) basis that can be ingested daily over a lifetime without appreciable health risk to the consumer[5]. 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 food additive per kilogram of body weight[6] on a daily basis. JECFA evaluates the estimated dietary exposures and, in the risk characterization step, compares the probable exposure to the food additive with the relevant ADI[7].

5. 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 by the CCFA should take into account the ADI, or an equivalent health based guidance value, established for the additive by JECFA and the probable daily dietary exposure to the additive from all food sources. When 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 dietary exposure to the food additive by those consumers.

6. There are different approaches for estimating 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 to facilitate the work of governments, particularly of developing countries, on the assessment of dietary exposure to food additives.

2. DIETARY EXPOSURE ASSESSMENT

7. 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 for the food additive, if available, as part of the risk characterization.

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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 (21stEd.) Section IV: Risk Analysis, Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius, pp. 107 - 113.

[3] Codex Alimentarius Commission Procedural Manual (21stEd.) Section IV: Risk Analysis, Definitions of Risk Analysis Terms Related to Food Safety, pp. 114 -115.

[4] Codex Alimentarius Commission Procedural Manual (21st Ed.) Section IV: Risk Analysis, “Risk Analysis Principles Applied by the Codex Committee on Food Additives”, pp. 116-120.

[5] 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; CODEX STAN 192-1995).

[6] 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.

[7] JECFA´s monographs are available at http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-additives/en/.

[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”,

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

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

9. There are different methods for estimating probable dietary exposure[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.

10. International assessments should provide dietary 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.

11. A stepwise approach is recommended in which screening methods based on conservative assumptions can be applied to identify those of no safety concern that may be present, among the large number of food additives 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).

12. The screening methods 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 may erroneously indicate no safety concern (i.e., underestimate exposure, particularly for high consumers). 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[11].

13. 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 the food industry and/or laboratory analysis to refine the concentration of the food additive in food; and consideration of the impact of food processing and preparation. Considering the aim of this guideline, two approaches 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)

14. The TMDI is calculated by multiplying the average per capita[12] daily food consumption for each food by the maximum use level (ML)[13] of the food additive established by national regulations or contained in the GSFA[14] or by the proposed use levels by the food industry and summing the resulting exposure values to

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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] EHC 240, Chapter 6, p. 45.

[12] 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.

[13] Maximum Use Level of an additive is the highest concentration of the additive determined to be functionally effective in a food or food category and agreed to be safe by the Codex Alimentarius Commission. It is generally expressed as mg additive/kg of food.” (Preamble to the GSFA; CODEX STAN 192-1995).The ML may similarly be established by national authorities.

[14] The use of the MLs established in the GSFA will necessarily overestimate the exposure to a food additive from its use in a given food. The MLs in the GSFA are *acceptable* MLs 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

give total dietary exposure.

15. The TMDI only approximates the dietary exposure to a food additive since it does not take into consideration the food consumption by special populations groups. This approach assumes that:

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

(b) the food additive is always present at the ML;

(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 the food additive in the food does not change as a result of storage, 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)

16. The 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, or b) if the food additive is used according to Good Manufacturing Practice (GMP), an approximation as close as possible to the actual uses levels.

3. DATA AVAILABLE

17. 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 body weights of the population of interest) to assess the dietary exposure to the food additive.

18. It is recommended to use national data on food additive concentrations, food consumption and body weight, and international toxicological reference values[15].National toxicological reference values may also be used, if available.

3.1 Concentration of the food additives in food

19. 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 should be available from or estimated by the manufacturer.

20. MLs established for food additives by national authorities can be used in post regulation dietary exposure assessments. In the absence of a national regulation for the use of the food additive, the assessment can be conducted using the MLs in the GSFA[14]. It is recognized that the use of these MLs will overestimate the dietary exposure to a food additive because it is not typical that a person would consume all foods containing the food additive at the corresponding ML.

21. In a post-regulation exposure assessment, in addition to all pre-regulation data sources, information on the specific foods containing the food additive in the market and the actual use levels of the food additives in those foods may be obtained from food manufacturers or food processors. Available analytical data on the concentrations of the food additive in food may also be used 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.

22. 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, analytical parameters such as 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

23. 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.

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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).

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

24. 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 ML 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 and analyzed to determine the levels of the additive present in foods.

(c) The food additive is authorized according to GMP in all foods, but the use in certain foods is under specific provision. This legislative situation requires close collaboration with the food industry and/or a rather complete sampling and analytical evaluation of the levels present in foods. The financial consequences of this approach may limit its applicability.

25. 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 these cases, information on the ML authorized by the exporting countries and/or the actual use levels may be provided by exporters.

26. 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 national food balance sheet data, depending on the reporting requirements.

3.2 Food consumption data

27. Food consumption data reflect what individuals or groups consume in terms of solid foods, beverages (including drinking water), and food supplements. Food consumption can be estimated through surveys at an individual, household level or approximated through national food balance sheet statistics. The latter two provide gross annual estimates of the type and amount of food available for human consumption within a household or country, respectively, and can be used to derive a gross estimate of average food consumption per capita without indicating the distribution of consumption in the population. Such data at international level can be obtained through FAOSTAT[16] and/or OECD.stat[17].

28. 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 combined analysis of both types of data may be performed.

29. A summary of the generally used methods is given in Table 1.

Table 1: Approaches for Determining Food Consumption Data

Approaches	Method	Characteristics
Inferred data on the movement and disappearance of food in a region or home		
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.

[16] http://faostat.fao.org/
[17] http://stats.oecd.org/

Approaches	Method	Characteristics
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.
Personal data on the actual food consumption by an individual or 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. Data from individual dietary surveys are also understood to more closely reflect actual consumption. However, these data may be prone to bias. For instance, individuals may tend to overestimate consumption of foods perceived as "good" foods and underestimate consumption of foods perceived as "bad" foods.

30. When examining existing food consumption data, the possible variation of food habits within subgroups of the population should be considered. The methodologies should take into consideration non-average individuals, which may be possible at the household or individual survey level.

31. Some subgroups within the population will show patterns of food consumption that 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 these cases, data from individual-based methods are the most useful.

32. Sub-population groups 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). Individual survey methods typically contain food consumption data for different sex, age, ethnic, economic, and regional populations[18].

3.3 Body weight

33. 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[19].

34. It is important that the average body weight used is representative of the individuals in the country or region or population sub-group of interest 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

35. 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 dietary is lower than the ADI. However, if the estimated dietary exposure using this approach exceeds the ADI, a more refined estimate would be necessary. The TMDI can be refined by taking into account food consumption by appropriate population subgroups.

[18] A discussion of approaches to estimating exposure for "high" consumers is provided in EHC 240, Chapter 6, pp. 56-57.
[19] EHC 240, Chapter 6, p. 42.

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

36. The following criteria may be used to prioritize those food additives for which a dietary exposure assessment is applicable. A low priority can be given to additives that have been assigned an ADI of "not specified" when they are used according to GMP[20].

(i) Additives authorized for use at a high level in foods consumed in large quantities or by a significant proportion of the population.

(ii) Additives consumed by potentially-at-risk subgroups (e.g., children, diabetics, pregnant women, elderly), as appropriate.

(iii) Additives assigned a low ADI.

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

37. 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. This approach assumes 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 MLs 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.2.3 Proposed use levels before the food additive has been approved for use (pre-regulation).

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 the 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 Annex).

38. If the TMDI < ADI, the actual dietary exposure 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 Check the list of foods:

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

[20] 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)

B.2 Check the actual levels of use:

Determine whether the additive is used at the maximum authorized level for all the foods, or only for some subcategories. Use actual maximum reported levels of use of the additive obtained from the food industry and/or determined from the analysis of foods (see example in the Annex), as appropriate.

B.3 Introduce these more refined data (B.1 and B.2) in the TMDI previously calculated (see section A).

39. If the EDI < ADI, the actual intake is considered to be lower than the ADI. If the EDI > ADI, check the need and the possibility to conduct a more refined exposure assessment and, when appropriate, discuss with the food industry reviewing the MLs of the additive and the foods in which it is used.

5. SUMMARY

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

ANNEX

Example of Calculation for Benzoic Acid and its Salts (INS nº. 210-213)

Table 1 – ADI and acceptable daily amount per person

ADI 0-5 mg/kg bw		
Average body weight (kg)	**ADI x bw**	**Acceptable daily amount per person (mg)**
Adults (Asian) = 55	5 x 55	275
Adults = 60	5 x 60	300
Children = 15	5 x 15	7 5

Table 2 – Example of MLs by food category

Food categories and subcategories with permitted use of benzoic acid and salts		**MLs (mg/kg food)[21]**
1.	Dairy products and analogues	-
	1.1 Dairy-based desserts	-
	1.1.1 Dulce de leche	1000
2.	Fats and oils, and fat emulsions	-
	2.1. Fat spreads, dairy fat spreads and blended spreads	-
	2.1.1. Margarine	1000
3.	Processed fruit	-
	3.1. Jams, jellies, marmalades	1000
	3.2. Coconut milk	3000
4.	Processed vegetables	-
	4.1. Pickled vegetables and olives	1000
5.	Fruit and vegetable juices and nectars	1000
6.	Water-based flavoured drinks, including "sport," “energy,” or "electrolyte" drinks and particulated drinks	-
	6.1. Carbonated water-based flavoured drinks	500
7.	Alcoholic beverages, including alcohol-free and low-alcoholic counterparts	-
	7.1. Aromatized alcoholic beverages	-
	7.1.1. Cooler-type beverages	500
	7.1.1.1. Sangria	500
	7.2. Distilled spirituous beverages containing more than 15% alcohol	-
	7.2.1. Cachaça	500
	7.2.2. Aperitifs	500
	7.2.3. Liqueurs	500
8.	Table-top sweeteners (liquid form)	2000
9.	Salts, spices, soups, sauces, salads and protein products	-
	9.1 Seasonings and condiments (including mayonnaise)	1000

[21] Brazil, Federal Legislation on Food Additives (www.anvisa.gov.br).

Theoretical Maximum Daily Intake (TMDI)

Table 3 – Example of TMDI of benzoic acid and its salts

Food categories and subcategories	MLs (mg/kg food)	Mean consumption per capita (g or ml/day)[22]	Benzoic acid intake (mg/day)
1. Dairy products and analogues	-	-	-
1.1. Dairy-based desserts	-	-	-
1.1.1. Dulce de leche	1000	0.36	0.36
2. Fats and oils, and fat emulsions	-	-	-
2.1. Fat spreads, dairy fat spreads and blended spreads	-	-	-
2.1.2. Margarine	1000	4.0	4.0
3. Processed fruit	-	-	-
3.1. Coconut milk	3000	negligible	0.0
3.2. Jams, jellies, marmalades	1000	0.84	0.84
4. Processed vegetables	-	-	-
4.1. Pickled vegetables and olives	1000	negligible	0.0
5. Fruit and vegetable juices and nectars	1000	2.0	2.0
6. Water-based flavoured drinks, including "sport," “energy,” or "electrolyte" drinks and particulated drinks	-	-	-
6.1.Carbonated water-based flavoured drinks	-	-	-
6.1.1 Soft drinks	500	57.1	28.55
7. Alcoholic beverages, including alcohol-free and low-alcoholic counterparts	-	-	-
7.1. Cooler-type beverages, sangria, aperitifs and liqueurs	500	0.74	0.37
7.2. Cachaça	500	0.76	0.38
8. Table-top sweeteners (liquid form)	2000	negligible	0.0
9. Salts, spices, soups, sauces, salads and protein products	-	-	-
9.1. Mayonnaise	1000	0.96	0.96
9.2. Other seasonings and condiments	1000	0.72	0.72
TMDI (mg/day)	**-**	**-**	**38.18**

Remarks: The TMDI is lower that the acceptable daily amount for adults and children (see Table 1). To obtain a better estimate of food consumption, check whether the average consumption of “eaters” is not much higher than the average consumption of the population (see Section A.3.3).

[22] Food consumption data derived from a household economic survey (Survey on Household Budgets- Brazilian Institute of Geography and Statistics - IBGE, 1998).

Improved Theoretical Maximum Daily Intake (TMDI)

Average consumption of soft drinks and juices of "eaters" in Brazil:

- Vegetable juices and nectars: 275ml[23] (instead of 2.0ml average intake of the population).

- Soft drinks: 259ml[24] (instead of 57.1ml average intake of the population).

As the average consumption of soft drinks and juices by "eaters" is much higher than the average consumption of the population, consumption data for "eaters" were used to refine the estimate (See Section A.3.3.)

The revised consumption values for these two food categories are indicated in **bold** in Table 4.

Table 4 – Example of improved TMDI of benzoic acid and its salts

Food categories and subcategories	MLs (mg/kg food)	Consumption (g or ml/day)*	Benzoic acid intake (mg/day)
Dulce de leche	1000	0.36	0.36
Margarine	1000	4.0	4.0
Jams, jellies, marmalades	1000	0.84	0.84
Fruit and vegetable juices and nectars	1000	**275**	275
Soft drinks	500	**259**	129.5
Cooler-type beverages, sangria, aperitifs and liqueurs	500	0.74	0.37
Cachaça	500	0.76	0.38
Mayonnaise	1000	0.96	0.96
Other seasonings and condiments	1000	0.72	0.72
Improved TMDI (mg/day)	**-**	**-**	**412.13**

*Average consumption per capita, except for bolded figures where average consumption for "eaters" were used.

Remarks: The estimated dietary exposure exceeds the acceptable daily amount for adults (275 and 300 mg – see Table 1) and children (75 mg - see Table 1). A more refined evaluation is therefore needed.

[23] Machado, R. M. D. and Toledo, M. C. F. (2007) **Analytical determination of sulphites in wines and fruit juices and estimation of their intake.** Thesis (Ph.D. in Food Science) - University of Campinas

[24] Camargo, M.C.R. (1999) Caffeine daily intake from dietary sources in Brazil. **Food Additives and Contaminants**, 16 (13), pp. 79-87.

Estimate Daily Intake (EDI)

As the Improved TDMI exceeded the acceptable daily amount of benzoic acid and its salts for adults and children consumers (Table 1), the EDI approach was then followed. The actual levels of use (based on analytical data) of benzoic acid in the most representative sources of the additive in the diet (soft drinks, juices, nectars and margarine) were used in the calculations. (See Section B.2.)

Analytical data on the concentrations of benzoic acid[25]:

- Mean concentration in margarine: 552.7 mg/kg (instead of 1000 mg/kg).
- Mean concentration in fruit and vegetable juices and nectars: 533.6 mg/kg (instead of 1000 mg/kg).
- Mean concentration in soft drinks: 259.2 mg/kg (instead of 500 mg/kg).

The revised concentration of benzoic acid for these three food categories are indicated in **bold** in Table 5.

Table 5 – Example of EDI of benzoic acid and its salts

Food categories and subcategories	MLs or actual mean and concentration of benzoic acid (mg/kg)*	Consumption (g or ml/day)**	Benzoic acid intake (mg/ day)
Dulce de leche	1000	0.36	0.36
Margarine	**552.7**	4.0	2.21
Jams, jellies, marmalades	1000	0.84	0.84
Fruit and vegetable juices and nectars	**533.6**	**275**	146.74
Soft drinks	**259.2**	**259**	67.13
Cooler-type beverages, sangria, aperitifs and liqueurs	500	0.74	0.37
Cachaça	500	0.76	0.38
Mayonnaise	1000	0.96	0.96
Other seasonings and condiments	1000	0.72	0.72
EDI (mg/day)	**-**	**-**	**219.71**

*MLs from the Brazilian legislation, except for bolded figures where actual levels of use (based on analytical data) were used.

**Average consumption per capita, except for bolded figures where average consumption for 'eaters' were used.

Remarks: This estimated daily dietary exposure exceeds the acceptable daily amount of benzoic acid and its salts for children (75 mg – see Table 1). Check the need and the possibility to conduct further refinement, using more specific data (e.g., average food consumption and specific weight by children, specific types or brands of foods in which the additive is used, and the impact of food processing and preparation). If appropriate, discuss with the food industry to review the current MLs of benzoic acid and/or its salts and/or the foods in which it is used.

[25] Tfouni, S.A.V. and Toledo, M.C.F. Estimates of the mean per capita daily intake of benzoic and sorbic acids in Brazil. **Food Additives and Contaminants,**19(7), pp. 647-654.

Annex II

GENERAL GUIDANCE FOR THE PROVISION OF COMMENTS

In order to facilitate the compilation and prepare a more useful comments' document, Members and Observers, which are not yet doing so, are requested to provide their comments under the following headings:

(i) General Comments

(ii) Specific Comments

Specific comments should include a reference to the relevant section and/or paragraph of the document that the comments refer to.

When changes are proposed to specific paragraphs, Members and Observers are requested to provide their proposal for amendments accompanied by the related rationale. New texts should be presented in **underlined/bold font** and deletion in ~~strikethrough font~~.

In order to facilitate the work of the Secretariats to compile comments, Members and Observers are requested to refrain from using colour font/shading as documents are printed in black and white and from using track change mode, which might be lost when comments are copied / pasted into a consolidated document.

In order to reduce the translation work and save paper, Members and Observers are requested not to reproduce the complete document but only those parts of the texts for which any change and/or amendments is proposed.