
First Draft

PROJECT DOCUMENT

Background

1. The 44th Session of the Codex Committee on Food Additives, that took place in Hangzhou - China, from 12th to 16th of March 2012, agreed to establish an electronic Working Group (eWG) on the revision of the Guidelines for the Simple Evaluation of Food Additive Intake (CAC/GL 3-1989), hosted by Brazil, open to all interested Members and Observers and working in English only, due to the request of the 34th Session of the Commission to consider the need to revoke or revise this text.

2. 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).

3. The mandate of the eWG is to prepare a project document for new work in the revision of the Guidelines for the Evaluation of Food Additive Intake (CAC/GL 3-1989) and possibly include an outline of the revised Guidelines, for consideration at CCFA’s next Session.  

1 REP 12/FA, para. 13

ADDITIONAL QUESTIONS:

1) Are there other updated scientific references on food additive exposure assessment that may be taken into account?

2) Is the simple approach for the evaluation of food additive intake proposed in the document (TDMI and EDI) still appropriate? Please provide detailed information on other possible approaches for the simple evaluation of food additives intake.

3) 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.
ANNEX: OUTLINE OF THE REVISED GUIDELINES FOR THE SIMPLE EVALUATION OF FOOD ADDITIVE INTAKE (CAC/GL 3-1989)

Proposed revisions is presented in bold font (addition) and strikethrough font (deletion)

GUIDELINES FOR SIMPLE EVALUATION OF FOOD ADDITIVE INTAKE
CAC/GL 03-1989

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5. SUMMARY

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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 (Code General Standard for Food Additives – GSFA, Codex Stan 192-1995).

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” (Codex Alimentarius Commission Procedural Manual, 20th ed. Rome, Food and Agriculture Organization of the United Nations, Codex Alimentarius Commission, p. 105).

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 (Codex Alimentarius Commission procedural manual, 20th ed. Rome, Food and Agriculture Organization of the United Nations, Codex Alimentarius Commission, p. 112).

The Joint 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 (Procedural Manual, 20th ed. Rome, Food and Agriculture Organization of the United Nations, Codex Alimentarius Commission, p. 117).

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. The Acceptable Daily Intake (ADI) is an estimate by JECFA 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. 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 (a standard adult person weighs 60 kg).2

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 (CCFA). 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, 1996) which states that “Approval or temporary approval for the inclusion of a food additive in an advisory list or in a food standard should... (iii) as far as possible take into account any Acceptable Daily Intake, or equivalent assessment, established for the food additive, and the probable daily intake of it from all sources. Where the food additive is to be used in foods eaten by special groups of consumers, account should be taken of the probable daily intake of the food additive by consumers in those groups.” Codex General Standard for Food Additives – GSFA (Codex Stan 192-1995) which 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, high levels of an additive in a food of high consumption food additives added in high levels into highly consumed foods, and/or food additives added to foods consumed by special population groups.

Comment [4]: This list should match to the list in new section 4.1.

1 For this purpose, “without appreciable risk” is taken to mean the practical certainty that injury will not result even after a lifetime’s exposure (Codex General Standard for Food Additives – GSFA, Codex Stan 192-1995).
2 The methods used to establish health-based guidance value such ADI are described in chapter 5 of the publication Principles and Methods for the Risk Assessment of Chemicals in Food - Environmental Health Criteria 240 (Food and Agriculture Organization of the United Nations and the World Health Organization, 2009).
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, which may pose difficulties to some countries in initiating such studies on intake of food additives. Therefore, the present guidelines are intended for a simple evaluation of food additive intake, in order to facilitate the dietary exposure assessments.

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

2. BACKGROUND

2.1. Acceptable Daily Intake

The Acceptable Daily Intake (ADI) is an estimate by JECFA of the amount of a food additive, expressed on a body weight basis, that can be ingested daily over a lifetime without appreciable health risk (standard man - 60 Kg) (WHO Environmental Health Criteria document No 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 rev. 2.2.3, WHO, 1989). However, in some countries, and especially in the developing ones, a 50 kg body weight would better represent the average body weight of the population.

2. DIETARY EXPOSURE ASSESSMENT

Dietary exposure assessment3 combines food consumption data with data of the concentration of 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 have to be taken into account: (1) concentration of food additive in food; (2) food consumption patterns; (3) average body weights of the population (kg). The general equation for dietary exposure is:

\[
\text{Dietary exposure} = \sum (\text{Concentration of food additive in food} \times \text{Food consumption}) / \text{Body weight (kg)}
\]

3 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 (Principles and Methods for The Risk Assessment of Chemicals in Food - Environmental Health Criteria 240. Food and Agriculture Organization of the United Nations and the World Health Organization, 2009, Chapter 6, p. 3).
Different methods exist as regards the estimation of the probable dietary intake. The method applied should be clearly stated and reproducible. Information about the model and data sources used, assumptions, limitations and uncertainties should also be documented. National or regional food consumption should be used whenever possible.

International dietary exposure assessments should provide exposure estimates that are equal to or greater than the best available 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, 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 deterministic or point conservative methods and the aim is to identify the food additives for which a more comprehensive dietary exposure assessment is necessary. Examples of these methods are poundage data, budget method, model diets, theoretical added maximum daily intakes (TAMDI) model diet for flavourings and single portion exposure technique (SPET).

The screening methods do not assess true dietary exposure and should overestimate dietary exposure of high consumers using conservative assumptions in terms of food consumption and food additive concentration. This will avoid situations where the dietary exposure estimated by the screening process would erroneously indicate no safety concern (i.e. understate 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 consumption should be taken into account (Principles and Methods for The Risk Assessment of Chemicals in Food - Environmental Health Criteria 240. Food and Agriculture Organization of the United Nations and the World Health Organization, 2009, Chapter 6, p. 45).

Further steps to allow the refinement of the dietary exposure assessment should be designed in such a way that potential high dietary exposure to a specific 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. Some consumers may also be loyal to those foods or brands of food containing the highest concentrations of the chemical of interest or may occasionally consume foods with very high concentrations of the chemical.

If the existence of a safety concern cannot be ruled out on the basis of dietary exposure assessed at the initial steps, more accurate assessments of dietary exposure may be needed. Refinements could include more defined information about the foods that are consumed (less conservative assumptions about the amounts consumed, the concentrations of the chemical in the foods, impact of processing and food preparation, etc.), or more complex exposure assessment models can be employed to allow more realistic simulation of consumer practices. Thereby, a probabilistic analysis of exposure variability may be necessary.

1 For more detailed information on the dietary exposure assessment methods, see the chapter 6 of the publication Principles and Methods for the Risk Assessment of Chemicals in Food - Environmental Health Criteria 240 (Food and Agriculture Organization of the United Nations and the World Health Organization, 2009).

2 For this purpose, there is no safety concern if the estimated dietary exposure to a food additive doesn’t exceed its ADI value.

3 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 concentration data, the point estimate typically consists of the mean, the median, a high percentile of all observed values or even the ML proposed by national or international food authorities. Concentrations can be further modified using additional correction factors as appropriate. For food consumption data, the point estimate typically consists of the mean or a high percentile of all the consumption values of a considered food in a population of (Principles and Methods for The Risk Assessment of Chemicals in Food - Environmental Health Criteria 240. Food and Agriculture Organization of the United Nations and the World Health Organization, 2009, Chapter 6, p. 45 -66).

Comment [j5]: It would appear as though this suggestion is driving towards a dietary intake assessment that would be overly conservative.

The comment indicates that an international estimate be used when a national estimate is not available regardless of dietary habits. Although this may not be preferable, it may be practical. However there is a concern with the term ‘best available’ and how that will be established. What are the criteria that would help determine which national government estimate is best?

Some national estimates may take on highly conservative approaches due to a variety of factors to include:
- National dietary habits,
- Sophistication of intake data,
- Percentile of consumers, etc.

The concern is that best available would, by default, be set as the highest national exposure estimate, which would be extremely overly conservative and would not be representative of the international situation.

As indicated in the below paragraph, the first steps of the procedure should not consider unsustainable diets, or the results will be too unrealistic to be useful.

Comment [j6]: In most exposure estimates, there is such a degree of conservatism and/or refinement of intake data that high consumers of specific food items are automatically captured.

The counterpart to this statement is in the intake data itself and the technical limitations in the foods. For example, you may have a multitude of high consumers of soda such that the intake of soda is very high. So when, for example, a sugar substitute is assessed for exposure, consumers of full calorie soda should be excluded because that is not a food category where the substitute would be used. This is a concern because even developed nations may not be able to provide this level of detail to their intake methodology resulting in an excessive overestimate of dietary exposure.
The fundamental difference between a probabilistic analysis and deterministic or point estimate methods is that at least one variable is represented by a distribution function instead of a single value and the model sample from each distribution is a distribution of potential dietary exposures generated using several thousand iterations. The probabilistic assessments can be conducted by a simple empirical distribution estimate, e.g., in which a distribution of a food additive intake is determined by the multiplication of a point estimate to represent the concentration of food additive in the food product by the points of a distribution curve of food consumption (or conversely), or by more complex methods, as random sampling (Monte Carlo simulation).

Considering the aim of this document, two deterministic methods have been proposed for a simple evaluation of food additive intake: Theoretical Maximum Daily Intake (TMDI) and Estimated Daily Intake (EDI).

2.2.1 Theoretical Maximum Daily Intake (TMDI)

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

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

(a) all foods in which an additive is permitted contain that additive;
(b) the additive is always present at the maximum permitted level;
(c) the foods in question containing the additive are consumed by people each day of their lives at the average per capita level;
(d) the additive does not undergo a decrease in level as a result of cooking or processing techniques;
(e) all foods permitted to contain the additive are ingested and nothing is discarded.

2.2.2 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) according to Good Manufacturing Practice (GMP), or c) an approximation as close as possible to the actual use level.

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

3. ACCEPTABLE DAILY INTAKE ESTIMATES

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

Groups of animals (e.g., rats) are given daily diets containing different levels of the additive under examination. For example, levels of the additive in the diet could be 0.1%, 1%, 2%, 5%. If a toxic effect is found at the 2% level and a "no-toxic effect" at 1% level, the 1% level (expressed in mg/kg body weight) will be the "no-observed-effect level", and it is from this level that the extrapolation to humans is done. In this case, the no-observed-effect level lies between the 1% and 2% levels, and if no toxicological evaluations are done at intermediary levels (1.25%, 1.50%, 1.75%) the choice of the 1% level as the no-observed-effect level introduces already a first safety factor.
The extrapolation from the no observed effect level to an ADI is often done by using a safety factor of 100 (10 x 10), which assumes that humans are 10 times more sensitive than experimental animals and that there is a 10-fold variation in sensitivity within the human population. This safety factor of 100 is based on the experience and common sense of toxicologists and therefore cannot be compared to a physical value such as the boiling point of a pure substance. More information regarding the no-observed-effect level and the use of safety factors can be found in “Principles for the Safety Assessment of Food Additives and contaminants in Food” (Environmental Health Criteria No.70, WHO, Geneva 1987, p. 77-79).

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

4.3 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 food additive in food, food consumption data and average body weights of the population.

It is recommended to use national food data, but international nutritional and toxicological reference values. It would be helpful for the JECFA to receive data from national and regional authorities on food consumption and food additive concentrations, as well as the results of their dietary exposure assessments (Principles and Methods for The Risk Assessment of Chemicals in Food - Environmental Health Criteria 240, Food and Agriculture Organization of the United Nations and the World Health Organization, 2009, Chapter 6, p. 4 -5).

3.1 Concentration of food additive in food

The type of data required for assessing dietary exposure is determined by the objective of the assessment. Dietary exposure can be assessed for a food additive before it has been approved for use (preregulation) or after it has potentially been in the food supply for years (post-regulation). In the first case, food additive concentration data are available or estimated from the manufacture or food processor. In the other case, more refined and additional food additive concentration data could be obtained from food in the marketplace.

Maximum levels (MLs) established for food additives by national authorities can also be used in preregulation dietary exposure assessments. In the case of absence of a national regulation, the assessment can be conducted using the MLs set by GSFA or by a specific Food Codex Commodity Standard. Thereby, it is recognized that a person would not always consume foods containing chemicals at their corresponding maximum levels/limits.

The reported use levels from the industry, in addition to all preregulation data sources, are used in post-regulation dietary exposure assessments. Analytical data on concentrations of food additive in food are needed to more accurately estimate the levels 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 governments 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.

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 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

<table>
<thead>
<tr>
<th>Approaches</th>
<th>Method</th>
<th>Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population-based methods</td>
<td>food balance sheets; food</td>
<td>Represent the total annual amount of a commodity</td>
</tr>
<tr>
<td></td>
<td>disappearance data</td>
<td>available for domestic consumption per year. A daily consumption amount may be estimated by dividing the total annual amount by 365. The major limitation is that they reflect food availability rather than food consumption. Losses due to cooking or processing, spoilage and other sources of waste and additions from subsistence practices cannot easily be assessed. Because consumption is expressed in terms of raw and semiprocessed commodities, these data are not generally useful for estimating dietary exposure to food additives.</td>
</tr>
<tr>
<td>Household-based methods</td>
<td>data on foodstuffs purchased by a household; follow-up of consumed foods or changes in food stocks</td>
<td>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.</td>
</tr>
<tr>
<td>Individual-based methods</td>
<td>food record; 24 h dietary recall; food frequency questionnaires (FFQs); diet history survey; food habit questionnaire</td>
<td>Provide detailed information on food consumption patterns. However, individuals tend to overestimate and underestimate food consumption.</td>
</tr>
</tbody>
</table>

When examining existing food consumption data, the possible variation of food habits within groups of the population should not be forgotten. The methodologies should take into consideration non-average individuals. 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; diseases (e.g., diabetics); and individuals who consume

\[7\] The GEMS/Food consumption cluster diets are databases collected through population-based methods developed by WHO, based on selected FAO food balance sheets and represent average per capita food consumption. Using a cluster analysis approach where countries with similar patterns of consumption of 20 key foods were grouped together and then sorted by geographic location, 13 consumption cluster diets were produced based on all available FAO food balance sheet data for the period 1997-2001 (http://www.who.int/foodsafety/chem/gems/en/index1.html). The consumption cluster diets are expected to be updated every 10 years.
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 chemical of interest or may occasionally consume foods with very high concentrations of the food additive.

4.3.2.1 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 Intake of Chemical Contaminants" WHO/OEH publication NO. 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 those data can provide sufficient information on the consumption of the food additive 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 (glutamate, 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 food additive authorization 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 authorized are only needed, but can be further refined with actual use levels if necessary.

(b) The food additive is authorized 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 authorized 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 food additive is authorized 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.

In the case of imported foodstuffs, the following information might be provided by the exporter:

(i) Compliance with the legislation of the importing country, and/or existing Codex standards;
(ii) Relevant food additive regulations of the exporting country, export country, and/or existing Codex standards 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

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individual</td>
<td>Food diary, weighed intakes, Duplicate Portion Studies, Dietary Recall, Food frequency,</td>
</tr>
<tr>
<td>Population</td>
<td>Food diary, weighed intakes, Dietary recall, Food frequency, Food disappearance method - Household - National</td>
</tr>
</tbody>
</table>

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:

\[
\text{national food balance} = \text{food production} + \text{food imported} + \text{food taken from stocks} - \text{food added to stocks} - \text{food exported} - \text{food used for seed} - \text{food used for non-edible purposes} - \text{food loss from harvest to kitchen} - \text{animal feed}
\]
**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.

**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 population may differ significantly from 60 kg. For the adult Asian population, an average body weight of 55 kg is assumed (Principles and Methods for the Risk Assessment of Chemicals in Food - Environmental Health Criteria 240. Food and Agriculture Organization of the United Nations and the World Health Organization, 2009, Chapter 6, p. 42).

**5. 4. SIMPLE APPROACH FOR THE EVALUATION OF FOOD ADDITIVE INTAKE**

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).

**5.4.1 Additives for which an evaluation of intake would have to be done is be applicable**:

The following priority list criteria may be used to help identify and prioritize for which food additives an intake evaluation have first should be done:

1. Additives authorized at high levels in highly consumed foodstuffs,
2. Additives having received a low ADI (0-5 mg/kg of body weight), indicating a greater severity of toxicity,
3. Additives consumed by potentially-at-risk subgroups, e.g. children, diabetics, pregnant women, etc.

Comment [17]: Paragraph from p.13 should be retained, and reinserted here.

It is important to specify the use of precise data on foodstuff consumption when available.

Comment [18]: Many of the criteria to help identify and prioritize additives that would benefit from an intake evaluation are redundant. The following distilled points would be adequate:

- Additives authorized at high levels in highly consumed foodstuffs, (redundant with highly consumed, number of food portions, and technological function)
- Additives having received a low ADI (0.5 mg/kg of body weight), (redundant with the severe tox endpoints)
- Additives consumed by potentially-at-risk subgroups, e.g., children, diabetics, pregnant women, etc.

Comment [19]: It might be worthwhile to specify what constitutes “high” and “highly” in a footnote to this criterion.

Comment [20]: High levels, high food consumption, ADI, and sensitive subpopulations together are relevant factors to help identify and prioritize additives for intake evaluation. And, all of these factors are covered in criteria 1, 3, and 4 already.

Perhaps including criterion 2 was intended to clarify that all foods containing additives are included, and not just those that are authorized at high levels. However, mere presence in a highly consumed foodstuff should not in itself be considered an adequate criterion.

The purpose of these guidelines, and this section specifically, is to provide countries with the tools necessary to identify and prioritize food additives worth further evaluation (in view of limited resources) thereby necessitating relative ranking among food additives. Higher priority should be given to those additives satisfying all of the three listed criteria (i.e., 1, 3, 4). Criterion 2 would be relegated to a lower ranking, and its usefulness and applicability is questionable in these guidelines.

Comment [21]: What reference source suggests that a low ADI is in fact from 0 – 5 mg/kg of body weight/day?
5. the number of food portions required to reach the ADI.
6. the spectrum of technological function-purposes of the additive serves relative to the ADI.
7. the severity of toxicological end-point.

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

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

The following stepwise procedure is proposed:

A. Evaluation of the TMDI

A.1 Elaboration of the list of foodstuffs in which the additive is permitted;
A.2 Determination of the levels of use;
   A.2.1 Maximum permitted levels according to the regulation;
   A.2.2 Actual levels if authorization is given according to GMP (figures obtained from industry or from analysis);
A.3 Determination of the average consumption of the foodstuffs in which the additive is permitted;
   A.3.1 Collection of all available information regarding food habits in the country;
   A.3.2 When little information is available, the national population-based method should be used as a first step;
   A.3.3 Check if, for some foodstuffs, the average-median consumption of eaters is not much higher than the average consumption of the population. Consumption data for eaters should be used when the special food habits persist for a long period (additive taken daily in the diet during a lifetime. ADI definition);
A.3.4 Obtain a better estimate of food consumption by replacing average values obtained from the national food disappearance method by average consumption for eater (see example in the Annexes).

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

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

B. Evaluation of the EDI

B.1 Checking the list of foodstuffs:
   - Modify the food intake in such a way that only foods these foods are considered which may contain the additive that may containing the additive(s) are

---

Comment [j22]:
This criterion would depend on the combination of foods, and which foods, which is already reflected in the consumption patterns and covered in criterion 1 above. Portion size per se seems inappropriate. Suggest deleting.

Comment [j23]:
Relevance of technological function with ADI is unclear.

Comment [j24]:
It would seem that low ADI additives would qualify as the most severe toxicological endpoints which is already covered in criterion 3. This criterion is redundant and should be deleted.

Comment [j25]:
If the formulae are not provided in an earlier section as previously suggested, they should be provided here. Adding greater specificity to these guidelines will help clarify exactly what needs to be completed. Additionally, an illustration of how the formulae may be used to do the appropriate calculation would be extremely helpful. Same would be true for EDI.

Comment [j26]:
Replace "average" with "median" to reflect users v. non-users.

Comment [j27]:
What difference between eater and population would require further in-depth evaluation?

Comment [j28]:
EHC 240, 6.56: "Model diets for high consumers can be developed on the basis of published data from food consumption surveys...[A] model diet has been used in Europe to estimate chronic dietary exposure based on the assumption that a person might consume average amounts of several different foods but only one or two at high levels. (EC, 1998) The behavior of such a consumer in the European model is determined by adding 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 with the mean potential exposure for all other food categories. [EFA, 2008] The choice of the upper percentile of dietary exposure that represents a high consumer is, however, dependent on the purpose of the dietary exposure and the data available to the risk assessor and risk manager. The European high-consumer model has the advantage of being applicable to surveys for which only data on mean and high consumption of large food groups are
considered. For example, if an additive is used only in fruit-flavoured soft drinks, use consumption value for this more precise category rather than consumption of all soft drinks.

B.2 Checking the actual levels of use:
- is the additive used at the maximum authorized level for all the foodstuffs, or only for some of them?

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

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

C. Use at Home

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

6.5. 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.
**ANNEX 1**

**Example of Calculation for Benzoic Acid and salts**

<table>
<thead>
<tr>
<th>ADI</th>
<th>0-5 mg/kg b.w.</th>
</tr>
</thead>
<tbody>
<tr>
<td>For person weighing 55 kg: 5 x 55</td>
<td>= 275 mg/person</td>
</tr>
<tr>
<td>For person weighing 60 kg: 5 x 60</td>
<td>= 300 mg/person</td>
</tr>
<tr>
<td>For child weighing 15 kg: 5 x 15</td>
<td>= 75 mg/person</td>
</tr>
</tbody>
</table>

**Permitted Use**  
**Maximum Level mg/Kg Food**

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

**Comment [j29]:** Examples of benzoic acid and sweeteners are somewhat confusing. It may be worth substituting the examples given in the current guideline with MSG for the following reasons:

- **It is an additive that is particularly relevant to diets in developing and emerging countries and so will likely lead to easier understanding of the example calculations.**
- **It is an additive that is likely consumed by a broad section of the population and therefore simplifies the example calculations by eliminating the need to factor in/out consumption patterns within sub-populations.**
- Consumption of this additive is related to the consumption of foods within a product category rather than being driven by preference, as sweeteners are consumed.

**Comment [j30]:** To add clarity, it may help to reference the source of these use levels/food categories. This doesn’t seem to be a comprehensive list.
### TMDI ESTIMATES

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

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

**Sources:**

- National Institute of Statistics
- Federation of Fisheries Federation of Soft Drinks

**Comments:**

- [j31]: Sample calculation should be included here as well. It's not clear how one goes from daily food intake consumption data to determining daily intake of additive, and then to determine the TMDI estimate.
- [j32]: Please specify sources. This is unclear.
- [j33]: This amount does not seem realistic?!
- [j34]: Sources should be referenced properly. More detail necessary.
**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

<table>
<thead>
<tr>
<th>Improved TMDI Estimate</th>
<th>Daily Intake mg/person</th>
</tr>
</thead>
<tbody>
<tr>
<td>- semi preserves of fish and invertebrates</td>
<td>5.4</td>
</tr>
<tr>
<td>- shrimps</td>
<td>11.2</td>
</tr>
<tr>
<td>- gherkins</td>
<td>1.3</td>
</tr>
<tr>
<td>- soft drinks</td>
<td>60.0</td>
</tr>
<tr>
<td>- mustard</td>
<td>0.2</td>
</tr>
<tr>
<td>- emulsified sauces</td>
<td>20.0</td>
</tr>
</tbody>
</table>

**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.*
EXAMPLE OF CALCULATION FOR SWEETENERS

Maximum Permitted Quantities of Sweeteners

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

The preparation of This table was realised on the basis of a consumption estimate of the different sweeteners. The consumption estimate was carried out on the basis of using 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:

<table>
<thead>
<tr>
<th>Sweetener</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>saccharin</td>
<td>135.7 mg</td>
</tr>
<tr>
<td>cyclamate</td>
<td>659.4 mg</td>
</tr>
<tr>
<td>aspartame</td>
<td>669.6 mg</td>
</tr>
<tr>
<td>acesulfame</td>
<td>538.6 mg</td>
</tr>
</tbody>
</table>

These TMDIs being below the respective ADIs for a 60 kg person were considered acceptable.
<table>
<thead>
<tr>
<th>Foodstuff or beverages</th>
<th>Saccharin mg/kg</th>
<th>Cyclamate mg/kg</th>
<th>Aspartame mg/kg</th>
<th>Acesulfame mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>soft drinks</td>
<td>125</td>
<td>400</td>
<td>750</td>
<td>600</td>
</tr>
<tr>
<td>syrups (ready to drink)</td>
<td>125</td>
<td>400</td>
<td>750</td>
<td>600</td>
</tr>
<tr>
<td>sugar confectionery</td>
<td>1000</td>
<td>4000</td>
<td>2500</td>
<td>2500</td>
</tr>
<tr>
<td>pudding powder</td>
<td>50</td>
<td>250</td>
<td>750</td>
<td>1000</td>
</tr>
<tr>
<td>pickles</td>
<td>400</td>
<td>1100</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>pickles herring</td>
<td>50</td>
<td>0</td>
<td>140</td>
<td>200</td>
</tr>
<tr>
<td>flour confectionery</td>
<td>0</td>
<td>0</td>
<td>1500</td>
<td>500</td>
</tr>
<tr>
<td>chocolate</td>
<td>300</td>
<td>900</td>
<td>5000</td>
<td>3000</td>
</tr>
<tr>
<td>chocolate spread</td>
<td>300</td>
<td>900</td>
<td>0</td>
<td>3000</td>
</tr>
<tr>
<td>edible ice desserts</td>
<td>150</td>
<td>1500</td>
<td>1000</td>
<td>1000</td>
</tr>
<tr>
<td>special beer</td>
<td>0</td>
<td>0</td>
<td>1000</td>
<td>0</td>
</tr>
<tr>
<td>chewing gum</td>
<td>60</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>liquid milk products:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>fruit yoghurt</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>others</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>fruit quark</td>
<td>2000</td>
<td>3000</td>
<td>5500</td>
<td>2000</td>
</tr>
<tr>
<td>salads</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>jam products: jam</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>and jellies sugar</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>reduced jams fruit</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>nectar</td>
<td>150</td>
<td>250</td>
<td>300</td>
<td>0</td>
</tr>
<tr>
<td>canned fruits</td>
<td>50</td>
<td>250</td>
<td>750</td>
<td>200</td>
</tr>
<tr>
<td>vitamin preparations</td>
<td>150</td>
<td>250</td>
<td>300</td>
<td>0</td>
</tr>
</tbody>
</table>

**TABLE 1**
Maximum Permitted Quantities of Sweetener
TABLE 2

Estimation of the possible consumption of some sweeteners (14.11.1988)

<table>
<thead>
<tr>
<th>Product</th>
<th>Saccharin consumption via product (mg/day)</th>
<th>Cyclamate consumption via product (mg/day)</th>
<th>Aspartame consumption via product (mg/day)</th>
<th>Acesulfame consumption via product (mg/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Soft drinks</td>
<td>162</td>
<td>125</td>
<td>400</td>
<td>64.8</td>
</tr>
<tr>
<td>Syrup concentrates*</td>
<td>5.1</td>
<td>625</td>
<td>2000</td>
<td>10.2</td>
</tr>
<tr>
<td>Sugar confectionery 1/2</td>
<td>13.5</td>
<td>1000</td>
<td>4000</td>
<td>27</td>
</tr>
<tr>
<td>Pudding powder</td>
<td>1.5</td>
<td>50</td>
<td>250</td>
<td>0.1</td>
</tr>
<tr>
<td>Pickles</td>
<td>3.8</td>
<td>400</td>
<td>1100</td>
<td>1.5</td>
</tr>
<tr>
<td>Pickles herring</td>
<td>2.2</td>
<td>50</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Flour confectionery</td>
<td>29.3</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Chocolate</td>
<td>12.1</td>
<td>300</td>
<td>900</td>
<td>3.6</td>
</tr>
<tr>
<td>Chocolate spread</td>
<td>1.2</td>
<td>300</td>
<td>900</td>
<td>0.4</td>
</tr>
<tr>
<td>Edible ice</td>
<td>8.8</td>
<td>150</td>
<td>1500</td>
<td>1.3</td>
</tr>
<tr>
<td>Desserts</td>
<td>?</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Special beer</td>
<td>?</td>
<td>60</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Chewing gum</td>
<td>1</td>
<td>2000</td>
<td>3000</td>
<td>2</td>
</tr>
<tr>
<td>Liquid milk product:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fruit yoghurt</td>
<td>1.0</td>
<td>150</td>
<td>250</td>
<td>0.1</td>
</tr>
</tbody>
</table>

Note: Values are approximate and represent the possible consumption of sweeteners through various products.
<table>
<thead>
<tr>
<th>Product</th>
<th>Saccharin Consumption via Product (mg/kg)</th>
<th>Cyclamate Consumption via Product (mg/kg)</th>
<th>Aspartame Consumption via Product (mg/kg)</th>
<th>Acesulfame Consumption via Product (mg/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Others</td>
<td>24.4</td>
<td>50</td>
<td>1.2</td>
<td>250</td>
</tr>
<tr>
<td>Fruit quark</td>
<td>1.7</td>
<td>150</td>
<td>0.2</td>
<td>250</td>
</tr>
<tr>
<td>Salads</td>
<td>4.9</td>
<td>-</td>
<td>-</td>
<td>700</td>
</tr>
</tbody>
</table>

* Assumes 5:1 dilution

1/ Consumption sweetener via product calculated with half the amount of sweetener
TABLE 2 (Cont.d)

Estimation of the possible consumption of some sweeteners (14.11.1988)

<table>
<thead>
<tr>
<th>Product</th>
<th>Consumption in g per day</th>
<th>Saccharin mg/kg</th>
<th>Cyclamate consumption via product mg</th>
<th>Aspartame mg/kg</th>
<th>Acelsufame product mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>jam products:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>jams and jellies</td>
<td>4</td>
<td>300</td>
<td>1.2</td>
<td>1000</td>
<td>4</td>
</tr>
<tr>
<td>sugar reduced jams</td>
<td>0.3</td>
<td>200</td>
<td>0.1</td>
<td>500</td>
<td>0.2</td>
</tr>
<tr>
<td>fruit nectar</td>
<td>5.8</td>
<td>150</td>
<td>0.9</td>
<td>750</td>
<td>4.4</td>
</tr>
<tr>
<td>canned fruits</td>
<td>3.6</td>
<td>380</td>
<td>1.4</td>
<td>1500</td>
<td>5.4</td>
</tr>
<tr>
<td>coffee (cups)</td>
<td>4.3</td>
<td>2/</td>
<td>26.7</td>
<td>3/</td>
<td>147.4</td>
</tr>
<tr>
<td>tea (cups)</td>
<td>1.8</td>
<td>2/</td>
<td>11.2</td>
<td>3/</td>
<td>61.7</td>
</tr>
<tr>
<td>subtotal</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2/ Only 70% of the sweetness of a sweetener may be provided by saccharin.
3/ Only 30% of the sweetness of a sweetener may be provided by cyclamate.