

## Guidance Document for the use of the Concise European Food Consumption Database in Exposure Assessment

### TABLE OF CONTENTS

<i>Introduction</i> -----	1
<i>Objective of this guidance document</i> -----	3
<i>Completion of the Concise Database</i> -----	3
<i>Food classification system</i> -----	4
<i>Summary statistics from the Concise Database</i> -----	5
<i>How to use the Concise Database</i> -----	6
<i>Future steps</i> -----	7
<i>Acknowledgement</i> -----	7
<i>References</i> -----	8
<u><i>Annexes</i></u>	

### INTRODUCTION

Risk assessments are performed in a four-step process: hazard identification, hazard characterisation, exposure assessment, and risk characterisation (Codex Alimentarius Commission, 2004). The first stage of a risk assessment, hazard identification, is primarily a question of identifying the effects that are considered as adverse, irrespective of the dose needed or the specific mechanism involved to elicit this effect. The next step, hazard characterisation, is centred on the quantification of these effects whereas dietary exposure assessment is the qualitative and/or quantitative evaluation of the likely intake of biological, chemical or physical agents via food (WHO, 1997a). Risk characterisation is the final stage of risk assessment that integrates information from exposure assessment and hazard characterisation into advice suitable for use in decision-making.

In order to calculate reliable estimates of the amounts of a specific agent ingested through the diet, three elements have to be taken into account: (1) levels and fate of the agent in food; (2) food consumption patterns; (3) integration of these elements to determine exposure.

Ideally, dietary exposure to chemical substances should be assessed by combining data on their concentration, in all food products, with data on their consumption. However, with the exception of duplicate-diet studies, surveys are not performed on the basis of consumption, occurrence and concentration data related to the same individuals within a population. Thus, assessments of exposure to dietary components usually require some extent of modelling in an attempt to create a representation of the real-life exposure situation.

In general, it is considered neither cost-effective nor necessary to collect detailed food consumption and chemical concentration data for every hazardous substance. A stepwise procedure is commonly used to minimise costs and to focus resources by targeting refined dietary exposure estimates to agents for which there is a potential health concern. Exposure is therefore first assessed using methods that follow a deterministic approach based on conservative assumptions. In order to protect most consumers, the methodologies adopted for the assessment of exposure give special consideration to individuals that consistently exhibit non-average consumption patterns. In the case of hazardous chemicals, the focus is on subjects who consume relatively large quantities of foods, which are likely to contain higher concentrations of hazardous chemicals substances (high-level consumers). In this connection, there is a need to use inexpensive screening tools for identifying those agents for which safety limits of exposure may be exceeded.

EFSA Scientific Panels perform risk assessment for a variety of agents: biological components such as micro-organisms (BIOHAZ Panel) and a variety of chemicals substances such as nutrients (NDA Panel), additives, food contact materials and flavourings (AFC Panel), pesticides (PPR Panel), additives used in animal feeding (FEEDAP Panel), substances produced from GM micro-organisms (GMO Panel) and contaminants (CONTAM Panel). Exposure assessment to chemicals is generally aimed at identifying situations where intake in segments of the population may be above safety limits; in the case of nutrients, situations where intake may be under the requirements are also of interest. During the first step of the process of exposure assessment, most EFSA Panels perform conservative estimates of exposure to identify such situations. The assumptions currently made in terms of food consumption may differ according to the opinions; in many cases exposure is based on limited food consumption and occurrence data, sometimes related to only one Member State (EFSA, 2005).

The EFSA opinion on exposure assessments (2005) reaffirmed a statement from the World Health Organization (1997) and made it clear that “In order to be protective of public health for the whole of Europe, international calculations should provide exposure estimates that are equal or greater (or lower in the case of nutrient deficiency) than the best estimate carried out at national levels”. If the international dietary exposure is not of concern with respect to safety limits, the level of exposure will then be acceptable at the national level because the international exposure assessment will overestimate exposure or deficiency. Food consumption data are therefore required for each EU country. Food consumption patterns vary with, for example, consumption of fruit and vegetables being higher in Southern than in Northern Europe.

The EFSA colloquium on European Food Consumption database held in Brussels in April 2005 (EFSA, 2008) made it clear that a common database on food consumption would improve the consistency and reliability of exposure assessments carried out by the various EFSA Panels and other experts in Europe. Food supply data, i.e. food balance sheets prepared and published by the Food and Agriculture Organization (FAO), are commonly used for exposure assessment at the international level. However, food supply data overestimate food consumption, since wastes are included, and do not take into account variability of consumption between individuals.

The collection of harmonised individual food consumption data should be promoted in order to obtain a fully harmonised European database. Suggestions have been made on how to proceed in this direction and in line with the recommendations for a European food consumption surveillance provided by the DG SANCO-funded project “European Food Consumption Survey Method” (EFCOSUM, 2002). In the meanwhile, the compilation of existing food consumption data can be performed in order to make data as comparable as possible across Europe.

Following the recommendations of the above mentioned colloquium, in 2007 EFSA started the development of the Concise European Food Consumption Database (hereafter called Concise Database). This database is intended to be used by EFSA Panels and others, including Member States, in order to perform preliminary exposure analyses during the first step of the exposure assessment. This will allow for the assessment of high and/or low level of exposure to the substance/agent of interest.

#### **OBJECTIVE OF THIS GUIDANCE DOCUMENT**

The aim of the present document is to give an overview of the Concise Database developed by EFSA and to provide guidance on its use to experts from the EFSA Scientific Panels or national authorities.

#### **COMPLETION OF THE CONCISE DATABASE**

The Concise European Food Consumption Database is called “concise” since it is intended to provide a limited number of data that will allow easy performance of a conservative exposure assessment. In order to build-up the Concise Database, EFSA created in 2007 the “Expert group on food consumption data” (hereafter called Expert Group). Each member of the Expert Group represents a European country and is in charge of coordinating the collection, formatting and transferring local national food consumption data to EFSA. For this purpose, Expert Group members have been asked to identify the most recent and relevant dietary survey available in their countries and to re-codify the food consumption database of the identified survey according to ad hoc broad food categories and subcategories.

Individual food consumption data are then transferred to EFSA by using either a Microsoft Excel<sup>®</sup> template or as an Extensible Markup Language (XML)<sup>1</sup> file compliant with a schema developed by the EFSA IT Department. For the correct interpretation of the data, members of the Expert Group have also been requested to describe the survey methodology, to list all the food items that have been included in the food categories and to describe the level of aggregation of composite foods and recipes (e.g. a pizza might be composed of cereal-based product, vegetables, meat and cheese). Moreover, it was asked, as far as possible, to disaggregate recipes (e.g. separate meat from the vegetables from a composite dish) before re-codifying food consumption data according to the requested broad food categories and subcategories.

Consumption data are submitted as average daily consumption per person, in order to assess chronic exposure, which is needed, for example, to compare potential dietary exposure to food additives with their respective Acceptable Daily Intake (ADI). In order to verify the consistency of the consumption data, the average daily energy intake (in kcal) over the survey period was also requested per each individual. There was no exclusion of under-reporters since the methodologies to identify them are not yet harmonised across EU countries.

In addition to the consumption data, in order to verify their quality and refine the calculation of exposure, Expert Group members have been also requested to provide basic information on each individual included in the identified dietary survey (i.e. gender, age and bodyweight).

At the present time, the Concise Database is planned to contain food consumption data only for the adult population (16 to 64 years old).

## **FOOD CLASSIFICATION SYSTEM**

Food consumption data are available in a majority of European countries, but data obtained at national level can often not be compared directly because of various survey methodologies and various food categorisation systems. To overcome the categorisation problem, EFSA has developed an ad hoc system with 15 broad food categories. Since a large amount of work had already been done within the EFCOSUM (2002) project and in Cost 99 action (Schlotke et al., 2000) in order to standardise codification of foods among databases from different countries, the food categorisation system adopted for the Concise Database has been largely built by aggregating the Euro Food Grouping (EFG) categories. The list of food categories is reported in Annex I.

In some cases, and when the information was available, some of the broad food categories have been split into subcategories. The list of food subcategories is reported in Annex II.

Food categories were created in such a way as to distinguish, as much as possible, solid from liquid foods (Annex II), since in some cases a preliminary assessment could be done on the

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<sup>1</sup> <http://www.w3.org/XML/>

basis of overall liquid or solid food consumption. Moreover, the number of broad food categories was limited to 15 in order to increase comparability between countries and to allow the use of a conservative technique for exposure assessment, such as the one developed within the SCOOP 4.2 project (European Commission, 1998).

## **SUMMARY STATISTICS FROM THE CONCISE DATABASE**

Individual food consumption data are stored by EFSA but only summary statistics from the Concise Database are made available to the public on the EFSA web site. Data from different countries are never pooled or compared because of the different methods used to collect dietary information. For each country, food consumption data are elaborated according to both broad categories and subcategories and in the total population and for consumers only. The summary statistics include the total number of individuals and, for each food category and subcategory, numbers of consumers, the mean, the standard deviation, low and high percentiles. Summary results are also provided for total solid foods and total liquids in case consumption data are available for the relevant food categories and subcategories.

The use of food consumption data at individual level is restricted to EFSA staff and requires preliminary notification to the countries providing the data. Any further use of the data at individual level requires a formal authorisation by each country providing the data.

In addition to the food consumption data, information on the surveys used as sources are also made available. A detailed description of the survey characteristics (i.e. method, duration, year, etc.) is provided in order to allow a correct interpretation of the data. This information is fundamental in order to explain some of the differences in the consumption levels among countries.

It is important to highlight that the duration of the survey is expected to affect the distribution of consumption, particularly at the upper tails. A short survey tends to under-estimate the proportion of individuals who consume particular food types, but at the same time, over-estimates the levels for high consumers (EFSA, 2006). This means that differences seen between countries (especially in higher percentiles) can simply be induced by the survey methodology which should be kept in mind in interpreting the results. In particular, high percentiles of consumption calculated from a one or two day survey are more likely an over-estimation with respect to those from a seven day survey.

However, the definition of high-level consumers is crucial to the outcome of the risk assessment because, in practice, it defines the proportion of the population that would have to exceed the “at-risk” dose before action is considered necessary to reduce dietary exposure. This problem could be scientific (statistical difficulties could prevent the measurement of high percentiles) but also political and ethical. For this reason a variety of high percentiles are provided in the summary statistics from the Concise Database so that risk managers can take the most appropriate decision.

Moreover the reliability of high percentiles is also related to the number of subjects used to calculate them. Percentiles calculated on a limited number of subjects bear a large uncertainty and only provide a rough indication of high levels of consumption. According to Kroes et al. (2002), a high percentile P can be assessed with sufficient precision if the sample size n satisfies the rule  $n(1-P) \geq 8$ . The minimum sample sizes for the 95<sup>th</sup>, 97.5<sup>th</sup> and 99<sup>th</sup> can be therefore estimated equal to 160, 320 and 800 respectively. Similar results can be calculated by using a binomial distribution (Conover, 1971). In particular, assuming a confidence coefficient of 0.99, the minimum sample sizes for the 95<sup>th</sup>, 97.5<sup>th</sup> and 99<sup>th</sup> can be estimated equal to 130, 263 and 662 respectively. The same limitations hold true for low percentiles.

## HOW TO USE THE CONCISE DATABASE

Due to its structure organised into broad food categories, the Concise Database is proposed to be used as a quick screening tool to assess average exposure to chemical substances, as well as the exposure of high consumers. It allows EFSA Scientific Panels to identify substances that might be of concern and prioritise the use of resources for safety assessments.

The Concise Database is therefore intended to produce conservative estimates of exposure. If the database is used for screening assessments, an analysis of uncertainty is not required, provided that appropriate conservative assumptions take account of uncertainty (EFSA, 2006). However, risk assessors are responsible for ensuring that the use of the database is conservative for the specific case. If data from the Concise Database are used for non-conservative assessments, the degree of uncertainty of the adopted model should be evaluated and discussed

Potential exposure for mean and high consumers can be calculated for each food category, through combination of concentration values with, respectively, average and high consumption values from the Concise Database. Although the intuitive approach to estimate the exposure from all food categories is to add up the high level of intake for each separate category, this results in a gross over-estimate since it assumes that high-level consumers of one food are also high level consumers of all of the others. However, it is very unlikely that there exist individuals being high-level consumers of more than one food category, unless the number of food categories is very high.

One approach proposed by the UK, which has been found to work reasonably well, is to estimate the total exposure from all food sources by assuming that an individual might be a high level consumer of two food categories and would be an average consumer of the others (SCOOP Task 4.2, European Commission, 1998). In practice, this method consists in summing the 95<sup>th</sup> percentile of exposure (calculated considering only consumers) for the two categories that are the main contributors with the mean exposure (calculated considering the total population) for the other categories. This approach has been tested using UK data for a range of pesticides and radionuclides (Pesticides Safety Directorate, 2004) and has been shown to give a reasonable approximation to the results obtained using the full computerised method.

It is important to note that this method is valid only when using a smaller number of food categories, compared to a larger number. For example, the validity of the method is acceptable when using the 16 food categories developed by the Confederation of the Food & Drink Industry in the EU (CIAA), but is not acceptable when using a database containing 800 food categories.

When the Concise Database is used to perform exposure assessments, the present document must be referenced with a special citation to Annex III, in which a reference publication is reported for each national food consumption survey included in the database.

### **FUTURE STEPS**

The Concise Database is limited so far to 15 broad food categories and is proposed to be used by EFSA Scientific Panels and Member States for screening purposes. The database will serve as a starting point for EFSA to develop a more comprehensive food consumption database with data on food subcategories and sub-populations. In the medium term, it is intended in particular to develop further the Concise Database with consumption data for children. Estimates of the distribution of portion size per eating occasions, which is needed in order to assess acute exposure (e.g. when assessing the risk of microbiological agents) or if not available, estimates of the distribution of portion size per eating day are not currently included in the Concise Database but could be requested as a next step.

Members of the Expert Group on food consumption data are responsible for the regular update of the information when a new relevant national dietary survey becomes available.

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## Annex I: Main food categories

	Food category		Example of items
1	Cereals & cereal products	Solid	muesli bars, biscuits, fried rice, buckwheat, quinoa, sarrasin, cereal-based snacks, pop corn, couscous, paëlla, pizza, sandwiches, lasagna, quiches, salt cake, pancakes, spring rolls. <b>Remark:</b> preferably expressed as raw cereals
2	Sugar & sugar products including chocolate	Solid	jam, marmalade, honey, toppings, chewing gum, toffees, fudges, chocolate, candies, chocolate confectionery, liquorice, marzipan, sugar free confectionery, cocoa powder, meringue, nutritive sweeteners (e.g. fructose) <b>List of items excluded:</b> intense sweeteners
3	Fats (vegetable and animal)	Solid	mayonnaise, dressings, sauces (béchamel, hollandaise), low fat dressings or mayonnaise, goose fat, coconut extract. <b>List of items excluded:</b> vegetable sauces
4	Vegetables, nuts, pulses including carrots, tomato and leafy vegetables	Solid / Liquid	cooked and raw products, vegetable sauces (tomato sauce, ketchup), vegetable condiments, vegetable soups, snack nuts, olives, caper, chestnuts, rhubarb, soya-based products (excl. milk), coconuts, peanut butter, advocado, quorn, tofu <b>List of items excluded:</b> starchy roots <b>Remark:</b> preferably expressed as raw vegetable; dehydrated soups expressed as such
5	Starchy roots or potatoes	Solid	tapioca, cassava, sweet potatoes, starch/potato based crisps <b>List of items excluded:</b> carrots
6	Fruits	Solid	dried fruits, canned fruit, fruit mousse, compote <b>List of items excluded:</b> fruit juice
7	Fruit and vegetable juices, soft drinks and bottled water	Liquid	
8	Coffee, tea, cocoa (expressed as liquid)	Liquid	ice coffee, herbal tea (infusion), water-based cocoa beverage <b>List of items excluded:</b> ice tea, milk based chocolate
9	Alcoholic beverages	Liquid	
10	Meat and meat products, offal	Solid	
11	Fish and seafood	Solid	fish eggs
12	Eggs	Solid	omelette, fried eggs <b>List of items excluded:</b> fish eggs
13	Milk and dairy based products	Solid / Liquid	cold milk chocolate, fermented milk, soya milk
14	Miscellaneous / Food for special dietary uses	Solid	salt, baker yeast, vinegar, mustard, condiment sauce (e.g. sweet sour sauce, soya sauce), herbs and spices, pepper, gelatine, intense sweeteners, fat-free sauces, glutamate based products (e.g. vetsin, marmite) / meal substitutes, food for special purposes, food supplements (e.g. fish oil, vitamins, brewers' yeast). <b>List of items excluded:</b> nutritional sweeteners (e.g. fructose)
15	Tap water	Liquid	

## Annex II: Food subcategories

	Food category		Example of items
1A	Cereal-based mixed dishes	Solid	pizza, sandwiches, lasagna, quiches, salt cake, pancakes, spring rolls, couscous, paëlla
1B	Cereals & cereal products excl. Cereal-based mixed dishes	Solid	muesli bars, biscuits, fried rice, buckwheat, quinoa, sarrasin, cereal-based snacks, pop corn
4A	Vegetable soups	Liquid	
4B	Vegetables, nuts, pulses except vegetable soups	Solid	
7A	Fruit and vegetable juices	Liquid	nectar, carrot juice, tomato juice, smoothies, coconut water, mixed vegetable juices
7B	Soft drinks with percentage of fruits lower than nectar, excl fruit juice	Liquid	syrops, almond milk, ice (herbal) tea, energy drink, sport drink, whey drinks <b>List of items excluded:</b> liquid milk substitutes, coating syrups (e.g. maple syrup).
7C	Bottled water	Liquid	
9A	Beer and substitutes	Liquid	non-alcoholic beer, panaché, shandy, cider, alcohol soft drinks
9B	Wine and substitutes	Liquid	sangria, kir, sparkling wine, “non-alcoholic” wine, fortified wine (e.g. porto, cherry wine, madeira, vermouth), fruit wine
9C	Other alcoholic beverages and substitutes	Liquid	alcohol-free anise, spirits
10A	Meat and meat products and substitutes	Solid	beef, poultry, pork, frog legs, tongue, sausage, ham, delicatessen, game, soya-based meat substitutes
10B	Edible offal and offal products	Solid	liver sausages, liver pâté, heart, tripes, sweet bread, andouillette, blood
10C	Meat based preparations	Solid	cassoulet, choucroute, pot-au-feu, meat stew, chili con carne, meat-based sauces, nuggets, poultry quenelle. <b>Remark:</b> if possible meat-based preparations should be disaggregated in their constituents.
11A	Seafood and seafood products	Solid	oysters, snails, jelly fish, squid, caviar, nuggets of shrimp/calamari, tarama, fish eggs
11B	Fish and fish products	Solid	surimi/sea sticks (crab fish), finger fish, battered fish
11C	Fish based preparations	Solid	fish soup, fish quenelle <b>List of items excluded:</b> paëlla
13A	Milk and dairy based drinks	Liquid	cold chocolate, fermented milk, milk substitute (e.g. soya, rice, oat), drinkable yoghurt, milk shake, coffee cream substitutes, milk powders, follow-up formulae
13B	Dairy based products	Solid	chantilly, rice pudding, ices and sherbets, creams, desserts (e.g. mousse chocolate, clafoutis, Siberian omelette, tiramisu, profiterolles), yoghurt, French fromage blanc, sour cream, custard. <b>List of items excluded:</b> drinkable yoghurt
13C	Cheese	Solid	mozzarella, spread cheese, cottage cheese, cheese substitutes (e.g. made of vegetable oil). <b>List of items excluded:</b> tofu
14A	Miscellaneous	Solid	salt, baker yeast, vinegar, mustard, condiment sauce (e.g. sweet sour sauce, soya sauce), herbs and spices, pepper, gelatine, intense sweeteners, fat-free sauces, glutamate based products (e.g. vetsin, marmite)
14B	Food for special dietary uses	Solid	Meal substitutes, food for special purposes, food supplements (e.g. fish oil, vitamins, brewers' yeast)

**Annex III - Reference publication of the national food consumption survey included in the Concise Database**

Country	Reference publication
Austria	1) M. Schaezter, I. Elmadfa: "Dietary intake of the Austrian adult population", (article in German), Ernaehrung/Nutrition, (in press). 2) H. Freisling, M. Schaezter, V. Nowak, I. Elmadfa: "Food consumption of Austrian adults - comparison of four different food classification systems" (submitted for publication).
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Bulgaria	Petrova S, Angelova K (2006) Food-Based Dietary Guidelines for Bulgarian Adults – Scientific Background for Development and Formulation. Advances in Bulgarian Science 4: 19 -33
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