Annex B   Original papers

Annex B-1

Could we find a suitable method for assessment of average dietary intake? In doubt between Scylla and Charybdis

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The method for assessment of average dietary intake in large European populations of different ethnicity, manifold nutritional habits must be

C   suitable for the purposes of study, i.e. comparable independently of the country where it is done,
C   suitable for the assessment and the analysis of desired parameters, e.g. foodstuffs, food groups, nutrients, non-nutritive ingredients, food supply, food security, nutritional habits, food safety (?),
C   suitable for evaluation of nutrition in several target groups (e.g. children, adolescents, elderly, pregnant and lactating women) or for that of cross-sectional characteristics of the whole or adult population,
C   time-saving both for the investigators and the investigated subjects,
C   requiring an ordinary skill in nutritional practice from the investigators,
C   matched to financial resources, i.e. inexpensive,
C   adequately sensitive, specific, of high predictive value.

There are some other significant requirements as prerequisite of a well-organized nutrition trial:

C   the target population should be definitively identified,
C   the selected sample should represent the target population; the sampling criteria are widely discussed in the special literature (Cole; Hall), the critical elements are the design and the sample size; increasing sample size or number of observed days improve the precision; already a single-day dietary intake data may be used for comparison if the sample is sufficiently large,
C   nothing but the findings of a well designed survey can be extrapolated confidently to the larger population of which the study sample is a part,
C   an appropriate quality control is needed,
C   analysis of nutrient intake requires an adequate food composition data bank.

        On the basis of above we have to evaluate the strength's and the weaknesses of the most frequently used methods. First of all we wish to emphasize that the comparison of food items in the European countries seems to be difficult because of divergent meal patterns, differences in preferred foodstuffs and meals, in processing and cooking technology. In our opinion the nutrient content of diet and maybe the main food groups could serve for background of the comparison.

A short review and appraisal of the most frequently used dietary assessment methods

The twenty-four-hour dietary recall

The 24-hour recall originally attributed to Wiehl means an interview. The investigator asks the respondent to enumerate the foods and beverages consumed in the preceding day or in the preceding 24 hours, including their quantity. The interview might be carried out by call over the phone or in person. The latter appears the better manner. The interview, the collection of data may be computer-assisted and so thus facilitated. The critical points of the method are the well-trained interviewers skilled in the choice of available foods and meals, in preparation practices used generally or in certain regions and by certain ethnic groups. They should be familiar with the nutritional habits (e.g. the foods eaten usually together) and consequently they are able to correct or to complete

the answers and to control the accuracy of data.

The recall is based on the memory of investigated subject. The interviewer should help to recall all the food eaten, but should pay attention to avoid influencing the answers. One deemed advisable the use of a preformed protocol and a series of photographs or outlines demonstrating different food, meal quantities, they are a living guide to both the interviewer and the responders. For an efficacious elaboration and evaluation a coding system of foodstuffs and meals moreover a computerized program is needed.

Advantages. The personal contact contributes to the reliability of the collected data. The time between eating and recall is relatively short, thus the ratio of forgotten foods is low or zero. The 24-hour recall is applicable for a wide population, non-respecting e.g. the illiteracy. It is relatively quick, for an interview roughly 15-20 minutes is necessary.

Disadvantages. The individuals' diet varies day by day and in addition the responders may forget some food items. The food eaten during 24 hour does not represent really the whole nutrition. This is why the recall cannot identify as well the individuals whose intake is too high or too low. But it characterises the average intakes of a group or the population. Repeated recalls enhance the accuracy. The 24-hour recall is inappropriate to analyse the association between nutrient intake and biochemical markers of supply or other health indices.

Dietary record

In accordance with this method the responder records the foods and beverages consumed during one day. Also the record of their amounts is needed. The amounts consumed may be measured by household utensils (e.g. cups, tablespoons, scale) or estimated. For the latter manner a collection of pictures seems useful. In general a record of 3 consecutive days is necessary for a reliable information. The reporting must be done at the time of consumption on paper or using a dictaphone. Before fact-finding the persons investigated will be trained in the adequate describing of their diet regarding the specification of foods, amounts, cooking methods etc. The report may be combined with a personal interview at least after the first day and at the end of reporting. A skilled interviewer can the reports make more accurate, clarify the entries and add to the omitted items or amounts. Also according to the Hungarian experiences the self-filling up of a mailed questionnaire is not reliable enough.

Advantages. The dietary record is fairly accurate respecting the foods consumed, thus the method is often regarded as the 'golden standard' among the dietary assessment methods used generally. It is more precise than the 24-hour recall. Its adoption looks rather easy, but the well-trained professionals are indispensable.

Disadvantages. The record method requires a good co-operation on part of the responders who should be motivated and moreover literate (when paper is used for recording). They are limiting factors. The reliability of records decreases over 4 days, mainly over 7 days because of responders' fatigue. If the investigated subject does not record the meals immediately as they are being eaten, the number of omitted foods or other faults increases. The investigator can hardly control the responders from this point of view: the quality control is difficult. Undoubtedly the requirement of recording may influence the choice of foods when the responder is somewhat familiar with the principles of healthy nutrition. Of course this phenomenon may be favourable for the individual nutrition, but unfavourable for the reliable actual data. Underreporting may be frequent in general but especially in obese women.

Food frequency questionnaire

In the case of food frequency questionnaire (FFQ) the heart of matter is to ask the subject investigated on his/her usual frequency of consumption of foods listed in questionnaire for certain periods. For estimation of quantities of foods eaten and/or nutrient intakes several FFQs include questions regarding the portion size (semiquantitative FFQ, SQFFQ). Sometimes the term 'semiquantitative dietary history' is used for FFQs allow a limited quantification of portion size. The nutrient intake may be estimated/calculated by summing of nutrient content of each food taken into consideration the reported quantity and frequency.

Advantages. FFQ seems a useful tool to estimate the usual foods eaten and to clear the nutritional changes in comparison with an earlier report. FFQ provides data to make groups of individuals according to usual

consumption of foods or to nutrient intake (if SQFFQ is used) and gives information on relationship between a specific food and nutrition-related diseases (e.g. consequences of alcohol consumption). The FFQ may be self-administered and it requires fairly little time to be completed by an interviewer. They are in general easily scannable, the cost of the data entries is low like that of data collection and processing, the computerization is fairly easy. There is not a negligible aspect that the respondents' burden is small. There are no observer biases. The FFQ may be used for large population surveys.

Disadvantages. Some factors of inaccuracy exist during the use of FFQ method: the consequences of an incomplete list of foods - food groups, errors in the report of frequency and serving size. On the base of a too short list the consumption and the intake will be underestimated, and inversely, a too long list leads to overestimation and that rises the respondents' burden. A list drawn up for general use is inappropriate for ethnic groups or people with distinct eating pattern, also the children need a particular one. For a quantitative approach the SQFFQ provides only approximate data. The development of the food list is crucial to a successful and reliable data collection. It is difficult to develop a comprehensive list including enough but not too much food items that gives opportunity to all responders of very different eating habits to find the right answer. Each type of questionnaire should be validated. The FFQs or SQFFQs may be self-administered, but the authenticity is lower than in the case of interview.

Diet history

The original diet history attributed to Burke starts with an interview to determine the usual meal pattern, most frequently with a 24-hour recall. The second step is a food frequency questionnaire and the third one a 3-day dietary record. Thus it is a combined method and the strengths and the weaknesses of each method will be partly equalised. It requires a large, skilled staff, a lot of labour, time and burdens the responders. Nowadays, there exist numerous modifications of the dietary history method. Often the 3-day estimated record is abandoned. Individuals are asked to recall their food intake for the past month, several months or a year. For instance, in the German Nutrition Survey 1998 a comprehensive dietary history was performed with the use of the software Dishes 98. This program is rather a combination of a food frequency and a 4 week recall (including estimation of meal pattern) and is integrated with a food composition database and portion size database (Mensink et al., 1999).

Selecting appropriate dietary assessment method for data collection in Europe and for comparison of results

Which criteria determine the selection of method? One of the criteria is the objective of the research, including the accuracy needed and type of data needed. The next issue is the study population (sample size, willingness for co-operation, time limits). Important preconditions face the skilled interviewers and the skill for coding the foods and last not least the financial sources and the adequate, complete, accurate nutrient database.

One of the most widely used methods for dietary assessment is the 24-hour recall. It is logical, logistically simple and suitable for large groups. The choice of the method depends on the stated targets of the study. In Europe a method is needed for a reliable comparison of large population groups' nutrition. We are not seeking unspecified dietary components may be related to health status but general features of food and nutrient intakes. The 24-hour recall is less burdening the population and relatively less costly. The method yields good information on the average dietary intake of a large population but it is not suitable for determining individual nutritional risk. There are differences between population groups regarding its usefulness. Elderly people are less good subjects (but they excellently record the diet). Women know better the serving sizes, the cooking methods and the ingredients used for preparing the meals than men. Children might forget any food item: the parents (above all the mothers) can help them, although the presence of parents may influence the answers of children.

The interviewers must be trained on the base of common principles. The interviewers' skill plays an important role to have a reliable data collection and to avoid the errors. It seems necessary to compile a 'European guideline on data collection for 24-hour recall'. A complete 24-hour recall should contain the following issues: time of consumption (hour, minute), the food item consumed (brand name, popular name, kind, type, additions),

the portion size, the preparing, cooking procedures (if any) including the used ingredients (e.g. fresh, chilled, deep-frozen raw material, lard, olive oil, sunflower oil, salt, flour, sour cream etc.) in the case of meals prepared at home, the source of other meals, the place of consumption or purchase (e.g. restaurant, fast food restaurant, mass catering, take-away meal). There are in many countries cookery books containing the exact recipes for meals frequently cooked in mass catering establishments. They may be often used for the household meals, too. Concerning the portion size a visual aid is necessary namely a collection of photos or drawings that illustrate the quantity of different food items.

The interviewers should very well know the kinds and types of local foods, the items consumed together (e.g. meat and customary garnishment), they should ask the adequate questions to complete the recall. Moreover a good interviewer is familiar with creating connection with responders, he/she must be well trained in this field, too. A checklist of interview should be made available for the investigators: the introductory questions (to obtain the responder's benevolence), the questions regarding point of time, food items, conditions of preparing etc.

Another crucial issue is the common coding system. Each repast should have a code: breakfast, brunch, lunch, dinner, supper, repasts in intermediate time. According to some statistical data about 38 000 food items exist in Europe. For their coding the EUROCODE 2 system developed by EUROFOODS and the interchange proposals from INFOODS may be used to establish compatibility between national databases but the differing cooked meals are out of this system. The food coding and descriptor system is based on 14 major food groups subdivided into 2500 subcategories. Is the marking or coding really necessary and useful? If those are not marked, the comparison of different diets is difficult unless impossible. On the other hand the enormous number means a nearly unmanageable thesaurus. It seems expedient to consider, whether the selecting of foods that are most important in the decreasing or increasing of nutritional risk, could solve the contradiction. Thus the coding of a limited number of foods could be needed. The solution gives opportunity to compare the most significant nutritional risk factors observed in different countries and based on food consumption.

The next step is the conversion of foods to nutrients. The prerequisites for this process are the food composition tables and databases. The goals of the calculation of daily nutrient content are (1) to estimate the adequacy of the dietary intake of population or population groups, (2) to compare the nutrient supply among groups, regions, countries, (3) to study the relationships between the nutritional status and the risk of diet-related diseases, (4) to evaluate the level of nutritional knowledge in the population, to have feedback on the efficacy of nutrition education, information, intervention. The nutrient intake calculated on the base of dietary recall data provides the way for an objective, reliable comparison of nutrition.

Many European countries have their own national food composition tables. The foods usually available in the given country should be included in the tables, but with the globalisation of trade several other foods are imported from abroad in considerable quantity. In this case the nutrient content of them could be obtained from other sources, i.e. from other tables or by analysing the food. Each food, each meal ingredient registered in recall must be calculated, not a single one may be omitted. For a good estimation only 24-hour recall does not give sufficient data. The required number of days depends on the nutrient and it is shown in the next table.

Table 1.1   Number of days required to classify 80% of the population into tertiles of nutritional intake with 95% confidence

Nutrient	Range in days
Energy	3-7
Total fat	5-9
Cholesterol	17-18
Protein	5-7
Carbohydrate	2-4
Fiber	5-10
Vitamin A	46-64
Vitamin C	6-14
Thiamin	6-11
Riboflavin	7-10
Iron	12-19
Calcium	3-5

Source: J M Karkeck (see 'References')

The table goes to show that at least threefold 24-hour recall is required. Nelson et al.(1989) think that the number of day needed is higher.

The use of national food composition tables has many advantages:
C   the tables contain the most popular foodstuffs consumed in the given country,
C   their nutrient content meet the characteristics of foods locally produced; the nutrient content depends on species of plants and animals, on agricultural technology, on climatic conditions, on processing and storing circumstances and they vary in different countries,
C   the naming of food and in the case of cooked dishes the raw material used for preparing the meal would be easily identified.

The international usefulness of national food composition tables considerably depends on range of nutrients included in them. For comparing the nutrient intake on international level a common structure of them together with a list of nutrients is essential. It may be a limited one for basic issues and a comprehensive one for detailed scientific evaluation. The list of ingredients would include macronutrients (protein, fat, carbohydrate), micronutrients (vitamins, macroelements, microelements), non-nutritive ingredients (e.g. dietary fibre, antioxidants, prooxidants, natural occurring toxic substances, enzyme inhibitors etc.). The quality of analytical methods employed for investigations of foodstuffs should be emphasized.
The conversion to nutrients renders possible to determine the main sources of favourable and unfavourable nutritional factors and to compare them.

For constructing national food composition tables or data bank it may be proposed to consult the guidelines prepared by Greenfield and Southgate. A conference organized by United Nations University was held in 1983 in order to an international network of food data system (INFOOD). In 1991 the INFOOD guidelines for describing foods has been published. An initiative of EUROFOODS started in the late eighties for creating national databases in Europe suited the international requirements. In that time other regional INFOODS databases have been established: LATINFOODS, ASIAFOODS, ASEANFOODS, OCEANIAFOODS, AFROFOODS, NORAMFOODS. It follows from this foregoing that there are useful tools for above-mentioned purposes. We may not neglect that a bibliography of food composition tables was published by FAO in 1975 and by INFOODS

Secretariat in 1988 (Heintze, Klensin, Rand). As a matter of course they should be updated. At the present time the crucial sources of international data on food composition are the tables published by FAO for various regions (Africa, Eastern Asia, Near East, moreover for amino acids) and by other organizations, institutions (Caribbean, Central America, Eastern Africa, Western Africa). There are some other pathways to find out a complete food classification system. The Codex Alimentarius is a basic source of information regarding foods. The Confederation of the Food and Drink Industries of the EEC has developed the CIAA Food Categorisation System. It was designed originally to serve as an allocation tool for food additives, but the system covers all foodstuffs even those that may not require additives. The Harmonized Commodity Description and Coding System compiled by the World Trade Organization suit the requirements of international trade. Also the Food Balance Sheets used by FAO, OECD and EUROSTAT is of practical importance similar to the PROCOME scheme based on the European Combined Nomenclature and used in household budget surveys, in EU DAFNE Project. The Langual thesaurus is used in Europe and the USA. Most recently recommendations for food data interchange have been elaborated by the European COST Action 99.

In the course of the calculation of nutrients one has to pay attention to nutrient losses and gains during the processing and preparation. The changes depend on the technology and/or method applied during the mentioned procedures. But if a guideline will be placed at disposal in European nutritional surveys, the evaluation and the comparison will be made much easier. Another complicated issue is the bioavailability can be defined as the proportion of macro- or micronutrients that will be utilised in the body. The bioavailability is a property neither of a nutrient nor of a diet by itself, but is the result of an interaction between the nutrients and other food ingredients and it is determined by the total diet. Thus the databases are unable to give the exact value for bioavailability of a single nutrient.

The general use of 24-hour dietary recall

The method is used worldwide very largely. It has been applied in the course of National Health and Nutrition Examination Surveys (NHANES), the Hispanic HANES conducted by United States Department of Agriculture, furthermore in Canada, in the Ten-State Survey, in the European dietary investigations among others in Poland, Hungary, Russia, Ukraine, Kazakhstan, the former GDR, Czechoslovakia, Yugoslavia, USSR. In Western Europe the food record is preferred (British National Diet and Nutrition Survey Program, Dutch National Food Consumption Surveillance System, Denmark). On the Flair Eurofoods-Enfant Project Meeting in 1992 a European Health and Nutrition Examination Survey was proposed that would resemble NHANES III including a 24-hour recall. The determination of a 'Food consumption basket', the calculation of the nutrient composition and the dietary adequacy was carried out in several rural communities of Mexico on the basis of a dietary recall.

The validity of 24-hour dietary recall

The validity means on one hand whether the findings of a study give a reasonable representation of the true situation (external validity, it relates more to the interpretation of epidemiological findings), on the other hand whether a measure of exposure or outcome actually measures that exposure or outcome (internal validity). The external validity does not exist without the internal validity. Measures of sensitivity, specificity and predictive value relate to the latter type.

In the case of dietary recall the correlation between recalled and observed nutrient intake (external validity) according to Carvetti and Knuts is in the range 0.58-0.74. The validity is unsatisfactory on the individual level and satisfactory on the group level. The best validity has been observed in the middle-aged group. Fanelli and Stevenhagen emphasize the stability of results (like the 1-day food record). A divergent situation is shown in preschool children. The data obtained by dietary recall correlated highly with the children's weighed food intake, but they poorly correlated on two consecutive days of data collection (Klesges et al.., 1987.). The results are similar to the previous report which indicated that dietary intake of preschool children is greatly variable. In the study of Johnson et al... children of age 4-7 years were investigated by means of dietary recall regarding the energy intake, as well as total energy expenditure determined by doubly labelled water method. Data from three

times 24-hour recalls were sufficient to estimate the energy intake in a group, but insufficient for individual measurements. Beaton et al... reported on the sources of variance in 24-hour recall. The variance changes by gender, by the day of week, by nutrient. Knowledge of its partitioning may be favourable also in diet-lipid-heart diseases studies. In Germany the former BGA (Bundesgesundheitsamt, Federal Health Office) published the recommendations for the analysis and the measurement of errors in nutritional epidemiological studies.

Conclusions

Certainly, an ideal method for epidemiological purposes should provide an adequate degree of accuracy about the foods or nutrients consumed by individuals to test the hypothesis of interest in a powerful fashion' (Kohlmeier, 1994). Undoubtedly, the 24-hour dietary recall does not perfectly fulfil the requirements of an ideal method. But – in spite of its insufficiencies – the method is easily practicable in all age groups, relatively inexpensive, useful for groups, the elaboration of data and their evaluation is rather simple. The burden of investigated subjects is not too great, from this point of view it has a positive cost-benefit ratio, spends little time. If the data collection meet the generally accepted guidelines, the results are well comparable. The 24-hour recall means a suitable method to clarify the nutritional features, the nutritional habits, the nutritional risk in large population groups, but for more confident results it is reasonable to repeat it at least three times.

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Annex B-2

Experience from previous multi-centre research and monitoring programmes

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WHO MONICA:	Multinational Monitoring of Trends and Determinants in Cardiovascular Diseases

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Introduction

The WHO MONICA (Multinational **MONI**toring of Trends and Determinants in **CA**rdiovascular Diseases) is a global collaborative project, which was essentially designed to collect data in the perspective of three main hypotheses to be tested:

1) Is there a relationship between trends in the main cardiovascular risk factors and trends in incidence of CVD morbidity and mortality?
2) Is there a relationship between trends in acute medical care for CHD and trends in lethality of the disease?
3) Is there an association between trends in incidence of CHD and trends in incidence of stroke?

For this purpose, data were collected in 38 geographically well-defined areas (called Monica Populations - MP's) from originally 26 countries, spread over 4 continents – the majority of the MP's however being European.

In order to study the basic questions, two types of databases were set up in each MP within a time window of ten years:

1) Repeated cross-sectional data on the prevalence of cardiovascular risk factors in the general adult population aged 35-64 years. At least two (at the beginning and at the end of the ten year period) and preferably three of these risk factor surveys were carried out in each MP .
2) Longitudinal data on the incidence of CVD on the basis of a continuous registration of fatal and non-fatal coronary and/or stroke events.

The Project started in the early eighties and ended in the mid-nineties. The overall design, objectives and methodology as well as the main results have been published (Tunstall-Pedoe et al., 1998, 1999, 2000; Böthig et al., 1989; The WHO MONICA Project, 1989; Kuulasmaa et al., 2000).

From the beginning, the MONICA Project has given great attention to training of field workers, standardization of procedures and measurements, communication between the coordinating centre and the participating centres, continuous guidance and quality control procedures and quality assessments during and at the end of the project. Epidemiologists and statisticians from all over the world have collaborated – and still do – to obtain the highest possible degree of standardization between centres and over time. Most of this collaborative multidisciplinary methodological thinking has been published as internal documents and distributed among participating centres, altogether several hundreds of so-called Monica Memo's. The most essential procedures for recruitment, field work, quality control, data transfer, etc. have been brought together in one comprehensive document, the MONICA Manual (WHO MONICA Project, 1989-1999). A lot of quality assessment reports are available on the MONICA website (http://www.ktl.fi/monica), while some of them have been published in the international literature (a complete list of all MONICA publications can be found on the above mentioned MONICA website). The volume and the intensity of the efforts for standardization make the MONICA Project a high quality reference

model for multi-investigator collaborative research in the field of epidemiology.

Optional study on nutrition – **EURONUT**
A number of Monica Collaborating Centres (MCC's) took part in optional studies and one of these was the EURONUT study on nutrition. Apart from the MONICA core variables, a three day food record method was used to assess the food consumption in the male 45-64 years old subgroup of the MONICA sample.

Sampling procedures *(elaborated in detail by Wolf et al., 1998)*
Some important *definitions* used in MONICA.
The **target population** is defined as "(…) all the individuals (…), to whom the survey data should apply". In other words it is the set of individuals for whom one aims to infer conclusions on the basis of the observed results in a sample drawn from this set of individuals. The criterion in MONICA to consider an individual as a member of the target population is for this subject to have its "chief residence" within the geopolitical area, to which the target population is confined.
The **sampling frame** is the list of sampling units from which the sample is selected. In an ideal situation, it should exactly represent the target population. However, it is clear that – in practice - the sampling frame gives an instantaneous picture of the population, while the target population continuously changes ; therefore, the sampling frame is by definition never fully up-to-date.
Subjects were called **ineligible** if they moved out of the target population area or died in the period between the last update of the population register that was used for sampling and the actual invitation for participation in the study.

All other subjects were considered eligible and were then further subdivided into **respondents** and **non-respondents**.

[NB: the definition of "ineligible" was to some extent subject of discussion in MONICA as this had repercussions on the respondent and non-respondent fraction. Subject of the debate concerned whether or not the "ineligible fraction" should include also the subjects that were in the sample but who could not be contacted for the actual survey even after several attempts through various means (invitation letter, visit at home, telephone, etc). It was recognised by a number of centres that their samples contained considerable amounts of "foreign elements" (defined as subjects who are in the listed sample but who – for one reason or another – are not valid members of the target population at the time of the actual survey) and that this should be taken into account for the calculation of the participation rates. When the sampling frame includes a large number of foreign elements and there is no way to identify such individuals, the response rate will indeed be under-estimated, because subjects who are ineligible become classified as non-respondents. It was recognised by the project management that this type of bias was significant and beyond control of the investigators in 5 MP's].

Sampling frame
The basis for sampling for the MONICA risk factor surveys (and at the same time the denominator for the disease registers) was the total population aged 35-64 years (males and females) within a specific geopolitical area and using the administrative criterion of "having his or her chief residence within this area" for determining whether or not a particular subject belongs to that area. According to the MONICA Manual, sampling had to be done on the basis of the most recent vital population register and/or census data and had to be as close as possible to the actual invitation for participation in the study. Sampling was preferably done on the basis of single-stage sampling. Every deviation from this sampling procedure by an individual MCC had to be discussed in detail and approved by epidemiologists and statisticians from the MONICA Data Centre in Helsinki-Finland.

The actual implementation of the sampling in the different MONICA centres gives an interesting picture of the

common practice and possibilities for sampling for the purpose of general population based research in Europe.

The MONICA quality assessment report entitled '**Participation Rates, Quality of sampling frames and sampling fractions in the MONICA surveys** " (Wolf et al., 1998) shows that there is – also within Europe - an important heterogeneity with respect to the quality and availability of demographic data as a basis for sampling the general population.
Table 1.2 in that report (Wolf et al., 1998) shows that, in the MONICA Project, different types of enumerative population databases have been used as sampling frames for the population surveys. A majority of the centres used population registers, but other databases that were used include electoral lists, census data, lists of patients of GP's, household inventories and registers from health services.

In this quality assessment report, a so called "**sampling frame quality score** " was developed on the basis of a number of characteristics of the sampling frame:
- The type of sampling frame (cf. above)
- The age of the sampling frame (defined as the difference between the last update of the sampling frame and the time when it was used to draw the sample)
- The proportion of persons who were ineligible in the original sample indicates how commonly the sampling frame includes identifiable "foreign elements".
  (NB: the opposite, the proportion of missing elements, i.e. the proportion of the members of the target population who are not included in the sampling frame, is also very important but such data are not routinely available nor traceable within the context of a study like MONICA). The proportion of ineligibles is used as a general indicator of the accuracy of the sampling frame.
- The proportion of "subjects not possible to contact"
  One of the possible reasons for non-response in the non-responder survey of the MONICA project was "*not possible to contact*". This refers to those subjects with whom no contact could be made, but no information was available to indicate that they were ineligible for the sample. As some of the subjects in this category may actually be foreign elements of the sampling frame, their proportion in the original sample may also reflect the inaccuracy of the sampling frame.

More than 10% of the reporting units in MONICA had a score "0" for the sampling frame quality score, which means that the quality of the sampling frame has "major problems". The MONICA QA report concludes in this context the following : *"There were big differences in the availability of good sampling frames among the MP's. Only about 40% of the sampling frames were found to be of good quality, and 25% were clearly of poor quality. There still exists a lot of uncertainty about the specific properties of the sampling frames in the various MP's. For example, it is not clear whether all population registers can be considered equal in terms of being up-to-date. Also, there appear to be significant differences in the quality of electoral rolls. We therefore feel that our use of* "proportion of ineligibles" *and* "proportion of not located" *for quality assessment was probably the best choice under the circumstances".*
And further:
 "It is assumed that all MCCs used the best available sampling frame at their disposal. Therefore, a low sampling frame score does not usually indicate bad performance by the MCC, but reflects local constraints. However, it still means that the sample may be biased because of the poor quality of the sampling frame. On the other hand, the score is not only a reflection of the quality of the sampling frame but also depends to some extent on the efforts of the MCC. Therefore, some of the MCCs with a score of zero probably used a good sampling frame but failed to put enough effort into pursuing persons who were hard to locate".

About half of the surveys used multistage sampling. In some of those, the precision of the estimates of population mean values suffered from a too small number of primary units.
Most surveys were stratified by sex and 10-year age groups. As the population areas were usually small, other

stratification was uncommon.

For the purpose of measuring trends in the incidence of CVD, MCC's also had to collect demographic data for the areas under study and this was very crucial as it served as denominator for calculating incidence rates and attack rates.

These data have also been the subject of an elaborated QA report, entitled "**Quality Assessment of demographic data in the WHO MONICA Project**", also available on the internet (Moltchanov et al., 1999). Some important issues and conclusions are briefly summarised here.

The demographic data in MONICA were derived from routinely available local demographic statistics. Each MONICA Collaborating Centre (MCC) was to collect the best available estimates of the mid-year (30 June) population size and structure and report them annually to the MONICA Data Centre (MDC) in Helsinki.

The quality of demographic data in MONICA was first assessed in 1992 and again in 1996. During the preparation of the quality assessment reports, and after they had been distributed to the MONICA Collaborating Centres, major shortcomings of the data were corrected by several MCCs. Furthermore, many MCCs corrected the intercensal estimates after data from a new census became available.

The term *system for demographic data collection* (*SDDC*) is used in the report for the full process through which the demographic data are collected in a population. It includes components such as the individual enumeration and collecting the data in a census, population registers and the processing of the data to get the final published reports on the annual figure and characteristics of the population. A brief description of the system for many countries is maintained in the World Wide Web by the International Monetary Fund (http://dsbb.imf.org/index.htm).

For estimates of the population size for the years when census data are not available, the following terminology is used.
- *Postcensal Estimates* are estimates of demographic population parameters produced for the years after the last year for which census data are available.
- *Intercensal Estimates* are estimates produced for the period between two census years after the data from both censuses are available.

For MONICA purposes, the essential characteristics of an SDDC were:
- Regularity of the direct count of the target population through a census or a population register;
- Availability of a direct count of deaths, births and migration in the target population for the years when direct count of the full target population is not available.

In some countries, the direct count of the target population is provided by census, while in others an annual report is produced from a computerized population register which contains records of all individuals in the population and is updated continuously. In many countries and local areas some special agency registers the births and deaths and immigration/emigration events, and thus provides useful information for the inter- and postcensal estimates. Sometimes the data on births, deaths and migration are only available at the level of large administrative units. In such case the intercensal estimates for the districts may be biased. The extent to which directly measured vital and migration data are used for intercensal estimation varies from country to country. In extreme cases, the intercensal estimates are based exclusively on data from two subsequent censuses, no other information is used. Every new census always provides a good basis for revising the previously made estimates.

The SDDCs which provided demographic data for the MCC's can be roughly classified into three categories:

Population register (*PR*) involves:
- maintaining records on each individual on a current basis
- reporting facilities, enabling regular reporting of the population size and structure.

Register adjusted by census (*RC*) involves:
- periodic census counts, providing age/sex specific size of the target population for the census years
- continuous registration of the vital and migration events for the target population
- reporting facilities, enabling annual reporting of yearly changes in age/sex groups and, as a result, annual estimates of the population size.

Census/intercensal estimates (*CE*) involves:
- regular census counts, providing age/sex specific size of the target population for census years and possibly some additional measurements (e.g. micro-census) in the intercensal period
- a consistent procedure for producing estimates for the non-census years, based on the census data and possible other information, such as data from a micro-census or estimates of vital and migration statistics which may be available for a larger population, but not directly for the target population.

The classification of the MP's into these three categories of SDDC is shown in table 2 of the report. Among the 79 MP's considered, 18 had a PR, 31 had an RC and 30 had a CE. The borderlines between the categories are often obscure, and the knowledge of the actual SDDC in each RU is not necessarily complete.

Exclusion criteria
Provided that the administrative criterion of "main residence" was fulfilled and that subjects fell within the age range, no specific exclusion criteria were used in MONICA.

Sample size
Sample size calculations were done on a classical basis of power calculations. In order to estimate how many people had to be contacted, each centre had to estimate the expected participation on the basis of previous experience and/or a pilot study and enlarge the sample size accordingly. In this context, two important points were put forward in the MONICA manual:
- In general, a lower participation may be expected in younger people, and in men as compared to women.
- The self selection resulting from low participation rates may introduce biases in the estimation of means, rates, etc and in their trends.

Recruitment
Remarkably, In the MONICA manual no specifications are given regarding the standardization of the recruitment procedures (invitation modalities, incentives, etc.).

Response rates
Participation rates in MONICA varied substantially with extreme values above 90% and around 50% (cf. table 5.1 in reference Wolf et al., 1998).
In the above mentioned QA report, it was considered that *"If the response rate exceeds 80%, we can be quite confident in applying the results of the survey to the whole population, provided that the quality of the data is otherwise good. Only one third of the populations in the initial survey, one fifth of the populations in the middle survey, and one sixth of the populations in the final survey reached that level. The 70% limit, which we might still consider satisfactory, was exceeded by two thirds of the populations in the initial survey, three-quarters in the middle survey, and two thirds again in the final survey. The fact that a noticeable number of populations remained below 70% and the extreme ones even below 50% is a concern. It may be erroneous to assume that the risk factor changes, which are observed in these surveys, reflect the situation in the population"*.

In MONICA, the response rates were assessed centrally, and they are therefore reasonably comparable between the populations. For other surveys, the details of the definitions of the response rate is usually unknown, but this is what the surveys have reported locally.

Handling of non-responders

The WHO MONICA Project attempted to estimate the magnitude of non-response bias through surveys among the non-respondents. This attempt was not successful, because the response rates of the non-respondent surveys were very low. Instead, it was suggested that, where possible, comparisons should be made with other available data, such as census data, to compare the demographic composition of the population and the survey respondents.

The MONICA manual states the following with respect to non-responders data:

"*Even though it is not possible to get the complete data required for the core study for the non-respondents, the MCC should try to collect information about their age, sex, marital status, education, smoking history and blood pressure. The objective is to estimate the selection bias which non-response inflicts on the core study. Age and sex are often known at the time of the sample selection. For other data, a telephone interview or a postal questionnaire can be tried. It is recommended that all non-respondents are asked to provide the information. However, it is acceptable that only a random sample of non-respondents are investigated in full. The reason for non-response should be recorded in all cases.*

The survey non-respondent data should be submitted to the MONICA Data Centre for every non-respondent, regardless of how much information was received from the non-respondent. In most cases the MCC should at least elicit the age group, sex and reason for non- response".

In the MONICA QA report, it is concluded : "*The data available for this report do not provide hard evidence for the representativeness of the respondents. The crucial problem is the low availability of information about the non-respondents, a problem shared with most other surveys. Even if more data were available, they would have to be treated with caution, in comparison to the data about the respondents. The conclusions one could draw from the non-respondent data would hardly be more than qualitative. Nevertheless, such data would help in understanding the full risk factor profile and trends in the population. Perhaps the next step for investigating the non-respondents in more detail has to be taken locally by the MCCs. The MCCs have the best knowledge of the available sampling frames, the procedures used to achieve high response rates, the procedures used to investigate the non-respondents, and possibly other information which helps to characterize the non-respondents. Suggestions for conducting such investigations are:*

1. If the level of education of the target population is available from census data, it can be compared with the level of education in the MONICA sample. Note, however, that the questions for establishing education levels have to be comparable between census and MONICA surveys.

2. Evaluate the changes for "Reason of non-response" between different surveys.

Field work

The field work for the core study included questionnaires, anthropometrical and biological measurements and study of medical records.

Quality assurance

Quality assurance in MONICA was based on several procedures described in the manual like international training sessions, continuous internal and external quality control procedures, continuous communication with so-called quality control centres (for core items) and with reference centres (for guidance of optional studies) and the elaboration and publication of several retrospective quality assessment reports – for which different quality assessment scores have been developed. On the basis of all this, it can be concluded that within MONICA, a huge

body of expertise and experience has been developed over the past 15 years or so, which will be of use for many other upcoming collaborative population based research projects.

Data handling
All subjects in the sample were allocated a unique identification number.

Core data from the MONICA Project were centralised in the MONICA Data Centre in Helsinki.

In the MONICA manual (WHO MONICA Project, 1998-1999), a separate section is dedicated to "data transfer to the MONICA data centre", in which formats, extraction procedures, data cleaning, shipment procedures, error correction procedures, deadlines and additional quality control measures are elaborated.

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EPIC: European Prospective Investigation into Cancer and Nutrition

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Introduction
EPIC is a multicentre prospective cohort study aimed at investigating the complex relation between nutrition and various lifestyle factors and the etiology of cancer. The study is executed in 23 centres in 10 European countries

(Denmark, France, Germany, Greece, Italy, The Netherlands, Norway, Spain, Sweden, United Kingdom) and co-ordinated by an International Agency for Research on Cancer (IARC) from the WHO in Lyon (France). (Norway only recently joined the project.) Advantages of such an international study are the high variation in both cancer incidences and diet and other lifestyle factors. Data are collected on diet, physical activity, sexual maturation and reproductive history, lifetime consumption of alcohol and tobacco, previous and current illnesses and current medication; anthropometry is measured and blood samples are collected.

EPIC was initiated in 1990 with some methodological studies and pilot feasibility studies. These studies were used to finalize the study protocol. The field work took place from 1993 to 1998. Over 484 000 subjects were included in the cohort (Note: Norway not yet included). From all subjects dietary data were available and from over 387 000 subjects blood samples were collected and stored.

Sampling frame
As a rule, eligible subjects were from the general population residing in a given geographical area, a town or a province. A necessary condition for this type of sampling frame was that cancer registries provided complete coverage in this area and that long-term follow-up was ensured. Some countries used a different sampling frame. In France, the cohort was based on members of the health insurance plan for state school employees. The Utrecht cohort of the Netherlands was based on women attending breast cancer screening. A small component of the Italian and Spanish cohort included members of a local blood donor association. These deviations were largely influenced by practical possibilities of obtaining good subject participation and ensuring long-term follow-up. Subjects were eligible from 35 years of age for women and from 40 years of age for men. The upper age limit differed between 60 and 74, depending on the logistics of subject recruitment in each of the centres.

Exclusion criteria
Data on this aspect are not available at this moment.

Recruitment and handling of non response
Recruitment procedures in each study centre were adapted to the local target population (letter, phone, personal contact). In general, eligible subjects were invited by mail to participate in the study. In some cases (e.g. blood donors) the first invitation was by personal contact. Those who accepted signed an informed consent form, and diet and lifestyle questionnaires were mailed to them to be filled in, generally at home. Study subjects were then invited to a centre for blood collection, anthropometric measurements and to hand in the completed questionnaires.

Fieldwork
Data on a large number of lifestyle and health factors were collected by questionnaires. A common core set of questions and possible answers was agreed upon and translated into national questionnaires. Some optional sections of questions were added and implemented in some centres only. The physical activity questionnaire was the same in most of the countries. The three Nordic countries which joined the EPIC project afterward (Sweden, Denmark Norway) differed in questionnaires on non-dietary variables and physical activity, because they already had their own Cohort study.

A standard common protocol was used for anthropometric measurements (weight, standing and sitting height, waist and hip circumference), including some checks of between- and within-observer variability.

Procedures for blood storage differed between the seven countries which originally started with EPIC and the three countries which joined later.

To measure diet, country specific dietary questionnaires were used to assess habitual food intake at the individual level. For calibration of dietary measurements between the various study centres highly standardized 24-hour recalls were used.

Dietary Questionnaire (DQ):
The DQ's aimed to measure the individual's habitual consumption of all main food items during the previous year, allowing calculation of intake of energy and a minimum (core) list of nutrients and major food groups. The questionnaires were developed locally, adapted to the local food habits. The DQ's were 'semiquantitative', meaning that for a number of food items besides frequency of consumption habitual portion sizes were assessed using photographs. In most countries a self-administered DQ was used (providing data on up to 300-350 food items per country), designed to be read by optical scanning or suitable for quick manual data entry (pre-coded options for answers).
Because in Spain and Sicily (Ragusa) the response rate of such a self-administered DQ was expected to be too low, questionnaires were developed (similar in content to those described above) to be used in a direct computerized interview by dieticians. In the UK two separate baseline dietary assessment methods were used: a food frequency questionnaire and an individual 7-day food record. Sweden used a combined method including a food frequency questionnaire and menu book parts.

24-hour recall:
A single 24-hour recall interview was used as an internal calibration method, in order to correct for systematic over- and or underestimation of dietary intakes, among a random sample of about 8% of the cohort. A software program named 'EPIC-SOFT' was developed to ensure the highest possible level of standardization. Common rules were pre-entered into the system to describe, quantify and probe on foods and recipes. "EPIC-SOFT" was translated and adapted for each participating country.

Data handling
All EPIC dietary, non-dietary, anthropometric and biological variables are stored in a central ORACLE database located at IARC in Lyon. Standardized procedures were developed to obtain the same definition, format, check etc.

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CALEUR: Calcium intake and peak bone mass: a European Multicentre Study

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Introduction
CALEUR is a European multicentre study conducted from 1994 to 1997 in six countries: Denmark, Finland, France, Italy, The Netherlands and Poland. The study was co-ordinated by TNO Nutrition and Food Research

Institute (The Netherlands, Zeist). The aim of the study was to assess the association between dietary calcium intake and radial bone density. This was studied in a cross-sectional design in two age groups: adolescent girls aged 11-15 and young women aged 20-23.

Sampling frame

Random samples from females in the required age groups (11-15 and 20-23 years of age) were obtained from the local population registries in Denmark, Finland, The Netherlands and Poland. In France, girls and women were recruited via general practitioners and gynaecologists in the geographic areas. In Italy, girls were recruited form all secondary schools in one town, and women from one University.

Exclusion criteria

Exclusion criteria were:
- chronic diseases in general and diseases related to bone or calcium metabolism in particular;
- use of corticosteroids;
- non-caucasian origin;
- sporting more than 7 hours per week;
- (previous) pregnancy;
- irregular menstruation (for the women only);
- vegetarianism or macrobiotism;
- any prescribed diet, except energy restricted diet.

Recruitment and handling of non-response

Subjects received a letter with information about the study, a reply form and a selection form with some questions with respect to the exclusion criteria. If no reply was received, a reminder was sent once. Subjects who wanted to participate and who were eligible (about 750 adolescent girls and 375 young women per country) were sent a self-administered food frequency questionnaire to assess habitual calcium intake during the previous month. In each country, 50 women from the low end and 50 women from the high end of calcium intake distribution were selected for the actual study. The girls were stratified on age, in 1-year categories, before selecting persons with low and high intakes (20 low, 20 high, for each category). Those subjects were invited for an information meeting to explain the study in further detail, to give instructions about the data collection (3-day food records and urine collection), and the participants (and their parents when required) signed an informed consent form. Only in France all eligible subjects were invited, because the sampling frame limited the number of eligible subjects.

Food frequency questionnaire (FFQ):

The 20-item FFQ was developed and validated in an adult population in the Netherlands and was adapted to the use for adolescent girls. In collaboration with the co-ordinating centre, the FFQ was adapted for each country, to include specific sources of calcium. Frequencies were reported in 10 standardized categories. Portion sizes were asked in household measures to which (country specific) standard weights were assigned. For some foods individual portion sizes were calculated from the number of glasses obtained from one litre. Moreover, the use of food supplements was asked, with respect to brand name, frequency and amount.

Questionnaires were entered and processed using the same automated processing system in each country (FOFRIPS, developed in the Netherlands). Data were checked with respect to completeness and credibility of reported number of servings and portion sizes, according to a procedure manual. If necessary, participants were contacted for further information. Data on mean daily consumption of food products in grams were converted to calcium intake using the local food composition tables.

Fieldwork
Data collection:

The following data were collected:
- 3-day food records;
- bone mineral content and bone mineral density by dual-energy X-ray absorptiometry (DEXA);
- anthropometry (height, weight, triceps skinfold, mid upper arm circumference, hand grip strength);
- Tanner pubertal stages (breast development);
- questionnaire on menstrual function and use of oral contraceptives, smoking habits, alcohol use, daylight exposure, physical activity, height and weight of parents, education of parents;
- blood sample (vitamin D status);
- 2 times overnight urine (sodium intake).

The questionnaire was self-administered at home and checked by the nurse at the visit to the study centre for the other measurements.

Bone mineral measurements and anthropometry were performed by the same two highly trained operators in each country (only in France one operator was replaced, and for Poland a new team was trained). The Osteoscan was calibrated every day against a reference phantom.

3-day food records:

All participants were asked to record everything they consumed during a consecutive Wednesday, Thursday and Friday, the week before their visit to the study centre. The diaries were organized according to meal pattern. Time of day, food and quantity were recorded, as well as recipes of composite dishes. The procedure was explained during the information meetings, at which parents of the girls were present. The parent responsible for meal preparation was asked to assist in completing the diary. At the visit to the Institute, the diary was checked by a dietician for completeness and obscurities; household measures were verified by comparison with standard measures.

The food records were coded by the dietician, entered into the computer, checked and mean nutrient intake (calcium, energy, protein, fat, carbohydrate, dietary fibre, phosphor, magnesium, iron and vitamin C) as the average over three days was calculated. Every country used their own processing system and food composition table.

Data handling

All data were coded by each country in a standard format and sent to the co-ordinating centre. Data from the various countries were pooled for statistical analyses, conducted by the co-ordinating centre.

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TRANSFAIR: **Assessment of trans fatty acid intake and relationship with risk factors for cardiovascular disease in European countries**

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Introduction

The TRANSFAIR study is a European Concerted Action, which comprises three parts:
1.   Determination of (trans) fatty acid contents of food products in European countries (100 food samples per country).
2.   Calculation of (trans) fatty acid intake in different population groups based on the results of part 1 in combination with existing representative food consumption surveys.
3.   Cross-sectional study on the relationship between intake of (trans) fatty acids and cardiovascular disease risk factors in countries varying in (trans) fatty acid intake levels.

TNO Nutrition and Food Research Institute (The Netherlands, Zeist) co-ordinated this study. 14 European countries participated in part 1 and 2 and 8 countries in part 3 (Finland, France, Greece, Iceland, The Netherlands, Portugal, Spain and Sweden). Transfair part 3 was executed in 1997. This description is further restricted to Transfair part 3.

Sampling frame

Each centre selected about 40 men and 40 women aged 50-65 years. For this study it was not necessary to have a representative sample from the whole population of this age group of each country. Only some form of local random sampling was required, in order to increase the variation in dietary habits and in serum cholesterol levels. The way of sampling differed between countries: 4 countries recruited subjects from the population registers of one city (Finland, Iceland, The Netherlands and Sweden), one country recruited University employees (France), and three countries used a combination of employees and subjects recruited via registers (Spain, Greece and Portugal).

Exclusion criteria

Eligible were apparently healthy (postmenopausal) women and men aged 50-65 years. Exclusion criteria were:
-   women: premenopausal status and use of hormone replacement therapy in the past
    6 months;
-   use of lipid lowering medication;
-   change in use of cholesterol lowering diet in the past 6 months;
-   change in use of food supplements containing fatty acids in the past 6 months;
-   known cardiovascular disorders or other chronic diseases in the past 12 months;
-   more than 5 kg weight change over the last year;
-   mental disability;
-   specific dietary regimens (e.g. veganism, macrobiotism) for which the structured dietary history was not suitable.

Recruitment and handling of non response

General:

Recruitment procedures were not standardized between countries. In most countries subjects were invited by means of a personal mailing. Response rates varied from 20-72%. In Greece interest for the study was elicited through a note with details on the study; when they were willing to participate, subjects were asked to contact the investigators on a fist come-first served basis. In Spain, women were recruited from members of a housewives' association who, after attending a lecture explaining the study, were asked to participate.

No detailed non response analyses were performed, because representativity of the study population was less important for this study.

The Netherlands:

In the Netherlands the recruitment procedures were as follows:

Subjects sampled from the population register of Zeist received a letter with information about the study and a selection questionnaire. Based on this questionnaire it was assessed whether the subject was eligible and willing to participate. If within two weeks no reply was received, a reminder was sent. The eligible and willing subjects were contacted by telephone to make appointments for the interview at home and the visit to the study centre. Afterwards the subject received gift vouchers with a total value of 100 Dutch guilders (45 Euro).

Informed consent:

In every country the local medical ethical committee evaluated the study protocol, and the study participants were informed about the study conduct and signed an informed consent form.

Field work

Data collection:

Data collection was standardized as much as possible. All procedures were discussed during a workshop with all the participating principal investigators and recorded in a study protocol. The following data were collected:
- life style factors (age, gender, educational level (years of full-time education), socioeconomic status (3 levels according to local division), smoking habits, physical activity (by questionnaire) and family history of coronary heart disease);
- cardiovascular questionnaire;
- anthropometry (height, weight and waist and hip circumference);
- blood pressure;
- dietary intake by means of a structured dietary history;
- blood sampling (total, HDL and LDL cholesterol and triglyceride);
- adipose tissue sampling (fatty acid composition as validation of dietary history).

If possible, the dietary history was held at the home of the participant. However, this was not feasible for all countries. The questionnaire on life style factors was completed at home by the subject and brought to the study centre, where the questionnaire was checked and where the other measurements were performed.

Dietary history:

The general principles of the dietary history were standardized:
- reference period of one month;
- general questions about dietary regimens and frequencies of consumption of meals preceded the main part of the interview;
- meal pattern based;
- frequencies were recorded in 10 standardized categories;
- for each food the number of portions per consumption day was asked for;
- individual portion sizes were assessed in household measures and afterwards weighed at the participant's home (2 grams accuracy). If this was not possible (at the study centre) photographs or food models were used;
- consistency checks on consumption frequencies of meals and foods were performed.

The order of meals included and the food items per meal were adapted to the national food habits. The co-ordinating centre advised on the development of the national dietary histories. A central training on the dietary histories was organized for the responsible dietician or nutritionist from each country. Afterwards, locally all the personnel involved were trained. Trained (student) dieticians performed all interviews.

Data handling

Subject identification:

Each subject in the study population was, before data collection, allocated a unique identification code of 5 positions, of which the first two related to the country.

Blood and adipose tissue:
Procedures for blood and adipose tissue sampling, storage and transport were standardized. Blood lipids and adipose tissue were analysed for all the countries in a central laboratory.

Dietary intake:
Intake of fat and fatty acids, cholesterol, carbohydrates, alcohol and energy were calculated locally by each country, using their own processing system. For fatty acids the databases developed in Transfair part 1 and 2 were used. The other nutrients were calculated with the national food composition databases. Checks for used food codes, amount per food code and completeness and reliability of each questionnaire were performed by the local dieticians or nutritionist. Subjects with extreme low or high intakes were individually checked. The dietician of the co-ordinating centre decided in consultation with the dietician of the country of origin whether or not a subject should be excluded.

Data formats:
All data were coded by each country according to protocol and the datasets were sent to the co-ordinating centre in a standard format (description of format per data set was included in the study protocol).

Statistical analyses:
Data from the various countries were pooled for statistical analyses conducted by the co-ordinating centre.

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SENECA: Nutrition and the elderly in Europe

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Introduction

In 1986 the Project Management Group of EURONUT, the Concerted Action on Nutrition and Health in the European Community, decided to embark on a study of nutrition in the elderly. An international mixed-longitudinal study was initiated to study the relationship of diverse food cultures with health and performance of elderly people in Europe. The first phase of the study was carried out in 19 centres in 12 European countries in the period 1988/1989. The follow-up study took place in 1993 in 9 out of the 19 centres. The aim of the first part of the SENECA study was to explore dietary patterns in the elderly living in different European communities in relation to health and performance. The follow-up study provided the opportunity to analyse the role of food and food habits with respect to disease incidence and prevalence in the elderly.

Sampling frame

Each centre selected one or two traditional towns to study the elderly born in 1913, 1914, 1915, 1916, 1917 and 1918. The selected towns - having a population size of 10.000-20.000 - had a population and socio-economical

structure comparable to the average country structure. Each centre obtained information of the town's inhabitants born in the years 1913-1918 by consulting the civil registration services.

Exclusion criteria

In principle all elderly of the 1913/1914/1915/1916/1917/1918 cohorts were eligible except for:
- psycho-geriatric patients in nursing homes;
- (foreign) people not fluent in the country's language;
- people that are not at all able to answer questions independently.

Recruitment and non-response

Investigators sent an introductory and explanatory letter to the randomly selected elderly subjects. The letter mentioned the reasons for the study, such as that the European Community shows substantial interest in the elderly and that this study focuses on the health of elderly in different (European) countries. It was also stressed that the particular town involved has been chosen as an example for the country and that the study might help for a better quality of life in the future. Subsequently these subjects were visited at their homes and personally invited to participate in the study. In the case of absence, a second or third attempt was made. If this did not result in the desirable number of participants (participation rate of 60%), the researchers sampled again. Persons who were unwilling to participate were registered and asked for their reasons to refuse to participate in this study. Furthermore, they were asked to answer a few questions of the so-called 'non-responders' questionnaire.

Fieldwork

The basic protocol, which was prepared in consultation with participating principal investigators, was common to all participating groups. This protocol was described in detail in a manual of operations. In this way interviewers were enabled to conduct the study in a standardized manner. In addition, representatives from each participating country had a simultaneous training in the Netherlands. Afterwards a training period was organized locally, with all the personnel in charge of the survey.

The protocol consisted of several parts, such as a general questionnaire, food consumption study, anthropometrical session and collection of blood, which were completed by visiting the subjects several times in their homes and/or by inviting them to come to a research or health centre.

In a personal interview food consumption data were obtained using a modified version of the dietary history method consisting of two parts: first, an estimated 3-day record including two weekdays and one weekend day, and secondly a frequency checklist of foods. Portion sizes were checked by weighing, or standardized household measures were used. Scales were not supplied centrally and therefore were not the same for all centres. Food consumption data were converted into energy and nutrients by using country-specific food consumption tables. In order to compare intakes of foods, foods were classified according to the main groups and some subgroups of the Eurocode coding system.

Data handling

As the data were analysed centrally, the data were prepared in a common way by all countries participating in the study. Instructions were provided for constructing the data files. Careful instructions for each item were given with respect to units used and rounding down of figures. The data were transferred directly from computer (in specific centre) to computer (in co-ordinating centre in Wageningen), by using the European Academic Research Network (EARN), which connects computers of research centra all over Europe.

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Annex B-3

Scanning of the bar code: new technology in food consumption methodology?

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EAN (European Article Numbering) bar codes are used for the identification of products and initially developed to facilitate logistic processes between producer and retailer. The bar code consists of a series of numbers, of which the first two numbers give information about the country, where the product is registered; followed by the ID number of the producer and the number of the product the producer has given. This number is unique in Europe and serves therefore as a unique ID for branded products coming onto the European market.
Bar coding of pre-packed fast moving consumer goods is standard nowadays and even for products that are sold with non-standard quantities (mainly fresh foods).

The question arises whether the bar code, as a unique ID can be used in food consumption research. Especially for the identification of product characteristics that are brand related.
At the Fourth International Conference on Dietary Assessments (Tucson, 2000) some initiatives in that respect were presented. In the UK, a study was done where cash receipts of a supermarket chain were used as an identifier of all foods brought into the household (Ransley et al., 2000).
Also TNO Nutrition and Food Research presented a poster, in which some results on a feasibility study were presented (Van Erp-Baart AMJ et al., 2000). This study was a joint action with a marketing research bureau (GfK Nederland) that collects purchase data by scanning all foods brought into the households (Luijten ALJM, 1994).
It would be interesting to find out how widespread this EAN code is used in Europe for identification of products, other than for the logistic reasons.
We also know of some initiatives where the EAN code is used as a key entry for product characteristics, such as ingredients, additives, etc. etc.
Although these actions are single ones and carried out at a national level, they all indicate that there might be serious possibilities for using the EAN code in food related research.
In general the following applications can be identified:
1 In the field of food consumption methodology: scanning of purchase data, in order to have 'relatively' easy access to food availability at the household level. A possibility that might be of use in the area of household budget surveys, where market research companies also collect household food information. However it should be stressed that accurate information requires high response rates, as well as representative samples (Buss, 1998). Interesting in this respect is also the comparison of INCA data with marketing data (ECODIP) in France (Volatier JL, 2000).
2 In the field of database management: use the EAN code as a key entry for databases with information of product characteristics/composition such as nutrient values, ingredient specifications, additives, weight of product etc etc.
3 In the field of operationalization of the food consumption survey at the individual level: the use of scanning techniques that enables the researcher to have easy access to a detailed level of branded products.

For EFCOSUM it can be discussed whether this technique might be a useful addition to the collection of food consumption data in the future.

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Annex B-4

How to get the distribution of usual dietary intake?

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1.   Introduction

One of the first steps of analysing dietary data is a precise definition of the purpose for which these data will be used. It is therefore the question whether these data will be used to elucidate associations between diet and risk of chronic diseases or whether they should describe the current status of dietary intake within a population. This distinction is important since different types and amounts of data are needed and specific study designs required. For relative risk evaluation, all important information about potential exposure factors including dietary data must be gathered for each study subject. For describing the status of a population, only a precise estimate of the population parameters is required without having the same precision on the individual basis. Each approach favors specific study designs such as cohort and case-control for relative risk evaluation and survey for estimation of population parameters.

Surveys are connected with etiological research by providing data of the prevalence and the distribution of exposure in the population. These prevalence data are used together with the relative risk information to calculate population attributable risks. Also further measures which describe the change of disease risk in connection with a change in exposure, such as the preventable proportion, require an estimate of population based prevalence. Population based data on dietary variables are also collected for statistical purposes which gave the basis for describing the public health situation and food safety considerations. Again, such data do not require the precise estimation of individual usual intake.

Given the different purposes for which descriptive data are used, in non of the instances an estimate of the usual dietary intake of an individual is required but a precise estimate of the population distribution. Naturally, the intuitively best approach to estimate a population distribution is based on a good estimate of the individual usual intake which forms the population distribution. However, due to the day to day variation of the individual diet, this approach requires a long-term quantitative recording of the diet for each study subject. Alternatively, other methods such as a food frequency questionnaire or a dietary history are used which are less quantitative and less accurate but cover a longer time period. In the context of a regional restricted study, long-term instruments aiming at the average intake of an individual are likewise useful for estimates of population parameters compared to recording methods so far substantial bias can be excluded and the validity of the instrument is known.

Clearly, long-term instruments such as food frequencies or diet histories need to be tailored to the specific study population. This adoption to the local study population has the unwanted consequence that such instruments are not directly comparable to each other in a multinational study. Due to the nature of such long-term instruments, not all aspects of a diet will be identically covered by each local dietary instrument and country or center specific bias of the dietary measurement might exist preventing a direct comparison of the results. At least in the current stage, no long-term dietary questionnaire is known which has been used in the European context and which deliver sufficiently detailed dietary data adjusted for study specific bias.

Alternatively to the approach of using long-term dietary instruments for estimating population distribution parameters, short-term instruments might also be applied corrected for intra-individual variation. The major advantage of this approach is the fact that short-term instruments usually give quantitative estimates and are open ended. The collection of dietary data without a predefined restriction to specific food items will give a more detailed picture of the current intake in a population and leaves room for new developments in food intake. An example of such an open ended quantitative instrument is the 24h-recall (Slimani et al. 1999). The 24h-recall requests information on all foods being eaten the day before with specifications regarding amount and type of food. This instrument is already been tested in the European context for 10 countries and seems to be applicable for all study populations in Europe. The version being applied based on a highly standardized computer program and a common food list. From this view, the 24h-recall is the ideal instrument for evaluating the dietary intake across Europe. However, the 24h-recall can not be effectively used for individual long-term assessments because of the high intra-individual variation of the day to day dietary practice and the need of a high number of repetitions.

An important task of food consumption surveys is the description of the usual daily intake distribution in the target population by location and scale parameters as well as by percentiles. The formulated problem is one of the topics that were addressed to study in more detail as recommended by working group 1 (Comparability of food intake assessment) of the EFCOSUM kick-off meeting in Amstelveen in January 2000. It is also closely related to topics of working group 3 (Statistics and software) of the same meeting. During this meeting preferences were given to short-term instruments such as the 24-hr-recall for future European-wide nutrition surveys because of their widespread applicability. However, there had been no clear statistical idea how the results of short-term instruments can be used to calculate population distributions of usual intake. This paper describes the statistical procedures of estimating the usual intake distribution.

2.   The strategy of calibrating FFQs

To obtain good estimates of parameters of the usual daily intake distribution, at least two strategies are possible that should be compared. The first strategy is to choose an assessment method (FFQ) that is planned to produce usual intake data directly which will be improved and standardized afterwards by calibration using a method of higher validity (24h recalls) performed in a substudy.

Food frequency questionnaires are country-specific, are not very flexible since they base on closed questions with predetermined food frequencies, and produce data with a considerable bias. On the other hand, they can be referred to the reference time period of the study, but their validity depend on the individual ability to recall and to aggregate food intake over a long period. Therefore, the empirical distribution function of usual daily intake obtained by FFQ will be markedly deviate from the true usual daily intake distribution in the study population. This deviation should be reduced if the FFQ data will be calibrated by 24h recalls as done in EPIC and other studies. Here, the following aspects should be considered.

- The best sampling design of the calibration substudy is to select a relatively large random subsample of the study population and to perform only one 24h dietary recall interview per individual.
- The 24h dietary recalls should refer to days that are equally distributed over the whole reference time period of the FFQ.
- In epidemiological studies the method of linear calibration is preferred. Here, the effect of calibration on relative risk estimation can be quantified by a single correction factor.
- The bias of the calibrated FFQ intake coincides with the bias of the 24h recalls.
- The variation of the FFQ intake is reduced by the calibration process.

The last aspect seems to be the most serious one since this reduction is often more than 50 % in empirical

investigations. Especially, if a linear calibration function is used, the extreme percentiles are shifted to the median and the whole distribution function is pulled tight. Thus, it should be expected that the resulting empirical distribution function of the calibrated FFQ intake does not reflect the true usual dietary intake distribution.

3. The strategy of repeated 24h recalls

The second strategy is based on repeated short-term measurements (24h recalls) in the whole sample that were used to construct a usual daily intake distribution by applying suitable statistical formulas and data transformations. Here, additional information on the percentage of users would be convenient that can be gained by a short questionnaire.

Using 24h recalls the empirical distribution function of the daily measurements cannot be considered as an appropriate reproduction of the usual daily intake distribution since especially the upper tail percentiles are overestimated due to high day-to-day variation. Although the distribution of the individual's mean daily intake would be a markedly better approximation if many repeated measurements are made per individual, the variance of the mean intakes will remain to be greater than the variance of the usual intakes because of mean intakes contain some within-individual variability. Fortunately, this difference can be evaluated and the following formula can be applied,

$$\hat{s}_{usual}^2 \quad = \quad \hat{s}_{\overline{X}}^2 - \frac{1}{k}\hat{s}_e^2 \;, \tag{1}$$

where k is the number of repetitions, $\hat{s}_{\overline{X}}^2$ is the estimated variance of the individual's mean intake and $\hat{s}_e^2$ is the estimated average within-individual variance. If the mean squares $MS_{BETWEEN}$ and MS_{WITHIN} are used as results of the ANOVA procedure, the formula has the form

$$\hat{s}_{usual}^2 \quad = \quad \frac{1}{k}MS_{BETWEEN} - \frac{1}{kn}MS_{WITHIN} \;, \tag{2}$$

where n stands for the sample size.

Thus, the mean and the variance of the usual daily intake can be estimated from the individual's mean daily intake. However, no mathematical relations exist between the corresponding percentiles, in general. But, in the special case of normal distributed intake data, percentiles of the usual daily intake distribution can be estimated so far estimators for the mean and variance are available. Thus, percentiles should be calculated after a suitable data transformation to normality and carried over to the original scale by applying the back transformation.

3.1 The transformation procedure of Nusser

Nusser et al. (1996) proposed a universal stepwise procedure for estimating the usual daily intake distribution based on a sophisticated transformation of the data to achieve a normal distribution. It takes into account nuisance effects (day of week, month, interview mode, interview sequence, etc.), survey weights and heterogeneous within-individual variances. It is based on the best power transformation and a subsequent approximation by grafted cubic polynomials (sometimes called splines). The procedure should be applied if the data are obviously non-normal and a simple logarithmic transformation or a power transformation fails to obtain a symmetric unimodal distribution. As a disadvantage of the Nusser approach, the transformation cannot be described in closed form by an explicit transformation formula. This impedes the reproducibility of the results and the widespread use of the procedure. In publications, the transformation function used should be stated explicitly as an important feature of the data analysis. Furthermore, the complex transformation process of Nusser et al. (1996) is not suitable to calculate confidence intervals for the percentiles directly and to describe the precision of the estimated percentiles as a function of the sample size. Consequently, no design-effect (see Callahan et al. 1995) can be calculated to handle with complex multistage probability sample designs.

3.2   Simpler transformation procedures

For lognormal distributed data, Wallace et al. (1994) and Slob (1996) gave simpler procedures to construct long-term exposure distributions from short-term measurements. The method of Wallace is based on considerations of the limit behaviour of series of average daily exposures, whereas Slob used the standard ANOVA technique to separate within and between individual variation. Slob showed that his procedure is preferable by presenting some simulation results. Moreover, it can be applied without any further non-standard software package. It should be noted that in the case of logarithmic transformations, confidence intervals for percentiles of the population distribution can be determined by applying formulas of Holst and Christensen (1992). Thus, the desired precision of the estimated percentiles can be required in advance and the minimal sample size needed can be calculated.

Another proposal is a simplified version of the Nusser procedure called best power procedure (Nusser et al. 1996). It is an extension of the suggestions of the National Research Council (1986). A simulation study showed that it is somewhat more biased than the original procedure but considerable better than the use of the smoothed empirical distribution of individual mean intakes (Nusser et al., 1996, Table 7). The method consists of the following steps.

Step 1: *Initial adjustments*
The weighted original data will be adjusted for some nuisance effects like weekday or interview sequence effects if these effects are significant predictors for the daily dietary intake in a linear regression model. (In contrast to the original Nusser method, no preceding temporary data transformation is made here. Also, no equal weight sample will be created since the subsequent steps can handle weighted data**.)**

Step 2: *Transformation to normality*
Before data transformation, a statistical test for normal distribution should be performed. In the case of non-normality, the best power transformation must be determined where the grid of possible values for the power is $\{1, 1/1.5, 1/2,....,1/10, 0\}$ and the optimality criterion is minimizing the error sum of squares (formula (1) of Nusser et al. 1996). The optimal power value should be stated in publications. After data transformation, a statistical test for normal distribution should be performed again. Here, the Anderson-Darling test should be preferred to the Kolmogorov-Smirnov test since it is more powerful. A significance level of 0.05 may be used as a rough criterion for acceptance of normal distribution. (A smaller significance level of 0.01 or 0.001 would increase the probability of an erroneous acceptance.) If this transformation step does not yield normal distributed data, an extended set of possible transformations must be chosen.

Step 3: *Estimation in the normal scale*
At first, the mean and the empirical variance of the individual means will be calculated and used to estimate the two parameters of the normal distribution of the transformed usual dietary intake. Here, the correction formula (1) of the variance must be applied. Then all desired percentiles can be estimated. For important percentiles like the 95. percentile or the median, 95% confidence intervals should be determined using tabulations of the non-central t-distribution (Johnson and Welsh, 1940).

Step 4: *Back transformation*
All percentiles and corresponding confidence intervals will be carried over to the original scale by using the inverse transformation function of Step 2.

The advantage of the best power procedure is that is based on an explicitly given transformation formula and that is sufficiently flexible to handle varying degrees of departure from normality, initial adjustments and incorporating survey weights.

3.3   The number of replications
To apply the formula (1) for the variance of the usual dietary intake, the within-individual variance or, in the general case of heterogeneous within-individual variances, its mean must be estimated. Therefore, the number k of daily measurements per individual must be at least 2. From the statistical point of view the number k of replications and the number n of individuals should be chosen in such a manner that the confidence intervals for the percentiles are as small as possible. Since the length of such an interval decreases if n increases whereas the length is not systematically influenced by a change of k, the best choice of k is 2 by simultaneously maximise the sample size n. However, if the study period is one year or longer, a choice of 4 replications should be advisable to include the whole annual variation in estimating the within-individual variances. Such a small number of replicates per subject was also been proposed in the framework of validation studies (Willett 1998, pp 133-134).

3.4   Statistical analysis of the transformed data
Beside monitoring and describing the exposure distribution of a population, national surveys should involve detailed investigations of specific subgroups and their comparison. A typical task is to explore whether two ore more groups (age groups, sex groups, regional groups) have significantly different usual dietary intakes. This can be done e.g. by the ANOVA F-test. But, these parametric tests should be performed for data which have symmetric unimodal distributions. Thus, it is better to apply such a test after transformation to the normal distribution. It should be noted to be very carefully by interpreting the results. For instance, significant mean differences of logarithmically transformed data must be interpreted as significant different geometric means instead of arithmetic means in the original scale. Moreover, other statistical methods like correlation and regression analysis should be based on the transformed data in cases of strongly asymmetric distributed original variables.

4   Concluding remark
In order to obtain a good approximation of the unknown distribution function of true usual dietary intake, the strategy of repeated 24h recalls should be preferred to the strategy of calibrating FFQs. The direct use of 24h recalls as original assessment method avoids the step of calibration, so that there is no necessity to perform an additional calibration substudy. 24h dietary recall interviews have the advantages that they can be standardized (e.g. EPIC-SOFT) and that they are very flexible. Results of standardized 24h dietary recall interviews in different countries and in different years can be compared directly. The disadvantage of the high day-to-day variation can be eliminated by applying a correction formula and the use of a suitable data transformation. Here, the application of the best power transformation seems to be a compromise to achieve sufficiently high accuracy and to yield an explicit transformation formula.
There remain some open problems. Especially, the approximation of the usual intake distribution for foods that are not consumed daily should be studied further. The extension proposed by Nusser et al. (1997) needs the assumption that usual intakes are uncorrelated with the frequency of consumption. Possibly, a short questionnaire to determine non-users of different foods should be added to the assessment tool of 24h recalls.

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Annex B-5

The role of portion sizes in dietary assessment

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Quantification of portion sizes is one of the sources of error in collecting food intake data. This is especially the case when the assessment of food consumed must be recalled from memory. In short- term dietary methods a certain portion of food has been consumed and the validity of the method depends on the accurate recording or recall of this portion size whereas long-term dietary methods concern the concept of 'usual' portion size. In this paper first information on the assessment of portion sizes in short-term dietary methods will be presented and thereafter more details of studies related to long-term measurements will be given.

Portion size and short-term dietary assessment

Guthrie (1984) studied the ability of young adults to estimate portion sizes of 12 common foods and observed that the ability of subjects to estimate portion sizes was poor without the aid of measuring devices or interviewer assistance. In estimated food records and 24 hour recalls several types of portion size measurement aids can be used to help individuals to quantify the amounts of food eaten. Roughly, one can distinguish three-dimensional measurement aids, such as real food samples, food replicas (models of real foods), food models (abstract models), household measures, and two-dimensional measurement aids, such as drawings of real foods, abstract shapes, household measures, food photographs, computer graphics, food package labels. They are used as point of reference to estimate the actual amounts as fractions or multiples of the size of the model. The use of different models have been validated in several studies.

Identifying portion sizes with the aid of measurement devices is a complex process in which perception, conceptualisation and memory play a role. Perception involves a subject's ability to relate an amount of food which is present in reality to an amount of food in a two- or three-dimensional model. Conceptualisation concerns a subject's ability to make a mental construct of an amount of food which is not present in reality, and to relate that to a portion size measurement aid, whereas memory will affect the precision of the conceptualisation (Nelson et al., 1994). In most of the reported studies the ability to estimate the quantity visualised as consumed and ability to recall (remember) the quantity consumed 24 hours or more previously are incorporated at the same time.

Wein et al. (1990) compared recalled estimates of portion sizes with portions observed in a cafeteria. In the interview several three- and two-dimensional food models were used as aids. Of the 39 foods studied, the mean recalled portion size was within 10% of the observed portion size for 20 foods, and within 20% of the observed portion size for 30 foods. There were no differences in accuracy of portion size estimations between men and women for 36 foods. Overestimation was more frequent than underestimation (33 vs. 6 foods). Overestimation was a particular problem with mashed potatoes, gravy, whipped topping, cheese and cake, and underestimation with milk added to coffee and tea.
Eggs, soup, bread, crackers, milk as beverage, coffee and tea appeared to be the easiest foods to estimate, while cheese, milk in coffee and tea, whipped topping, margarine, cake, mashed potatoes were the most difficult to estimate. The results partial support the conclusions of Yuhas et al. (1989) that the food form has an effect on the ability to estimate portion sizes. They found that solids were better estimated than liquids, which were better estimated than amorphous items (such as spaghetti, applesauce). Yuhas et al. observed that women tended to estimate more accurately then men, whereas Wein did not found differences according to gender. The study of Wein et al. (1990) also illustrated that foods served in a manner that makes them difficult to visualise alone are

among the most difficult to estimate.

Karvetti et al. (1992) determined the validity of the estimated food diaries (including pictures of standard portion sizes for common foods to aid estimation) with actual food intake observed during days at regular meals served cafeteria style. The recorded intake of fresh and cooked vegetables, margarine, fish, eggs and desserts did not differ significantly from the observed intake. With exception of cheese (-40%), processed meat (-17%), juice (+22%) and porridge (+27%), percent differences between mean food intake from food diary vs. observation deviated 15% at most. The validity was equally for men and women in the 15 to 34, 35 to 44, and 45 to 65 age groups.

Posner et al. (1992) investigated the validity of a two-dimensional food model chart by comparing food energy and nutrient intake calculated from quantity estimates derived from this chart with those derived from three-dimensional models. For men, the means were quite close and none of the differences was significant. For women, mean intakes were also close; only a significant difference existed for percentage of energy from protein. The correlation coefficients ranged between .90 and .99 in men and .89 and 1.0 in women.

Kuehneman and coworkers (1994) compared amounts estimated with different measurement aids (food models; food pictures; predetermined 'standard' portion sizes obtained from literature) with 'true' amounts that had been weighed in an earlier study. Fewest significant differences were found between the mean weighed amounts of foods consumed and the standard serving sizes of foods. Little difference was noted in portion-size accuracy among the other portion size measurement aids, whereby the graduated food models produces a greater number of significant differences from the weighed amounts.

Amounts obtained by household measures and by abstract models were compared with an observed and weighed cafeteria lunch by Werhan (1982). The abstract models and household measures were similar in the percentage of food items overestimated, underestimated and accurately estimated. The degree of error associated with overestimation, however, was larger for household measures than for abstract models for all food items. Mean differences between observed and recalled portions were significantly larger for the household measures than for the abstract models. Foods measured in volumes were better estimated by food models; foods measured in dimensions were poorly estimated by both methods. Accuracy was not correlated with age and income. A significant but very low correlation between educational level and the percentage of accuracy was observed.

Faggiano et al. (1992) compared weighed serving sizes with recalled estimates based on graduated photographs for 17 Italian dishes (seven portion sizes for each dish). The subjects overestimated portion size by more than 20% for six foods and underestimated portion size by more than 20% for four foods. Differences in estimates ranged from -50% for rice to + 89% for fresh cheese. Overestimation tended to be greater among those who eat smaller portions and underestimation by those who ate larger portions ('flat slope syndrome').

Haraldsdóttir et al. (1994) investigated the validity of estimated portion sizes from a self-administered food frequency questionnaire including photographs (eight sets of photographs, each set with four options), by comparison with portion sizes from 14-day weighed food records. Most subjects (85-95%) selected the most correct photograph or a neighbouring one. However, relationship between the estimated and measured portion sizes was relatively weak. Significant correlations were only found for three of the eight foods. Subjects selecting small portions underestimated their actual intake and subjects selecting large portions overestimated them.

The perception of food portion size from photographs was studied by Nelson and coworkers (1994). Subjects were asked to identify the portion size of 6 foods presented individually on a plate or in a bowl in varying amounts. The subjects used a) a visual analogue scale which related to eight photographs of the food ranging from the 5th to the 95th percentile of portion weight based on The Dietary and Nutritional Study of British Adults;

and b) a single photograph of the average (median) portion to estimate the portion on the plate as a fraction or multiple of the amount shown on the picture. The authors concluded that the use of a series of 8 photographs was associated with relative small errors in portion sizes, whereas use of an average photograph is consistently associated with substantial underestimation across a variety of foods (mean differences between presented and estimated portion size varied from -23 to + 9% for the single and from -4 to + 5% for the series of 8 photographs). Large portion sizes were likely to be underestimated, especially when using the average photograph. Large portion sizes, being female, 65 years and over, or retired, seeing photographs in colour, were all associated with small but statistically significant overestimations of portion size. Having a Body Mass Index (BMI) ≥ 30 kg/m^2 was associated with an 8% underestimate of portion size.

In another study, Nelson et al. (1996) investigated the role of conceptualisation in the use of photographs to help subjects to estimate portion size. Subjects served themselves between four and six foods at one meal (breakfast, lunch or dinner). The served food was weighed directly by the investigators at time of serving, and if any foods were left over, the weight was recorded, and the actual amount eaten was calculated. Within five minutes of the end of the meal subjects were asked to indicate the portion consumed in relation to the photographs (for each food 8 photographs). The nutrient content of meals was estimated from food composition tables.

In general, small portion sizes tended to be overestimated and large portion sizes underestimated. The percentage errors ranged from - 28% (baked beans) to + 242% (for butter or margarine on cracker). Excluding butter and margarine, over all foods there was an overestimate in portion size of about 11% and correlation coefficients ranged from 0.45 (for peas) to 0.97 for beef stew. Approximately 65% of foods (55% including butter and margarine) were estimated within $\pm$ 30% of actual portion size. In line with the general overestimate of portion size, nutrients also tended to be overestimated. Excluding butter and margarine, the nutrient content of meals based on estimated portion sizes was on average within $\pm$ 7% of the nutrient content based on the amounts consumed; the correlation ranged from 0.84 to 0.96. Of the estimates of the energy content of meals based on the use of photographs, 80% were within $\pm$ 25% of the energy content based on actual portion size. Older subjects overestimated portion size more often than younger subjects. In subjects with BMI <25 kg/m^2 the energy and fat content of meals based on the estimated portion size (excl. butter and margarine) were 5-10% greater than the nutrient content using actual (weighed) portion size, but for those with BMI ≥ 30 kg/m^2 the calculated energy and fat content were underestimated by 2-5%.

The errors related to conceptualisation plus perception were greater than those related to perception alone. The results suggested that in both men and women there was a marked tendency to overestimate small portion sizes (particularly in men) and to underestimate large portion sizes to a greater extent when relying on conceptualisation skills than when using perceptual skills alone.

In summary: the diversity of methods in the studies makes it difficult to compare the reported outcomes. In general, studies investigating differences between actual and recalled portion sizes (using short-term dietary methodology) have shown that certain types of foods are more likely to be overestimated than others and overestimation appears to be more frequent than underestimation.

In most studies overestimation tended to be greater among those who eat smaller portions and underestimation by those who ate larger portions.

Some studies have reported that women estimate portion sizes more accurately than men, but other investigators have found no differences according to gender.

Regarding the different portion size measurement aids, there is little conclusive evidence of the greater benefit of any one type. Practical reasons might affect the choice. Two-dimensional models have the advantages of being easily copied, making them suitable for incorporation into a diary or questionnaire and making them suitable for dietary assessment in large epidemiological studies. Photographs can include a wide range of individual foods, making them highly specific.

Portion size and long-term dietary assessment

Because short-term dietary assessment instruments, such as dietary recall and record do not provide information on the usual intake if only a few days are assessed and these methods are generally expensive, the semiquantitative food frequency questionnaire has become a widely accepted method for measuring (usual) dietary intake in large scale epidemiological studies. In assessing long-term dietary intake, the concept of portion size is necessarily more vague. Since it is impossible for persons to accurately recall the exact portion sizes of all foods they consumed over a period of weeks or months, often the concept of 'usual' portion size is introduced. However, whether to collect additional data on usual portion sizes to improve the validity of the method has been a controversial topic.

Pickle and Hartman (1985) found that frequency of consumption was the major determinant of variability, followed by portion size. Several other studies also indicate the relative importance of frequency (Hunter et al., 1988; Flegal et al., 1988; Harraldóttir, 1994).
In general, there is agreement that for foods that come in natural units (such as one egg, a slice of bread, a cup of tea) this additional specification can add clarity to the question and is useful and easy to include. However, incorporation of portion size measurements for foods that do not come in natural or typical units is still under debate. When portion sizes are included different approaches can be used. One approach is that the investigator may add a common standard. Alternatively, the respondent is asked to specify a 'usual' portion for each food. Then three- or two dimensional models can be chosen as option or subjects can be asked to identify their usual portion as small, medium or large, with the medium portion defined.

Subar et al. (1995) have observed that providing portion sizes in ranges appeared to be preferable to approaches that used a reference medium portion size. Smith et al. (1991) found that subjects had difficulties conceptualising specified serving sizes, especially when expressed as small, medium or large, whereas Nelson (1996) observed that qualitative descriptors for the use of milk on cereal were on average better related to the amount consumed than the quantitative descriptors.

Tjønneland et al. (1992) evaluated the influence of including individually estimated portion size data on the validity of a semiquantitative food frequency questionnaire. Intake of foods and nutrients from questionnaire data with and without individually estimated portion size data, were compared with data obtained by 2x7 days weighed records. The correlation coefficients for food groups between the use of individually estimated portion sizes for foods that do not come in natural units and weighed portions was 0.47 and 0.36 for men and women, respectively. Using a common average portion size, the correlation hardly changed (for men 0.45 and for women 0.35). For nutrients the mean values for the comparison changed from 0.51 to 0.49 for men and from 0.39 to 0.40 for women. The authors concluded that little extra information was added by including individual portion size information for food that do not come in natural units. Similar observations have been reported by other researchers (Hernandez-Avilla et al. 1988; Margetts et al., 1989), but a slight improvement in the relative validity has also been demonstrated (Block et al., 1990; Jackson et al., 1990; Chu et al., 1984). Kuskowska et al. (1992) reported that including portion sizes in the food frequency questionnaire led to a significant lower consumption for fat, milk, bread, vegetables and fish.

In a study of Clapp et al. (1991) individual intakes of 4 nutrients (retinol, carotene, vitamin C and folate) calculated from a food frequency questionnaire using reported portions sizes (quantified with measurement aids) were compared with intakes calculated using standard portion size information. The authors concluded that replacing reported portion size data with standard portion size data may lead to conflicting outcomes for specific nutrients in research concerning the relation between diet and disease. Humble et al. (1987), however, reported that calculated vitamin A intake by using a food frequency questionnaire with and without portion sizes was similar related to reduced risk of lung cancer.

Cummings et al. (1987) observed that calcium intake calculated from a questionnaire with portion size ratings

(small, medium, large) correlated somewhat more with calculations from a dietary record than did calcium intake obtained from a questionnaire without added information on serving size (0.76 vs. 0.64); however, the difference was not significant. Comparison of a questionnaire completed by the same women that asked for portion sizes in ounces or cups and the diet record resulted only in a correlation of 0.49.

Several studies suggest that there exists a substantial greater within- than between variation in portion sizes for most foods. This implies that it is difficult to characterise a 'usual' portion. Haraldsdóttir et al. reported that based on 14-day weighed records portion sizes varied from day-to-day, with intra-individual coefficients of variation of 34 to 40%. Hunter et al. (1988) investigated the variability of portion sizes for 68 commonly consumed foods based on four one-week weighed diet histories. For all but seven food items the within-person variance in portion size exceeded the between-person variance. The mean of the within-person to between-person variance ratios was 3.4 for untransformed portion sizes and 3.2 after portion sizes were $\log_e$-transformed. Tsubono et al. (1997) also found that the within-person variation in portion sizes was larger than the between variation (50 of 69 items >1.0; median ratio was 2.4 and 1.7 for untransformed and $\log_e$-transformed values, respectively). They also observed that the relative contributions of within- and between-person variations in portion size may vary among foods.

In summary: the concept of 'usual' portion size seems very complex. Some of the available data suggest that additional questions on portion sizes do not add substantially to the assessment of dietary intake whereas other data show an improvement in the relative validity. Including a specification for some foods, particularly for those that can be used in different forms, i.e. milk as beverage and milk added to coffee, might facilitate the respondents' conceptualization. Moreover, in the importance of portion sizes also culturally based differences might play a role. Therefore, a careful consideration of potential advantages and disadvantages of including portion sizes in a food frequency questionnaire has to be made.

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Annex B-6

The EURO-FOOD GROUPS (EFG) classification system

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The EFG classification system was developed, as a project of COST Action 99/Eurofoods, in an attempt to evaluate the level of food description and classification that would permit international comparisons of the results of food consumption and food availability surveys.

In order to formulate the EFG system, classification schemes used for recording food intake at the following international and national classification schemes were compared:

- International: FAO Food Balance Sheet, WHO GEMS/FOODS regional diets, DAFNE classification system for Household Budget Survey (HBS) data, and Eurocode 2 core classification (levels 1 and 2);
- National: French National Food Consumption Survey (1999), TNO Dutch National Food Consumption Survey (1998), and British National Food Survey.

The task was difficult, as these classification schemes are designed for different levels of reporting consumption: the FAO Food Balance Sheet and the WHO GEMS/FOODS regional diets describe food at the commodity level (e.g. CEREALS), the DAFNE classification describes ingredients and foods as purchased (e.g., FLOUR, PROCESSED FRUITS), whereas Eurocode and national classification schemes describe mostly foods as consumed (e.g., soups, sauces, snacks and products). An additional difficulty is that these classification schemes often overlap.

Table 1 lists the resulting 33 food groups chosen as the "least common denominators" of the above food classification schemes. For the EFG food groups it was decided to use the definitions of the corresponding food groups in Eurocode 2. **Table 2** compares some of the above classification systems and illustrates the difficulties in finding common grounds for food classification. The following discussion of food classification systems refers to Table 2 but is limited to the four main food groups judged priority by the EFCOSUM project: cereals and cereal products, vegetables excluding potatoes, fruits, fish and seafood.

Comparison of EFG with existing food classification systems
FAO Food Balance Sheet, WHO GEMS/FOODS regional diets
The FAO food balance sheet classification (http://www.fao.org/es/ess/list.htm) is based on trade balance of food and agricultural commodities. The WHO GEMS/FOODS (WHO, 1998) records consumption at the commodity level to estimate intake of pesticide residues. Both of these systems classify cereals at the commodity level, not by their use. **CEREALS** are classed by biological origin: **WHEAT, RICE, BARLEY, MAIZE, RYE, OATS, MILLET, SORGHUM, OTHER**. It is not possible to distinguish how the cereals were consumed (bread, bakery products, pasta…).
Both systems have separate classes for **VEGETABLES** and starchy roots and tubers, extended beyond the common potato. On the other hand, they do not differentiate **FRUIT** and **FRUIT JUICE** (separate in EFG). The main group **FISH AND SEAFOOD** corresponds to the EFG food group of the same name.

DAFNE classification

The DAFNE system for classification of foods declared in Household Budget Surveys (Trichopoulou & Lagiou, 1997 and 1999) emphasizes ingredients and foods as purchased. It was one of the international classification schemes used to create the EFG food grouping system. The DAFNE main group **CEREALS** corresponds well to the EFG system and covers all foods in EFG groups 1 to 6. Moreover, it distinguishes **BREAD AND ROLLS, PASTA** and **BAKERY PRODUCTS**. It does not, however, separate breakfast cereals (EFG 2) from other cereal products.

The main group **VEGETABLES AND POTATOES**, subdivided into **FRESH VEGETABLES** and **PROCESSED VEGETABLES** covers EFG groups 14, 15 and 16, but subclasses allow potatoes and pulses to be separated from the other vegetables.

The DAFNE main group **FRUITS AND NUTS** covers EFG groups 13, 17 and 18, as fruit juices are classed under **PROCESSED FRUITS**. A suggestion in this last case would be to create a separate class for fruit juices and vegetable juices in the DAFNE system, to facilitate comparison with the other food classification systems for consumption surveys.

Finally, the DAFNE main group **FISH AND SEAFOOD** corresponds well to the EFG group 27.

Eurocode-2 core classification

The definitions of EFG groups were taken from the Eurocode-2 (Unwin & Møller, 2001) food categorisation system. Eurocode classification (foods as consumed) puts more accent on nutritional aspects (e.g., dietetic use, fat content). Eurocode-2 category **6: Grains and grain products** includes grains and their milled products obtained from members of the grass family, dough products obtained from grain, such as pasta and breads, breakfast cereals, savoury and sweet products and dishes in which grain products are considered the predominant constituent, substitute flours and other starch products obtained from non-cereal sources; it excludes sweet corn eaten as a vegetable. This Eurocode-2 category corresponds to the following EFG groups: **1- Bread and rolls**, **2- Breakfast cereals**, **3- Flour**, **4- Pasta**, **5- Bakery products**, and **6- Rice and other cereal products**. The EFG and Eurocode-2 groups compare very well, except for EFG Groups 3 and 6, as they overlap several Eurocode sub-classes.

EFG Group **15: Vegetables excluding potatoes** corresponds to Eurocode-2 category **8: Vegetables and vegetable products** (with the exception of the section under **8.34: Tubers**). This category includes plants and parts of plants eaten as vegetables (i.e. normally consumed as a savoury), including immature pulses. A vegetable fruit is usually considered to be consumed as a vegetable when the starch content is high before ripening converts the starch to sugars. The group includes edible fungi and seaweed, preserved vegetables and mixed vegetables. EFCOSUM recommends that the EFG Group 15 include herbs (not in Eurocode-2 category 8) but not spices. This would lead to a recommendation for a modification of Eurocode-2.

EFG Group **17: Fruits** corresponds to Eurocode-2 category **9: Fruits and fruit products**. This group includes fruiting bodies of plants when they are consumed as dessert fruit. The group also includes food products whose predominant constituent is fruit, including fruit sauces with a single fruit as the predominant constituent. Some questions remain, for example concerning the classification of olives and rhubarb: in Eurocode-2 olives are considered to be fruit and rhubarb vegetables, whereas some other food classifications place olives with vegetables and rhubarb with fruit.

In EFG, fruit juices are classed separately (Group **18: Fruit juices**); in Eurocode-2, fruit juices and vegetable juices are sub-groups of **11. Beverages (non-milk)**.

EFG Group **27: Fish and seafood** corresponds to Eurocode-2 group **4: Fish and fish products**. This group

includes marine and freshwater fish, crustaceans, molluscs, amphibians, reptiles, insects, fish offal, and food products whose predominant constituent is fish (e.g. fish mousse). It excludes marine and aquatic plants. A question remains as to whether marine mammals and seaweed should be included in this group, as they are in FAO Food Balance Sheets, WHO GEM/FOOD and in national surveys of Scandinavian countries. Otherwise, the classification of foods in this group is very straightforward and does not pose any problems.

National food grouping systems

Most national and regional databases use country specific food classification systems, based on national criteria, and the food groups may be very specific. This is mainly due to national legal aspects and traditions, besides the economic and cultural importance of foods. For example, the food grouping system used for the French INCA-1 survey (Volatier, 2000) has separate classes for **Bakery products**, **Biscuits** and **Pastry**. The Dutch National Food Consumption Survey of 1998 (Anonymous, 1998) classes cereal-based foods as **Bread** or as **Pastry, cakes and biscuits** or as **Cereals and cereal products**; breakfast cereals and pasta are not separated. Neither national food grouping system has a group for **Flour** (EFG 3), as the national surveys only recorded foods as consumed.

As in EFG, both national systems have separate food groups for **Vegetables**, **Potatoes** and **Pulses**. The two national surveys treat **Fruit juices** (EFG 18) as **Non-alcoholic beverages.** In future surveys**,** it could be suggested to create a separate group for fruit juices.

The EFG group **27. Fish and seafood** corresponds to the Dutch group **Fish** and the French groups **Fish** and **Crustaceans and molluscs**.

EPIC SOFT food classification

The food classification used in the EPIC SOFT program (Slimani et al., 2000) was initially developed with the methodological purpose of grouping together foods that could be described, quantified and checked similarly. The EPIC-SOFT food classification system in 17 main groups and 124 (sub-) sub-groups was used to classify the 1500 to 2000 items reported in the EPIC study. However, more refined or other food classifications can be used depending on the etiological hypotheses to be tested on the relationship between diet and cancer or other chronic diseases. Even though this classification system was designed only for the EPIC software, it is interesting to examine it in the context of EFCOSUM, as it has already been used as a "least common denominator" for recording consumption data from 10 European countries.

Table 2 shows that there is generally good correspondence between EFG and EPIC classifications. The general class **06 Cereals and cereal products** has subclasses corresponding to the EFG groups 1,2,3 and 5; class **06.02 PASTA, RICE, OTHER GRAIN** corresponds to EFG groups 4 and 6. In this case, comparisons with other surveys may be facilitated if subgroups are created.

There are separate classes for **LEGUMES**, **VEGETABLES**, and **POTATOES AND OTHER TUBERS**, corresponding to EFG groups 14-16. Moreover, group **04.FRUITS** (EFG 17) is distinguished from **FRUIT AND VEGETABLE JUICES** (EFG 18). The general class **08 FISH AND SHELLFISH** corresponds to the EFG group 27.

If the EPIC SOFT classification system is to be used outside of the software, some labels should be changed, as several food groups bear the same name (e.g. **FRUITS** groups 04 and 04.01, **LEGUMES** groups 03 and 03.01, plus 25 groups called **UNCLASSIFIED**). The major drawback of the system, with respect to EFG (and Eurocode 2), has been its lack of documentation, food classification having been carried out at the IARC; however, this has been recently remedied by the addition of scope notes.

CONCLUSIONS

The reason why EFG classification compares well with the other classification schemes studied is that it was created as a "least common denominator" among them.

The definitions of EFG food groups were taken from Eurocode 2, but questions remain (e.g. the place of substitute flours and starches, soy milk, potato crisps, herbs, commodities), thus it is essential to review these definitions. The same could be said for the other food classification systems studied (both international and national): users have less difficulty in assigning correct classification of foods when scope notes are available, and it would thus be worthwhile to provide definitions for the food classification systems when they are lacking. Some problems of compatibility remain (e.g. fruit juice, olives) and it could be recommended that further work be carried out to harmonize classification systems used in food consumption surveys. It may be possible to create (semi-) automatic links between systems in order to compare results of surveys.

There is no universal food classification system, and the different approaches result from the different objectives of each system. Classification systems have been created for different purposes and reflect different legislations. They are often contradictory, and their very existence shows that there can be no single satisfactory international classification system. The EFG was created in an attempt to compare consumption data collected using different food classification systems, but more work needs to be done to refine this system and harmonize definitions.

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Table 1. EFG food grouping system

EFG	EFG class	Includes
1	Bread and rolls	Leavened and unleavened breads, crispbreads, bread sticks, rusks, breadcrumbs
2	Breakfast cereals	Breakfast cereals
3	Flour	Cereal flours and starches (wheat, rye, oats, maize, rice, buckwheat); Substitute flours and starches (soya, potato, carob, arrowroot, tapioca)
4	Pasta	Plain noodles, egg noodles, rice noodles
5	Bakery products	Fine bakery wares, savoury and sweet biscuits, croissants, dough cakes, scones, doughnuts, pastry, pies, cakes
6	Rice and other cereal products	Whole grain cereals, bulgar, semolina, rolled oats, barley meal, rice
7	Sugar	Sugar (sucrose), glucose, fructose, maltose, lactose, honey, maple syrup, molasses, treacle
8	Sugar products excluding chocolate	Jams & marmalades, non-chocolate confectionery (e.g. boiled sweets, chewing gum, nougat, cereal bar), sugar products (e.g. marzipan, candied fruit), non-dairy ices
9	Chocolate	Chocolate and chocolate products: cocoa powder, chocolate bar, filled chocolate, chocolate-coated confectionery bars
10	Vegetable oils	Vegetable oils (palm oil included)
11	Margarine and lipids of mixed origin	Margarines, fat spreads
12	Butter and animal fats	Butter, animal fats (e.g. beef, pork, goose, duck) and marine oils
13	Nuts	Nuts, peanuts, seed products
14	Pulses	Pulses (e.g. dried pea, lentil) and pulse products (e.g. soya paste)
15	Vegetables excluding potatoes	Leaf vegetables, brassicas, stalk vegetables, shoot vegetables, onion family, root vegetables, fruit vegetables, pod vegetables, sprouted seed vegetables, edible fungi, herbs, vegetable mixtures
16	Starchy roots or potatoes	Potatoes and other tubers (Jerusalem artichoke, sweet potato, yam, cassava, taro)
17	Fruits	Malaceous fruit, prunus fruit, berries, citrus fruit, apple sauce
18	Fruit juices	Fruit and/or vegetable juices and nectars
19	Non alcoholic beverages	Non-milk beverages (e.g. carbonated soft drinks, water), imitation milk products
20	Coffee, tea, cocoa powder	Infusion drinks (coffee, tea, herbal tea), cocoa powder, milk beverage powders
21	Beer	Beers and malt beverages
22	Wine	Wines, fortified and liqueur wines
23	Other alcoholic beverages	Ciders, perries and similar drinks, liqueurs, spirits, alcoholic mixed drinks
24	Red meat and meat products	Meat (beef, veal, pork, mutton, other mammals), meat products and preserved meats
25	Poultry and poultry products	Poultry meat (chicken, turkey, duck, other birds) and poultry products
26	Offals	Liver, kidney, tongue, heart, other offals
27	Fish and seafood	Fish, crustaceans, molluscs, amphibians, reptiles, insects and fish products
28	Eggs	Egg (e.g. chicken, turkey, duck, goose, quail) and egg products
29	Milk	Liquid milk (e.g. cow, goat), processed milk (flavoured, condensed, dried), whey, cream
30	Cheese	Cheese (fresh, soft, semi-hard, hard, blue, smoked, processed)
31	Other milk products	Yogurt and other fermented milk products, ice cream
32	Miscellaneous foods	Dishes, soups, sauces, condiments, dressings, spices, seasonings and extracts, baking goods and other ingredients

| 33 | Products for special nutritional use | Sugar substitutes, Substitute flours and starches |

EFG	EFG Class	FAO Food Balance Sheet	WHO GEMS/FOOD	DAFNE	Eurocode 2	French survey	Dutch survey	EPIC soft

1	Bread and rolls			CEREALS : BREAD AND ROLLS	6 Grains and grain products :
					  6.40 Leavened breads
					  6.44 Unleavened breads and crispbreads
					  6.48 Bread products
						1 Bread, crispbread, rusks	2. Bread	06 CEREALS AND CEREAL PRODUCTS :
								  06 03 BREAD, CRISPBREAD, RUSKS [and underlying categories]

2	Breakfast cereals				6 Grains and grain products :
					  6.70 Breakfast cereals
						2 Breakfast cereals	9. Cereals and cereal products	06 CEREALS AND CEREAL PRODUCTS :
								  06 04 BREAKFAST CEREALS

3	Flour	CEREALS (EXCLUDING BEER)	CEREALS [and underlying categories]	CEREALS : FLOUR	6 Grains and grain products :
					  6.10 Wheat basic products
					  6.12 Rye basic products
					  6.28 Substitute flours and starches
							9. Cereals and cereal products	06 CEREALS AND CEREAL PRODUCTS :
								  06 01 FLOUR, FLAKES, STARCHES, SEMOLINA USED AS FLOUR

4	Pasta			CEREALS : PASTA	6 Grains and grain products :
					  6.30 Pasta and noodles
						3 Pasta	9. Cereals and cereal products	06 CEREALS AND CEREAL PRODUCTS :
								  06 02 PASTA, RICE, OTHER GRAIN [only pasta and noodles]

5	Bakery products			CEREALS : BAKERY PRODUCTS	6 Grains and grain products : 6.50 Fine bakery wares	6 Bakery products 7 Biscuits 8 Pastry	8. Pastry, cakes and biscuits	06 05 SALTY BISCUITS, APERITIF BISCUITS, CRACKERS [except for chips] 06 06 DOUGH AND PASTRY (PUFF, SHORT-CRUST, PIZZA) 12 CAKES [and all underlying categories]

6	Rice and other cereal products	CEREALS (EXCLUDING BEER)	CEREALS [and underlying categories]	CEREALS : RICE AND CEREALS [excluding above]	6 Grains and grain products :
					  6.14 Oats basic products
					  6.16 Barley basic products
					  6.18 Maize basic products
					  6.20 Rice basic products
					  6.25 Basic products of other cereals
						4 Rice and semolina
						5 Other cereals
							9. Cereals and cereal products	06 02 PASTA, RICE, OTHER GRAIN [except for pasta]

7	Sugar	SUGAR CROPS SWEETENERS:
		  SUGAR NON-CENTRIFUGAL SUGAR (RAW EQUIVALENT)
		  SWEETENERS, NES
		  HONEY
			SUGARS AND HONEY [and underlying categories]	SUGAR	10.10 Sugar (sucrose)	30 Sugar and products [sugar only]	20. Sugar, sweets, sweet spreads and sweet sauces [only sugar]	11 01 SUGAR, HONEY, JAM [except for jam]

EFG	EFG Class	FAO Food Balance Sheet	WHO GEMS/FOOD	DAFNE	Eurocode 2	French survey	Dutch survey	EPIC soft
8	Sugar products excluding chocolate			SUGAR PRODUCTS [except for chocolate]	10 Sugar, sugar products, chocolate products and confectionery [except 10.10 and 10.50-55]	30 Sugar and products	20. Sugar, sweets, sweet spreads and sweet sauces [except sugar and chocolate]	11 SUGAR AND CONFECTIONERY [and underlying categories, except 11.02 and sugar]
9	Chocolate			SUGAR PRODUCTS [chocolate only]	10.50 Chocolate and chocolate products 10.55 Chocolate-coated confectionery bars	29 Chocolate	20. Sugar, sweets, sweet spreads and sweet sauces [except sugar and sugar products]	11 02 CHOCOLATE, CANDY BARS, PASTE, CONFETTI/FLAKES
10	Vegetable oils	VEGETABLE OILS [and underlying categories]	VEGETABLE OILS AND FATS [and underlying categories]	VEGETABLE OILS	5 Fats and oils : 5.60 Vegetable fats and oils	14 Vegetable oils	21. Fat, oils, mayonnaise and spicy sauces	10 01 VEGETABLE OILS 10 04 DEEP FRYING FATS
11	Margarine and lipids of mixed origin			VEGETABLE FATS	5.20 Margarine 5.30 Fat spread 5.70 Compound fats and oils	15 Margarine	21. Fat, oils, mayonnaise and spicy sauces	10 03 MARGARINES
12	Butter and animal fats	ANIMAL FATS: BUTTER, GHEE CREAM FATS, ANIMAL, RAW FISH, BODY OIL FISH, LIVER OIL	BUTTER OF COW MILK ANIMAL FATS AND OILS [and underlying categories]	BUTTER LIPIDS OF ANIMAL ORIGIN (BUTTER EXCLUDED)	5.10 Butter 5.40 Animal fat 5.50 Marine oil	13 Butter 16 Animal fats	21. Fat, oils, mayonnaise and spicy sauces	10 02 BUTTER 10 06 OTHER ANIMAL FAT 10 05 MARINE OIL
13	Nuts	TREE NUTS OILCROPS [and underlying categories]	NUTS AND OILSEEDS [and underlying categories]	NUTS	7 Pulses, seeds, kernels, nuts and products [and underlying categories, except 7.10 & 7.60]	27 Nuts and oleaginous grains	14. Nuts, seeds and snacks [Nuts, seeds]	04 02 NUTS AND SEEDS (+ NUT SPREAD)
14	Pulses	PULSES BEANS PEAS PULSES, OTHER	PULSES [and underlying categories]	PULSES	7.10 Pulses 7.60 Pulse products	25 Pulses	15. Pulses	03 LEGUMES [and underlying]
15	Vegetables excluding potatoes	VEGETABLES TOMATOES ONIOS VEGETABLES, OTHER	VEGETABLES [and underlying categories]	VEGETABLES EXCLUDING POTATOES : FRESH VEGETABLES PROCESSED VEGETABLES	8 Vegetables and vegetable products [and underlying categories, except 8.34]	23 Vegetables (excluding potatoes)	10. Vegetables	02 VEGETABLES [and underlying categories] 15 03 SPICES, HERBS AND FLAVOURINGS [only herbs]

EFG	EFG Class	FAO Food Balance Sheet	WHO GEMS/FOOD	DAFNE	Eurocode 2	French survey	Dutch survey	EPIC soft

16	Starchy roots or potatoes	STARCHY ROOTS:
		  POTATOES
		  SWEET POTATOES
		  CASSAVA
		  YAMS
		  ROOTS, OTHER
			ROOTS AND TUBERS:
			  CASSAVA
			  POTATOES
			  POTATOES, SWEET
			  YAMS
			  ROOTS AND TUBERS NES
				POTATOES	8.34 Tubers	24 Potatoes and similar	1. Potatoes	01 POTATOES AND OTHER TUBERS [and underlying categories]

17	Fruits	FRUIT (EXCLUDING WINE) [and underlying categories]	FRUITS [and underlying categories, except fruit juices]	FRUITS
				  FRESH FRUITS
				  PROCESSED FRUITS [except for fruit juices]
					9 Fruits and fruit products [all underlying categories]	26 Fruits
						42 Cooked fruits
							7. Fruit	04 FRUITS [and underlying categories]

18	Fruit juices		FRUIT JUICE NES ORANGE JUICE CONCENTRATED LEMON JUICE SINGLE-STRENGTH PINEAPPLE JUICE SINGLE-STRENGTH	PROCESSED FRUITS [juice only]	11.60 Fruit juices 11.64 Vegetable juices 11.68 Fruit and vegetable nectars	32 Refreshing non alcoholic beverages [juices only]	5. Non alcoholic beverages [juices only]	13 01 FRUIT AND VEGETABLE JUICES
19	Non alcoholic beverages			SOFT DRINKS AND SIMILAR BEVERAGES MINERAL WATER	11.40 Carbonated soft drinks 11.44 Non-dilution still drinks 11.48 Dilution drinks 11.56 Water	32 Refreshing non alcoholic beverages [except juices] 31 Water	5. Non alcoholic beverages	13 02 CARBONATED/SOFT/ISOTONIC DRINKS, DILUTED SYRUPS 13 04 WATERS

20	Coffee, tea, cocoa powder	STIMULANTS:
		  COFFEE
		  COCOA BEANS
		  TEA
			STIMULANTS:
			  CHICORY ROOTS
			  COCOA
			  COFFEE
			  GINGER, ROOT
			  TEA
				STIMULANTS:
				  COFFEE
				  TEA AND SIMILAR INFUSIONS
				  COCOA
					11.52 Infusion drinks	34 Coffee
						35 Hot beverages
							5. Non alcoholic beverages [coffee, tea only]	13 03 COFFEE, TEA AND HERBAL TEAS [and underlying categories]

21	Beer	BARLEY BEER		BEER	11.10 Beers and malt beverages	33 Alcoholic beverages [beer only]	4. Alcoholic beverages [beer only]	14 03 BEER, CIDER
22	Wine	WINE		WINE	11.20 Wines 11.24 Fortified and liqueur wines	33 Alcoholic beverages [wine only]	4. Alcoholic beverages [wine only]	14 01 WINE 14 02 FORTIFIED WINES (SHERRY, PORTO, VERMOUTH…)

EFG	EFG Class	FAO Food Balance Sheet	WHO GEMS/FOOD	DAFNE	Eurocode 2	French survey	Dutch survey	EPIC soft
23	Other alcoholic beverages	BEVERAGES, ALCOHOLIC ALCOHOLIC BEVERAGES, MISCELLANEOUS		SPIRITS	11.15 Ciders, perries and similar drinks 11.28 Liqueurs 11.30 Spirits 11.35 Alcoholic mixed drinks	33 Alcoholic beverages [other]	4. Alcoholic beverages [other]	14 03 BEER, CIDER [only cider, perries] 14 04 SPIRITS, BRANDY 14 05 ANISEED DRINKS (PASTIS…) 14 06 LIQUEURS 14 07 COCKTAILS, PUNCHES

24	Red meat and meat products	BOVINE MEAT MUTTON/GOAT MEAT PIG MEAT OTHER MEAT	ASSES MEAT
			BEEF AND VEAL
			BEEF CANNED/DRIED SALT SMOKED
			BUFFALO MEAT
			CAMEL MEAT
			CATTLE MEAT
			GAME MEAT
			HORSEMEAT
			MEAT (MAMMALIAN)
			MEAT (CATTLE, GOAT, HORSE, PIG, SHEEP)
			MUTTON AND LAMB
			PIG MEAT
			RABBIT MEAT
				MEAT :
				  RED MEAT
				  MEAT PRODUCTS
				  MEAT DISHES
					3 Meat and meat products :
					  3.10 Beef, carcass meat
					  3.15 Veal, carcass meat
					  3.20 Pork / piglet, carcass meat
					  3.25 Mutton / lamb, carcass meat
					  3.29 Mammals, other
					  3.50 Preserved meats
					  3.60 Meat products
					  3.65 Meat dishes
						17 Red meat
						20 Processed meats
							23. Meat, meat products and poultry [except poultry and offals]	07 01 01 BEEF
								07 01 02 VEAL
								07 01 03 PORK
								07 01 04 MUTTON/LAMB
								07 01 05 HORSE
								07 01 06 GOAT
								07 02 05 RABBIT (DOMESTIC)
								07 03 GAME [only mammals]
								07 04 PROCESSED MEAT [only mammals]

25	Poultry and poultry products	POULTRY MEAT	CHICKEN MEAT DUCK MEAT GAME MEAT GOOSE MEAT POULTRY MEAT TURKEY MEAT	MEAT : POULTRY	3.30 Chicken 3.32 Turkey 3.39 Birds, other	18 Poultry and game	23. Meat, meat products and poultry [poultry]	07 02 POULTRY [and underlying, except rabbit) 07 03 GAME [only birds] 07 04 PROCESSED MEAT [only poultry based]

EFG	EFG Class	FAO Food Balance Sheet	WHO GEMS/FOOD	DAFNE	Eurocode 2	French survey	Dutch survey	EPIC soft
26	Offals	OFFALS	CATTLE, KIDNEY CATTLE LIVER OFFALS LIVER OF CHICKENS EDIBLE OFFAL (MAMMALIAN) OFFALS OF GOAT OFFALS (CATTLE, GOAT, HORSE, PIG, SHEEP) POULTRY, OFFAL	MEAT : OFFALS	3.40 Liver 3.42 Kidney 3.49 Other offal	19 Offals	23. Meat, meat products and poultry [offals]	07 05 OFFALS
27	Fish and seafood	FISH AND SEA FOOD [and underlying categories]	FISH AND SEA FOOD [and underlying categories]	FISH AND SEAFOOD	4 Fish and fish products [all underlying categories]	21 Fish 22 Crustaceans and molluscs	22. Fish	08 FISH AND SHELLFISH [and underlying categories]
28	Eggs	EGGS	EGGS	EGGS	2 Egg and egg products [all underlying categories]	12 Eggs and products	6. Eggs	09 EGGS AND EGG PRODUCTS [and underlying categories]
29	Milk	MILK (EXCL. BUTTER)	MILK AND MILK PRODUCTS [and underlying categories, except BUTTER, CHEESE]	MILK	1 Milk and milk products 1.10 Liquid milks 1.15 Processed milks	9 Milk	13. Milk and milk products	05 01 MILK 05 02 MILK BEVERAGES 05 07 DAIRY AND NON DAIRY CREAMS [and underlying] 05 08 MILK FOR COFFEE AND CREAMERS
30	Cheese		CHEESE (SKIM COW MILK) CHEESE (WHOLE COW MILK)	CHEESE	1.40 Cheese	11 Cheese	12. Cheese	05 05 CHEESES (INCLUDING FRESH CHEESES)
31	Other milk products			DAIRY PRODUCTS	1.30 Yoghurt 1.35 Other fermented milk products 1.70 Ices	10 Fresh milk products 28 Ice cream 41 Desserts [milk based only]	13. Milk and milk products	05 03 YOGHURT 05 04 FROMAGE BLANC, PETITS SUISSES 05 06 CREAM DESSERTS, PUDDINGS (MILK BASED) 11 05 01 ICE CREAM

EFG	EFG Class	FAO Food Balance Sheet	WHO GEMS/FOOD	DAFNE	Eurocode 2	French survey	Dutch survey	EPIC soft
32	Miscellane ous foods	SPICES [and underlying categories]	SPICES [and underlying categories, except for PARSLEY]	MISCELLANEOUS FOODS	12 Miscellaneous, soups, sauces, snacks and products [all underlying categories]	36 Pizzas, quiches and savoury pastries 37 Sandwiches, snacks 38 Soups 39 Mixed dishes 40 Entrées 41 Desserts 43 Condiments and sauces	3. Other 11. Savoury sandwich spread 14. Nuts, seeds and snacks [snacks] 17. Mixed dishes 18. Soups 19. Soy products 21. Fat, oils, mayonnaise and spicy sauces [except fats & oils]	15 CONDIMENTS AND SAUCES [and underlying] 16 SOUPS, BOUILLON [and underlying] 17 03 SNACKS
33	Products for special nutritional use				13 Products for special nutritional use [all underlying categories]	44 Foods for special nutritional use	16. Preparations (products for special use)	17 02 DIETETIC PRODUCTS [and underlying]

Annex B-7

Measurement of energy and energy expenditure and physical activity

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Introduction

Intake of most foods and nutrients are correlated to total energy intake. Thus, accurate measurement of energy intake is very important for the interpretation of reported dietary intake. However, bias of reporting energy intake (EI) in relation to energy expenditure (EE) is a well-known problem in dietary surveys (Black et al., 1991).

The level of reported EI may depend on the dietary survey method used in the survey. EI is typically lower when evaluated by dietary records than by dietary history (Black et al., 1991). Thus, dietary surveys may include systematic errors in reported food consumption. Reported food and energy intake may also be biased by other factors such as age, gender, educational level, health consciousness, dieting (Ballard-Barbash et al., 1996) and degree of obesity (Livingstone, 1995; Prentice et al., 1996).

If bias of reporting EI is similar in different regions and subgroups of populations, and if subjects under- or over-report their consumption of food items in proportion to their total food intake, it would be a minor problem in epidemiological studies of diet and health. However, if this bias is unevenly distributed between regions and countries this introduces serious errors affecting the comparability of dietary data. Furthermore, if study participants systematically under- or over-report consumption of selected foods, and if the degree of biased reporting is unevenly distributed within the population, the search for associations between diet and health variables may be disturbed. Increasing prevalence of obesity in many cultures (Seidell, 1995) and enhanced focus on the benefits of healthy dietary habits in nutritional education and marketing may aggravate the problem with biased reporting of food intake in dietary surveys.

Thus measurements of energy expenditure and physical activity in combination with dietary surveys may give useful information for the validation of reported EI, interpretation of dietary data, and for the improvement of the comparability of dietary data between countries and between subgroups within countries. Furthermore, the close connection between physical activity and diet, and the increasing knowledge about the importance of physical activity for health, makes it natural to collect data about physical activity in dietary surveys.

Energy expenditure and physical activity

Energy expenditure is mainly determined by basal metabolic rate (BMR) and the level of physical activity (WHO, 1985). Total EE and can be measured with good accuracy by the doubly-labelled water method (Prentice, 1990).

BMR can be measured directly or estimated from standard equations based on weight, age and sex (EU, 1992). A comparison of reported energy intake with estimated basal metabolic rate (EI/BMR) can be used to calculate the degree of under- or over-reporting of energy intake (Goldberg et al., 1991; Black et al., 1996). E.g. a EI/BMR ratio of 1.35 is suggested as the lowest value for habitual energy intake of an individual that is compatible with a normal, not bed-bound life-style (Goldberg et al., 1991). EI/BMR above the range 2.0-2.4 is suggested as the maximum for sustainable life-style (Black et al., 1996). Evaluations have shown that the majority of dietary surveys underestimate the habitual energy intake (Black et al., 1991), however, still little information about overestimation of energy intake is available.

Physical activity can be measured directly or indirectly. Direct measurements can be made by instruments as pedometers, accelerometers or instruments that measure a combination of physical variables simultaneously. Indirect information about physical activity can be collected by different kinds of questionnaires, diaries or observation. Methods for measurement of energy intake and physical activity are described further elsewhere (Montoye et al., 1996; Anonymous, 2000).

The experience with use of instruments for the measurement of physical activity is rapidly increasing (Freedson & Miller, 2000; Bassett, 2000). Accelerometers that measure total physical activity during the day are validated against the doubly-labelled water method (Westerterp, 1999), and both Dutch (Bouten et al., 1996) and Norwegian (Hustvedt et al., 2000); Løvø et al., 2000) developed motion sensors have shown good accuracy. Pedometers counting steps were earlier found to be unacceptable for research. However, some newer electronic pedometers are very accurate for recording steps during self-paced walking, and are validated against other methods (Bassett, 2000). Although motion sensors are not perfect markers for physical activity, or energy expenditure, they eliminate subjectivity of obtaining physical activity information. As all instruments have their weaknesses and strengths the method of choice depends on how the measurement will be used and the demanded level of accuracy of the data.

Many kinds of questionnaires have been used to measure physical activity. This has created large problems for the comparability of data between studies (Sallis & Saelens, 2000). In order to better address physical activity on a global level a greater degree of standardization in definitions and assessment is required. Thus WHO has taken the initiative to develop an international physical activity questionnaire (IPAQ). The current version of IPAQ is now tested for reliability and validity in 16 centres in 13 countries and 6 continents.

EU now supports a project the European Physical Activity Surveillance System (EUPASS) that aims to contribute to the establishment of a Community health monitoring system. EUPASS aims at a close co-operation with national institutions in the EU involved in health monitoring and physical activity.

Selection of methods
The doubly-labelled water method may be a good choice for the validation of the dietary survey method developed by EFCOSUM. However, this method is costly and likely too expensive for routine use.

It would be a great advantage if a questionnaire measuring physical activity, and instruments as accelerometers or pedometers are used in combination with the EFCOSUM dietary survey. What kind of questionnaire or instruments should be recommended used by EFCOSUM is still premature. These matters should be discussed with persons involved with EUPASS and IPAQ.

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Annex B-8

Evaluation of European Monitoring System

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Through consultation with the following people:
Bernard Le Goff in the commission (DG Sanco)
Kevin Conlon from the IT department of the Department of Health
Hugh Magee and Tim McCarthy in the Department of Health, as National contacts for the Health monitoring programme.

Consideration was given to two main issues:
1)   Evaluation of the European monitoring system in terms of its software specifications.
     How are we supposed to deliver our data into this system?

2)   The type of data currently being collected (in EUPHIN - HIEMS)?
     Which variables have to be measured to ensure the possibility of data fusion with other health monitoring studies? Any necessary requirements for data fusion?

The structure
June 2000 - The system as it currently stands is far from operational. However, there are demonstration sets with test data and the idea is to have one or two connections in each country. In early June several countries received test data (which has been shown to worked).

The structure consists of a single centralised system that is currently operating in Belgium. All data on demography, mortality, morbidity comes from WHO, Eurostat, National census data, etc. The system is distributed using a Webb browser over a VPN link into the HIEMS database in Brussels from where all queries can and will be run. There is an Oracle database at back end, and the indicators are pre-set. Indeed, a key part of the database are the indicators or variables (definition which has been agreed by WHO). There may be a problem of data description where variables do not mean the same thing in different countries. For this it is necessary that variables be labelled and using the data dictionary it is possible to ascertain what they mean.

HIEMS has one central database with sub-platforms in Denmark and Germany due to legal constraints in these countries which does not permit its data to be based outside of its country. Essentially it is a repository of data. In each country there is a database manager (raw aggregate data (rad) administrator) in charge of maintaining national data. These database administrators are permitted to retrieve the data and work on it (in SAS) before putting it back into the central database. They cannot, however, work on any others country's data. Data should be in delivered to the system (the central database) in asci tab-delimited format. Running any subsequent queries on the data will be operated using SAS.

SUMMARY OF THE EUPHIN GIP

A-DESCRIPTION OF THE NETWORK
A-1- Context
The improvement of information exchange is a key element for the future development of public health in the

community.

The Community's role in public health has to evolve to deal with new challenges, changed circumstances and the greater role envisaged for public health in the Amsterdam Treaty. Drawing from these factors and the experience of the existing framework, the future public health policy as mentioned in the paving communication COM(98)230 of 15.04.98 should comprise three strands of action:

-Improving information for the development of public health
-Reacting rapidly to threats to health
-Tackling health determinants through health promotion and disease prevention.

These three strands would also enable the Community to respond effectively to the challenges of enlargement, and to the issues of health requirements in other policies. Therefore, the implementation of the EUPHIN network will play a major role in the achievement of results for these strands as it is intended to fulfil the need for rapid and reliable exchange of health information for EEA countries.

A-2-Objectives

The objective is to established the telematic network EUPHIN which will be a structured and comprehensive Community system for sharing, exchanging and disseminating information within the public health

The EUPHIN network is clearly mentioned in the public health programmes .It involves many competent authorities and a number of health issues are being to be supported by this network. The difference in sensitivity of the information to be exchanged and shared within the systems of EUPHIN also plays an important role in the technical description of the network and the project organization All these aspects increase the complexity of the project.

The ***EUPHIN telematic network*** has been put in place to support the following application requirements(the application components of which are at different levels of maturity):

a health monitoring application ***(EUPHIN-HIEMS*)**

a health surveillance application for communicable diseases (***EUPHIN-HSSCD)***

a blood transfusion chain application ***(EUPHIN-BLOOD)***

an injury data application ***(EUPHIN-INJURY***) integrating, in particular the home and leisure accidents database (EHLASS)

A-3 Participants

EC	European Commission	DG Health and Consumer, DG enterprise,DI ,EUROSTAT	
EEA Countries	Ministries, national statistical offices, communicable diseases centers, Organizations and institutes part of the blood transfusion chain, NGO's European citizens		List available on request
International Organizations	WHO,OECD Consumer organizations		

A-4-Functionalities and Technical description
The application requirements of EUPHIN will be hosted on the same backbone node server and use the **IDA generic services** such as TESTA /TESTA2, the CIRCA tool (communication and information resource centre for administrations) and the security practices developed within the IDA SECLEG projects. As regards the use of standards, EUPHIN is based on TCP/IP protocol.

The different application requirements are currently at different phases according to the Ida2 approach:
-**Preparatory phase** EUPHIN-BLOOD
-**Feasibility phase** EUPHIN-INJURY
-**Development and Validation phase** EUPHIN-HSSCD and EUPHIN-HIEMS

An overview of EUPHIN from the technical point of view is included in the annex 1.

The Health Information Exchange and Monitoring System (HIEMS) will be built with the Oracle Relational Database Management System (RDBMS), the Oracle Application Server Environment, the Netscape Web server software and the SAS statistical analysis tool with its SAS IntrNet extension for web presentation. The intention has been to re-use as much as possible from ENS-CARE in the development of HIEMS, in particular the methodology, i.e. utilising telematic networks and distributed databases to support national health administrations in their health policy development, and the data dictionary and databases for hospital statistics.

The HIEMS network logically consists of the central node, the distributed databases nodes, and the user sites. The central node hosts the database holding the Data and the predefined indicators. The data of most of the Member States (MS) will be uploaded into this central database. Participating Member State Administrations that wish to host their own RAD will be responsible for managing their own distributed database nodes. At present, three such nodes have been identified, one in Denmark (Copenhagen) and two in Germany (Wiesbaden, Bielefeld). An Intranet will be built on the Virtual Private Network (VPN) provided by the TESTA contractor as follows:
*The central database will be connected direct to the TESTA contractor Network
*Local loops to the distributed databases will be provided by the TESTA contractor
*The dial-up users will access the HIEMS databases by ISDN/PSTN dial-in calls in the TESTA frame relay network using this IDA generic service from other relevant community initiatives and network.

The Health Surveillance System for Communicable Diseases (HSSCD) application software and the central part of the databases will be hosted on the same backbone node server as the application HIEMS. It will have a web-based interface that closely resembles the look-and-feel of the application HIEMS. The HSSCD network consists of the central node, the distributed database's nodes, the internet site, the links with reference databases or internet sites, the user sites.
Some of the remote databases will use the Virtual Private Network (VPN) provided by the TESTA contractor as follows:
* The central database will be connected direct to the TESTA Network
* Local loops to the distributed databases will be provided by TESTA contractor
* Some other databases will be hosted directly in the system,
* HSSCD makes also great use of Internet technology. The users will have access to all the system only by Internet. Some databases will be reserved to European experts, other will give access to all the citizens. Some databases will have both types of access and data.
HSSCD provides a number of general-purpose telematic services to facilitate the HSSCD user community in accomplishing various tasks such as: sending electronic mail, reading articles posted to discussion groups, searching for people and resources and downloading documents from other hosts on the network.
Electronic Mail, Mailing Lists, Discussion groups, Directory services:

Early Warnings: The Early Warning application allows users to submit Early Warnings that describe incidents of communicable diseases outbreaks and distribute these warnings to public or restricted mailing lists, or mail them to specific group of people.

Reference Database: The reference database application accesses information published by the various health authorities of the member states of the European Union.

Remote Databases: The remote database integration application allows consulting the communicable disease databases.

> The system architecture for **EUPHIN-INJURY** is supposed to be defined after the analysis of the user requirement survey. It is assumed however that the system will have a similar functionality as the currently designed EUPHIN-HIEMS system. Thus, it will consist of both a relational ODBC-compliant relational database part and a central multidimensional database, to be implemented with SAS. The HLA(Home and Leisure Accidents) application will, like EUPHIN- HIEMS, be based on Internet-technology, with a web-based user interface. Client side installation will therefore only include a standard Web Browser. The system will contain a "bridge" towards the EUPHIN-HIEMS system, in order to periodically aggregate the HLA data.

B-ASSIGNMENT OF ROLES AND TASKS OF THE MEMBER STATES (MS) AND COMMUNITY (c) THROUGHOUT THE DEVELOPMENT AND VALIDATION AND IMPLEMENTATION PHASES

As EUPHIN-BLOOD and EUPHIN-INJURY are at different levels of maturity, they are not taken into account in this summary but more detailed information could be found in the specific implementation plan concerning these 2 applications.

The participants' roles and tasks including Management and Co-ordination, Protocol for Assignment of Tasks, are available on request. The roles of the sectoral committee ((HMP Pillar B Working Party (PBWP)), Member States, Host-site Member States, Commission, international organizations and the different companies in charge of the system are clearly defined in the specific implementation plan. The annex 2 shows a timetable for EUPHIN-HIEMS and HSSCD for the development and implementation phases.

In summary the roles and tasks during these phases are as follows:

- EC: continued overall management and co-ordination responsibilities.

- Sectoral Committees: assistance of the Commission in the implementation of programmes as described in the Decisions.

- Member States: implementation and operation of the system within the framework of agreed operating policies and procedures. Member States are also required to provide data to the system in accordance with their responsibilities enshrined in the governing legislation.

- Distributed sites databases and Remote Database Providers: operation of the databases and provision of new data in accordance with agreed operating policies and procedures

- The consortium for information services: ongoing operational support to the network until June 2000, including Help Desk and corrective maintenance. The consortium may also be contracted to develop further enhancements to the system within the terms of a Framework Contract

- QA Contractor : ongoing questions aQA services.

- Security contractor :ongoing security services such as draft agreement between participants ,overall security policy, integrity guidelines, database protection, audit on implementation of security policy

The associated major deliverables are included in the specific implementation plan.

C-DESCRIPTION OF THE EXPECTED BENEFITS

- EUPHIN will enable the exchange and the increased availability of the relevant information necessary:

    a)   to monitor developments in health status throughout the Community;

    b)   to facilitate the planning, monitoring and evaluation of Community programs and actions; and

    c)   to provide Community institutions , Member States with comparative information to monitor and develop their national policies.

    d)   to enable early warnings of communicable diseases outbreaks, co-ordinate response to such outbreaks, to identify the source and monitor the evolution of epidemics as well as perform administrative and policy making tasks.

    e)   will improve the timeliness and accuracy of blood transfusion chain reporting, the quality and depth of the collaboration and will allow the development of better prevention techniques. (note: there is a clear link between the blood supply and the control of communicable diseases, hence the requirement for an on-line interaction with the communicable disease application).

    f)   to help to reduce the incidence of injuries and to assess more accurately the consequences of injury not only for the individual concerned but also in social and economic terms (eg to facilitate the identification of dangerous products involved in and/or causing the accidents)

D-plan for the estimated costs to be shared BETWEEN COMMUNITY AND MEMBER STATES

The cost sharing between Community and MS could be foreseen as follows

COMMUNITY COSTS

Housing and hosting of hardware and software (Centre de Calcul)

Operation and maintenance of Euphin (DI)

Help desk(DG Health and consumer ,DI)

Eurodomains and link to Eurogates (TESTA)

Security issues of central hardware and software (Commission services)

Overall scientific and technical co-ordination(DG Health and consumer)

MEMBER STATES
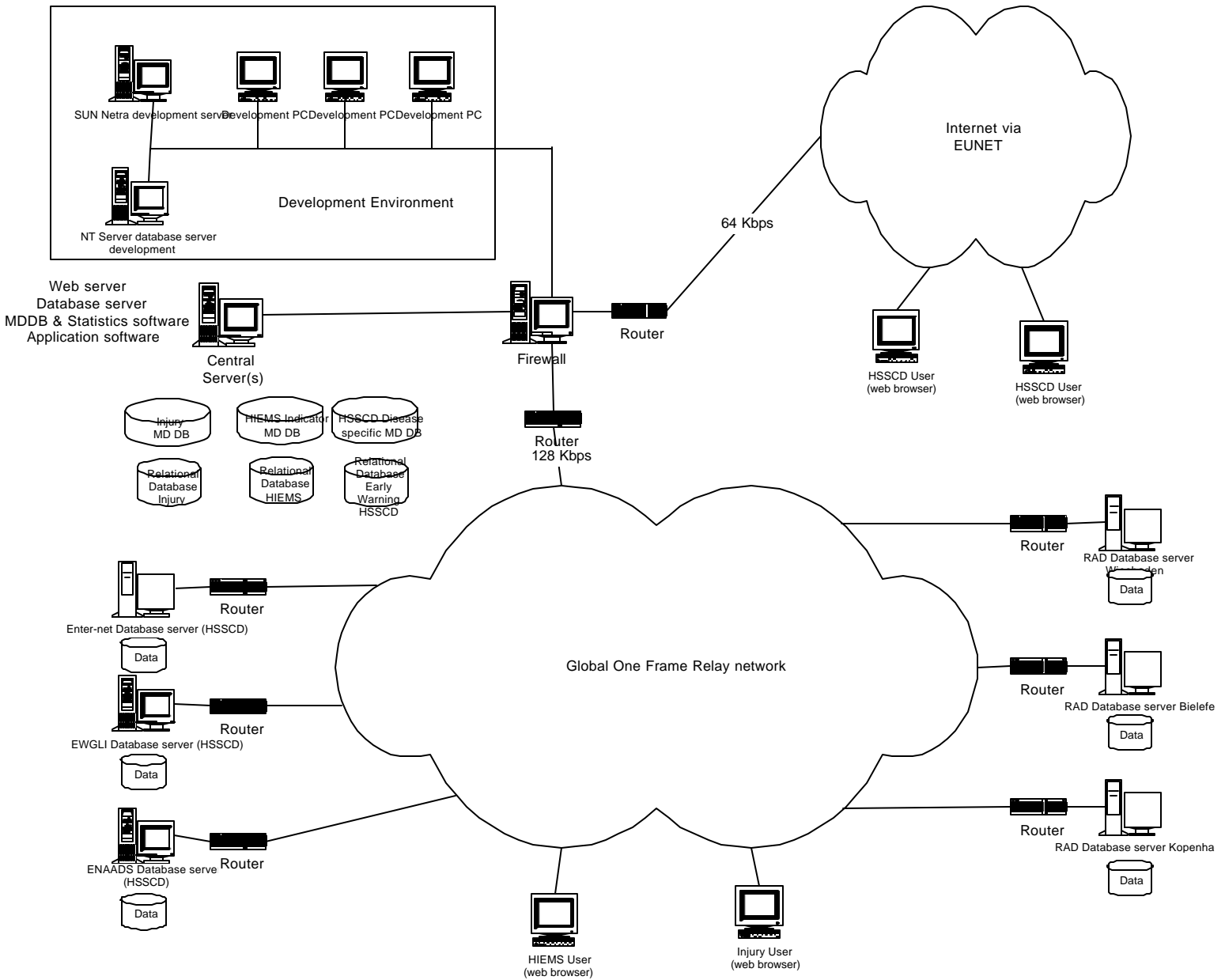
Communication costs (dial-up and internet)

Distributed sites databases informatic services costs

Connection of participants (administrations) to Eurogates

Security issues at national level

Data collection costs /uploading and validation of data costs

Participation in scientific and technical co-ordination

SUN Netra development server   Development PC   Development PC   Development PC

Development Environment

NT Server database server
development

Internet via
EUNET

Web server
Database server
MDDB & Statistics software
Application software

Central
Server(s)

Firewall

Router

64 Kbps

HSSCD User
(web browser)

HSSCD User
(web browser)

Injury
MD DB

HIEMS Indicator
MD DB

HSSCD Disease
specific MD DB

Relational
Database
Injury

Relational
Database
HIEMS

Relational
Database
Early
Warning
HSSCD

Router
128 Kbps

Router

RAD Database server
Wiesbaden

Data

Enter-net Database server (HSSCD)

Router

Global One Frame Relay network

Router

RAD Database server Bielefe

Data

Data

EWGLI Database server (HSSCD)

Router

Data

ENAADS Database serve
(HSSCD)

Router

Router

RAD Database server Kopenha

Data

Data

HIEMS User
(web browser)

Injury User
(web browser)

ANNEX 1: SCHEME OF EUPHIN

The data:

The home page of the HIEMS database requires a password and username before permitting entry into the system. There are three fields on this page:

Data Dictionary - gives a detailed description of the variables

RAD query - enables you to build tables and graphs from inputting a query

Indicators - the actual variables themselves

There are a number of HIEMS datasets including: Mortality, Demography, Home and Leisure Accidents, Hospitals and Overnight Patients. There is currently no datasets on lifestyles measurements such as diet and physical activity. Each of these datasets has a number of indicators. Demographic raw aggregate data (RAD) exists for migration, marital status, mortality, natality, for home and leisure accidents and for hospitals.

The demographic dataset for mortality includes the following indicators:
- Year of collection
- Sex
- Age groupings (according to WHO mortality groupings e.g. in days: 0, 1-6 days, 7-27 days, in years: 1,2,3,4, 1-4, 5-9, 10-14, etc)
- Marital Status
- Citizenship
- Region (3 levels or nuts: nuts1=country, nuts2=broad sub-regions in country, nuts3=specific sub-regions in country).
- ICD classification

There is currently no data on socio-economic variables in the demographic databases.

Annex B-9

The DAFNE Initiative

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The DAFNE (**DA**ta **F**ood **NE**tworking) initiative refers to the common effort of 13 European countries to compare the food habits of their populations, through the creation of a databank, thus setting the foundations for the development of the Europe-wide DAFNE databank allowing:
* the provision of comparable information on the food habits of people across Europe
* the monitoring of overtime trends of the food habits of Europeans
* the analysis of the effects of sociodemographic factors on these trends and
* the identification of segments of the population with inadequate dietary practices

The DAFNE databank is based on information collected in the context of household budget surveys (HBS), which are regularly conducted by the national statistical offices of most European countries in nation representative samples of the population and provide inter-linked data on food availability and sociodemographic characteristics. The main advantage of the DAFNE approach is the continuity of the data flow and the use of information which have already been collected with methodologies common enough to allow between countries comparisons, requiring only minimal adjustment.

Urged by the characteristics and the potential of HBS data, the thirteen DAFNE countries (Belgium, France, Germany, Greece, Hungary, Italy, Luxembourg, Norway, Poland, Portugal, the Republic of Ireland, Spain and the United Kingdom) have developed the methodology for rendering food and socio-economic HBS information comparable and have integrated all available information into the DAFNE databank (Trichopoulou and Lagiou, 1997 and 1998).

The DAFNE databank is a regularly updated, non-static database, which in its present form allows:
* inter- and intra-country comparisons on daily individual food availability;
* comparisons at different levels of detail, ranging from 45 analytical to 12 aggregated, main food groups;
* comparisons on the eating behaviour of different segments of the population. The databank tracks four socio-economic and demographic parameters with important public health implications, namely household locality, household composition, educational level and occupation of household head.

Information available in the DAFNE databank has been integrated in a user-friendly software programme, which is freely accessible and can be directly downloaded from the Internet at www.nut.uoa.gr.

Furthermore, in the context of the DAFNE initiative the methodology has been developed for estimating individual food availability by age and gender, based on information at household level. Comparisons of the derived estimates for 4 countries with data from individual nutrition surveys show that, given the limitations and inconsistencies present in both, the two datasets can converge, in order to describe the dietary habits of the studied populations (Trichopoulou and Naska, in press). This endeavor is of particular importance, since it allows the use of HBS-derived individual estimates for getting an overview of the eating choices of the populations, monitoring these changes, estimating the percentage of consumers and highlighting major differences between populations.
In the context of evaluating the compatibility of HBS and individual food consumption data, the quantities of raw edible food (ingredient level) were estimated based on the "as consumed" data (Naska et al., in press). This

methodology has been implemented in the national individual food consumption data of four European countries (Belgium, Greece, Norway and the United Kingdom).

The data available in the DAFNE databank can be used in nutrition epidemiology (Lagiou et al., 1999), as well as for nutrition policy making. Trends in the food choices of different European populations can be compared, and the factors most likely to affect these trends may be identified. The DAFNE database can also be used as the basis for formulating nutrition policy and further helps to identify the dietary habits in response to this particular policy, serving therefore as a tool to monitor how widely a policy is accepted by the general public (Naska et al., 2000; Soc Francaise de Publique, 2000).

At this moment, the DAFNE team, with the support of DG-SANCO of the European Commission, is working towards the incorporation of recent datasets from the DAFNE countries. The updated DAFNE databank, including data from 46 surveys, will be integrated in the Health Information and Monitoring System (HIEMS) of the European Union, and thus be combined with other health monitoring information, available at a European level.

Priorities for the future

Based on the need for a continuous flow of nutrition information in Europe, a proposal would be to benefit from the nationally representative sample of the HBS and conduct a pan-European food consumption survey in a sub-sample of the population already participating in the national HBS. Thus HBS may provide the first overview of the population dietary habits, which will, at the second phase, be studied in more detail, using a specially designed dietary method. Furthermore, such a study design may allow the profound evaluation of inherent limitations of the two datasets (such as lack of precise data on meals taken out of home).

The rationale for the above suggestion is the following:
1.   The HBS sample satisfies most of the criteria set for a nationally-undertaken food consumption survey.
2.   The DAFNE initiative has shown that the HBS data can describe and monitor the habits of the European populations, as well as of specific socio-economic groups. In the context of the DAFNE project, the methodology has been developed for conveying the dietary and socio-economic HBS data at a comparable level for 13 European countries. The DAFNE databank directly available through the DafneSoft programme, can be used for conducting international comparisons on food availability.
3.   The DAFNE food classific ation scheme is quite flexible, since it allows comparisons of food availability at various levels of details. Furthermore, the DAFNE classification system was selected as the base for the development of the EuroFoodGroup (EFG) System
4.   In the context of the DAFNE initiative, the methodology has already been developed for estimating individual food availability, taking into account the age and gender differences of household members and
5.   HBS are regularly carried out in all European countries, covering children, adults and elderly and data can be made readily available.

Conclusion

One of the aims of the EFCOSUM project is to ensure "the possibility of datafusion with other health monitoring studies". In the DAFNE initiative, this approach has already been taken under account and the implemented comparisons of the HBS data with those of individual surveys suggest that HBS data, handled according to the DAFNE methodology, can be easily linked with other dietary studies.

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Annex B-10

Biomarkers

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Some biomarkers of diet promise to provide accurate measure of dietary intake or nutrient status, and a more objective one. They are not reliant on the subject's memory or on the accuracy of recording food intake, neither are they dependent on the accuracy of food data tables. Biomarkers of diet can be categorised into two types (Kaaks et al. 1997):

1) those biomarkers which provide an absolute quantitative measure of dietary intake, e.g., 24-hour urinary sodium or iodine as a measure of the 24 h intake, and
2) those biomarkers which measure the concentration of a given factor, e.g., nutrient concentration in blood or other tissue, but for which there is no time dimension to the measurement. Although these biomarkers correlate with intake, they provide no absolute measure of it. However, they are nevertheless useful in categorising individuals into relative levels of intake.

Ideally biomarkers should be specific and sensitive, and not too invasive for human studies.
Intakes of iodine, sodium, iron, folate and vitamin D are highly relevant for health, but their intake assessments from diet surveys are notoriously inaccurate. For these nutrients the use of biomarkers would be more practicable to assess the adequacy of the supply.

Iodine
Since the majority of dietary iodine, over 90%, is excreted in urine and only a minor fraction in faeces, urinary iodine is a widely used biochemical marker of iodine status. However, large within person (within-day and day-to-day) variation is characteristic for urinary iodine.

The easiest urinary samples to collect in epidemiological studies are casual urine specimens (spot urine). To reduce variation, it has been suggested to collect first morning urine, express iodine excretion as a concentration or as a ratio between urinary iodine and urinary creatinine (Bourdoux 1998; Thomson et al. 1996). The reliability of the different estimates has been discussed intensively, and comparisons have been made, mostly in favour of iodine concentration (especially in areas of undernutrition where creatinine excretion is low). Recently, an age- and sex-adjusted iodine excretion, corrected for creatinine, in casual urine has been shown to allow for a better estimate of iodine excretion compared to non-adjusted iodine concentration and iodine/creatinine ratio (Knudsen et al., 2000).

Sampling of 24-hour urine is considered to be the most reliable specimen for assessing iodine status of an individual (Hetzel & Dunn, 1989). However, 24-hour collections are inconvenient for the subject and difficult to collect accurately. Because of the significant day-to-day variation in iodine excretion, Rasmussen et al. (1999) have suggested that the average of more than one 24-hour urine sample should be used to determine iodine status of an individual.
Thyroglobulin concentration in serum is inversely associated with urinary iodine excretion, and may turn out to be a sensitive marker of iodine status in a population (Knudsen et al., 2000).

The determination of thyroid size by palpation or by ultrasound has been used as a marker of iodine status in field studies. However, palpation is difficult with small goitres and ultrasound requires skilled operators.

Conclusion.   Iodine in casual urine samples gives a reasonable estimate of iodine intake in a population. Accuracy is increased if adjustments are made for sex and age. Single 24-hour urinary iodine excretion has an even higher accuracy, however, repeated 24-hour urine is necessary for an accurate assessment of the habitual iodine intake and iodine status of the individual.

Sodium

Sodium (salt) intake is the sum of the natural content in foods, sodium added in manufactured foods by the industry, and salt used in the kitchen and at the table. Dietary intake studies tend to overestimate true intakes (Pietinen, 1982), primarily attributed to the inability to precisely account for added salt (Caggiula et al., 1985) and the fact that much salt, about 75%, is discarded in the cooking water (James et al., 1987). Salt may also be lost when manufactured foods are cooked.

More than 90% of dietary sodium is recovered in the urine with sodium output in sweat and faeces amounting to a few percent (in temperate climates). Consequently, in theory total intake of sodium can be estimated precisely by measuring the urinary sodium excretion. However, there are generally large individual day-to-day variations in 24-hour urinary sodium excretions (Dyer et al., 1997) – even in subjects on a constant daily sodium intake, and it has been shown that several 24-hour urine collections are necessary to characterise an individual's usual sodium intake (Liu et al., 1979; Schachter et al., 1980). Shortt et al., (1988) have calculated that a sample size of at least 30 individuals would be required to estimate group mean sodium intake with an SE of less than 5% from a single 24-hour sample.

Information obtained from 24-hour urine will, provided they are complete, be more accurate than figures estimated from spot samples, samples from the first urination in the morning or timed overnight collections. However, as for iodine, such sampling has low accuracy, but all can probably be used to estimate group mean intakes in larger population studies.

Discretionary sodium intake can be measured with lithium-labelled salt via its excretion in urine (Leclercq et al., 1990).

Conclusion.   A single 24-hour urine collection from an individual is sufficient for an estimation of habitual sodium intake in a population. Accurate individual intake assessment requires multiple 24-hour urine collections.

Iron

A continued negative iron balance will result in depletion of iron body stores, eventually leading to a state of iron deficient erythropoiesis, and finally the most severe form of iron deficiency with overt anaemia (microcytic hypochromic).
Serum ferritin has been found to correlate well with body iron stores in healthy individuals (Walters et al., 1973). It is of value throughout the range of iron stores, including the earliest stages of iron depletion, however an optimal level has not been defined (Cavill, 1999). Ferritin is an acute phase reactant protein, which increases in response to inflammation and infection. Serum transferrin receptor has lately become the preferred marker for tissue iron availability (Ahluwalia, 1998), especially in the clinical situation. The level of receptor in serum is not confounded by infection and inflammation, and by pregnancy, and, hence, is more specific for iron depletion than ferritin. Further, it is a sensitive indicator for iron availability, increasing progressively in response to iron deficiency – and to enhanced erythrocyte production.

Further progression of iron deficiency results in changes in transport iron variables – (serum iron and transferrin). Serum iron is considered an unreliable iron parameter, primarily because it exhibits pronounced within-day and day-to-day variations. Serum transferrin is relatively stable during the day, however, increases with oral contraceptives and decreases with infections and inflammations. Indirect measures of transferrin concentration: transferrin saturation and total iron binding capacity, which, respectively, lowers and increases in iron deficiency, vary with changes in serum iron, and have low sensitivity and specificity. Free erythrocyte protoporphyrin accumulates with iron deficiency. The method is simple and rapid and has a high reproducibility,

and only requires a drop of blood and minimal technical expertise.

Decreased mean corpuscular erythrocyte volume, mean cell haemoglobin concentration and haemoglobin are late stages in iron deficiency, and are non-specific and have low sensitivity as iron status indicators.

The examination of bone marrow aspirates for iron content (total body iron stores) is considered the gold standard for assessing iron status, but is evidently impractical for use in field studies. Several recent comprehensive papers are available on the topic of iron status
determination (Worwood, 1997; Cook, 1999).
It has to be stressed that there are several causes for negative iron balance apart from low
dietary iron, e.g., blood loss, parasites and gastro-intestinal diseases.

Conclusion.   In epidemiological surveys comprising healthy individuals serum ferritin is a sensitive test of iron status (mobilisable storage iron) and continues to be the leading single determination. Serum transferrin receptor is a promising alternative. It is more specific than ferritin and can be used, especially if elderly (inflammations) and pregnant subjects are included. Another common – and better approach is to use various combinations of tests, e.g., haemoglobin, serum ferritin and serum transferrin receptor.

Folate

Intracellular folates exist predominantly as polyglutamates, incapable of cellular exit, while circulating folates are monoglutamyl derivatives. With increasing folate deficiency there is a progression of changes in laboratory tests prior to the development of clinical functional deficit, i.e., megaloblastosis and anaemia (Bailey, 1990).
Decreased extracellular (serum) folate is the first indicator of negative folate balance, but does not provide information regarding body stores. Serum folate is very sensitive to recent intake, and therefore, may be less suitable to use as a marker of folate status in epidemiological studies (Stites et al., 1997). Erythrocyte folate is a marker of the content of the vitamin intracellularly in tissues and its determination can be used as a measure of long-term status. While the level of erythrocyte folate discriminates between normal folate status and deficient body stores, it may be less suitable to diagnose incipient folate deficiency (Ueland et al., 1993). Further, erythrocyte folate is reduced in vitamin B12-deficiency (Selhub & Rosenberg, 1997).

Homocysteine in serum seems promising for the evaluation of folate status, and even a marginal folate deficiency increases homocysteine levels in blood (Jägerstad & Pietrzik, 1993; Ueland et al., 1993). However, levels of homocysteine are dependent on several other dietary factors than folate intake (Rasmussen et al., 2000), including intakes of pyridoxine and cobalamin (Selhub et al., 1993).

An abnormal deoxyuridine suppression test provides biochemical evidence of folate depletion, however the test is tedious to perform and not practical to use in population studies. Other indices of folate deficiency, such as increased mean cell volume of red cells in bone marrow and blood, and hypersegmentation of blood neutrophils and anaemia are the final stages in folate deficiency.

Smoking, alcohol and many drugs increase folate requirements. Although studies have shown good correlations between folate intake from diet and the level of folate biomarkers, it has to be stressed that biomarkers are an expression of folate status rather than folate intake.

Conclusion.   For long term folate status erythrocyte folate is the method of choice. Homocysteine in blood can probably be used as an alternative method. Both methods are able to discriminate between normal status and levels of insufficiency in the single individual.

Vitamin D

For assessment of the vitamin D nutritional status the concentration of 25-hydroxyvitamin D (25(OH)D) in serum is considered as an accurate, integrative measure reflecting an individual's dietary intake and endogenous (cutaneous) production (Parfitt, 1998). Dietary vitamin D intake alone correlates poorly with 25(OH)D (Takeuchi et al., 1995; Thomas et al., 1998). Degree of long-term solar exposure and time spent outdoors are better predictors of serum 25(OH)D than is dietary vitamin D intake (Thomas et al., 1998). However, the optimal level of serum 25(OH)D, and the supply of vitamin D from either source to attain that level in children and adults, is debated (Marriott, 1997; Vieth, 1999).

Since vitamin D deficiency tends to decrease calcium level in blood with consequent secondary hyperparathyroidism, the measurement of intact parathyroid hormone in serum has proven to be a valuable indicator of vitamin D status that can give additional information concerning the degree of compensatory changes. The level of serum 25(OH)D above which no further alteration in serum PTH is evident could define optimal levels of 25(OH)D (McKenna & Freaney, 1998).

Concentration of 1,25-dihydroxyvitamin D, the biological active form of vitamin D, will usually be normal or even slightly elevated in vitamin D deficiency, and therefore provides essentially no information with respect to nutritional status (Hollis, 1996; Parfitt, 1998). Blood concentration of vitamin D reflects recent intake of vitamin D and/or exposure to sunlight, and therefore may vary greatly over short time in an individual.

Other markers for vitamin D status which have been used are: 1) decreased urinary calcium excretion, and increased urinary excretion of certain bone biomarkers (e.g., pyridinoline crosslinks); 2) radiographic bone development of rachitis (in neonates and children); 3) histopathologic changes in bone biopsies; and 4) increased bone alkaline phosphatase in adults. However, these methods are cumbersome and costly, or only indicative of severe vitamin D deficiency.

Conclusion. Serum 25(OH)D is a good marker for vitamin D deficiency in the individual, and can distinguish between overt deficiency and marginal deficiency, especially if combined with serum PTH. However, the level of 25(OH)D which defines hypovitaminos D is not known.

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Annex B-11

Validity of dietary assessment methods in children and older people

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Assessment of dietary intake in children

Dietary intake assessment of population subgroups such as children and the elderly may present special problems. In children the problems relate primarily to their ability to recall both the types and amounts of foods consumed and their ability to conceptualise portion sizes. Thus, most dietary intake studies in children below the age of 7-10 years have been performed with the parent (or the guardian) as the informer (Eck et al., 1991; Beelu et al., 1996; Blum et al., 1999; Iannotti et al., 1994; Klesges et al., 1987; Rockett et al., 1997). Such studies in young children have generally found average correlation coefficients between methods similar to those found among adolescents and adults. There is some evidence that children below 10 years of age (and even as young as 7 years) are capable of recalling diet over 24 hours (Sobo et al., 2000), and studies in this age group have demonstrated that group means of intake correlate with intakes based on parental diet histories or observed intakes, however correlations are generally low (Haraldsdóttir & Hermansen, 1995; Lytle et al., 1993).

Sixth and seventh grade students demonstrated the ability to provide valid intake estimates of energy, however children in the fourth and fifth grades experienced some difficulties in completing a food frequency questionnaire (FFQ) (Field et al., 1999), and 15-year old girls were shown to be quite capable to give reproducible answers with the FFQ (Robinson et al., 1999). Also, girls aged 9 and 10 years demonstrated large absolute errors in food reporting with 24-hour recall, 3-day dietary record (DR) and 5-day food frequency record, though the agreement between observed and reported intakes was best for the 3-day DR (Crawford et al., 1994).

Livingstone et al. (1992) compared energy intakes from 7-day weighed DR and from diet history (DH) with energy intake determined by doubly labelled water (DLW) in children and adolescents aged 3-18 years. Results showed that DR tended to underestimate mean energy intake in the adolescents, but showed good agreement in the children, and that DH, which was taken in collaboration with parents, although overestimating energy intake somewhat, was fairly representative of habitual intake. Similar results were found in a study of pre-adolescent girls aged 8-12 years (Bandini et al., 1997). They had their energy intake assessed by 7-day DR based on household measures and their energy expenditure measured by DLW. Mean energy intake was underestimated by about 12%, but as age and daily energy expenditure increased the magnitude of the error of reporting increased. Kaskoun et al. (1994) showed that FFQ completed by mothers of children aged 4.2-6.9 years significantly overestimated habitual energy intake of the children compared with DLW. Lindquist et al. (2000) compared energy intake measured by interviewer-guided 24-hour recall technique with energy expenditure calculated by DLW in children ranging in age from 6.5 to 11.6 years (mean: 9.5 years). The recall method was shown to be a valid estimate of mean energy intake in the group, however energy intake and expenditure only correlated modestly. Use of taped records did not seem to improve accuracy.

Conclusion

Twenty-four-hour recall can be used with acceptable internal and external validity with children as the informants if the children are (7-) 10 years or older. Below that age parents' or guardians' help is necessary, and in that case the accuracy of reporting is comparable to that found in adults. FFQ seems to be an alternative method to 24-hour recall, however to comprehend the food frequency questionnaire children usually have to be older than 12 years. Prospective intake information is, of course, dependent on the child's reading and writing abilities. Adolescents,

just as obese subjects and female endurance athletes, seem to underestimate energy intake (individual errors in energy intake may reach 50%). Validation studies with DLW has demonstrated the 24-hour recall to be representative of energy expenditure in children while significantly overestimating habitual energy intake assessed by FFQ. Apparently, 24-hour urinary nitrogen (24-hour UN) cannot be used in children to validate intake, due to nitrogen accretion taking place during growth. There is no information to suggest that accuracy and precision of different food intake assessment methods is influenced by cultural background of children.

Assessment of dietary intake in the elderly

In the elderly memory defects, sensory deficiencies (loss of hearing and vision) and neuro-musculo-skeletal diseases may impede retrospective and prospective data information. DHs with 3-day diaries and checklists were compared with 3-day estimated DR in 807 elderly people aged 74-79 years to assess the internal validity in the Euronut SENECA study (van Staveren et al., 1996). The reported level of intake for most nutrients was 10-20% higher based on the DH, and of similar order to that reported for younger age groups. Correlation coefficients between the two methods ranged from approximately 0.5 to 0.75. Based on physical activity ratios (reported energy intake divided by basal metabolic rate), the authors concluded the DH to be the more accurate method. A 10% higher intake from FFQ compared to multiple weighed DR was found in a study of elderly Norwegian women (Nes et al., 1992). Rothenberg (1994) compared the FFQ with 4-day DR in elderly Swedish men and women (70 years). In this study FFQ also provided consistently higher intakes of nutrients and energy than the DR. The conclusion was that the FFQ gave a better estimate of energy intake than the DR, based on validation, which used UN as an external marker and on the finding of a plausible ratio of energy intake from the FFQ divided by basal metabolic rate.

A Dutch study compared the protein and energy intake obtained by DH (with a reference period of 1 month) with protein excretion and energy expenditure measured by 24-hour UN and calorimetry (respiration chamber), respectively, in women aged 69-82 years (Visser M et al., 1995). Mean reported energy and protein intake was somewhat, but not significantly, lower than measured protein excretion and energy expenditure (about 10%). Subjects with a relatively high energy expenditure (or a high protein intake) underestimated their energy intake to a larger extent. Indirect calorimetry and 24-hour UN was also used to validate intake from 3-day estimated DR in German men and women >60 years of age, and it was concluded that the DR was suitable to determine energy and nutrient supply of the elderly (Luhrman et al., 1999).

A study in Dutch men and women aged 55-75 years compared intakes from a semiquantitative adapted FFQ (simple self-administered questionnaire followed by a structured interview) with intakes from multiple DR's and 24-hour UN (Klipstein-Grobusch et al., 1998). A general overestimation was found with the FFQ compared to DR and 24-hour UN, however the FFQ could adequately rank subjects according to dietary intake. Adequate ranking of dietary intake in the elderly with the FFQ has also been demonstrated in several other studies (Grotenhuis et al., 1995; Horwath, 1993; Nes et al., 1992; Smith et al., 1998).

Ten older American women with an average age of 74 had their dietary intake assessed simultaneously by three different methods: weighed DR for 7 days, and duplicate 24-hour food recalls and FFQ's (Sawaya et al., 1996). Compared with DLW the FFQ gave mean energy intakes that were closest to measured total energy expenditure with DLW, while the 7-day weighed DR and the 24-hour food recall (albeit less than the DR) significantly underestimated mean energy intake. Individual energy intakes determined with any of the methods and expenditures did not correlate significantly. The authors speculate that food intake methods that rely on retrospective reports of dietary intake may be less suitable for older subjects than for young one, consistent with previous suggestions that there is an increased risk of problems with short-term memory in this age group (van Staveren et al., 1994). Not even multimedia dietary records (using voice recording and photography of all food and beverages when consumed for 4 consecutive days) seem to increase validity (Kaczkowski et al., 2000). Compared with DLW large underreporting of energy intake was demonstrated in elderly and middle-aged women, 50-93 years of age, with this innovative dietary intake assessment technique.

The sensitivity of different methods ("responsiveness") to changes in dietary habits has not been studied specifically with respect to elderly people, however, other studies have shown that inexpensive short

assessments can be as responsive as multiple-day DR (Kristal et al., 1994). Underreporting of dietary energy intake with increasing weight is also demonstrated among elderly (Rothenberg et al., 1997).

Conclusion

Several studies have been carried out to assess the internal and external validity of intakes in the elderly. The observation that food intake measurement methods that rely on retrospective reports may be less suitable in older people requires confirmation. Thus, there are no hard scientific data to conclude that healthy and well-functioning elderly present with specific problems compared to the younger age group with respect to dietary intake assessment. None of the dietary assessment methods give accurate estimates of the usual energy requirements of individual subjects. DH and DR seem to underestimate food intake in the elderly as in younger age groups. Well-conducted simple methods (24-hour recall and FFQ) for assessing group mean dietary intakes may give more accurate information than the more cumbersome weighed DR. However, it must be realized that most studies have been conducted in healthy and well-functioning elderly, and none of the common methods are probably applicable in elderly with memory deficits or other disabilities. There is no information to suggest that accuracy and precision of different food intake assessment methods is influenced by cultural background of elderly people.

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Annex B-12

Feasibility of using the EPIC-SOFT Program outside the EPIC Study

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The original rationale for developing EPIC-SOFT within the context of EPIC

The European Prospective Investigation into Cancer and Nutrition (EPIC) is a large multi-centre prospective cohort study involving about 480,000 middle-aged men and women from 10 European countries (Spain, Italy, France, Greece, Germany, The Netherlands, United Kingdom, Sweden, Denmark and Norway, which recently joined the project). Information on usual dietary intakes was collected using exhaustive dietary history or food frequency questionnaires developed and validated in each of the participating countries (Overvad et al*.,* 1991; Bingham et al., 1994, Margetts et al., 1997). In order to adjust, at the group level, for systematic over- or under-estimation of the true mean food (or nutrient) intakes estimated by the various EPIC questionnaires, it was decided to perform an additional dietary measurement, a 24-hour diet recall (24-HDR), in a subsample of the study subjects of about 37,000 individuals (Riboli & Kaaks, 1997). One of the principal statistical requirements to use the calibration approach in the EPIC context was that the reference dietary method (i.e. 24-HDR) must be highly standardized across the 23 European centres involved in the project. A software program (EPIC-SOFT) was therefore developed to ensure the highest possible level of standardization of the 24-HDR interviews within and between centres, and increase the likelihood that, if measurement errors, exist they apply equally in all centres (Slimani et al., 1999).

PRINCIPAL CHARACTERISTICS OF EPIC-SOFT

The EPIC-SOFT program was developed to collect interactive dietary interviews following a strictly standardized procedure to prevent or minimize systematic and random error measurements within and between the EPIC centres. The main characteristics of EPIC-SOFT are that:

1) Information on all the foods and beverages consumed during the recall day is collected, entered, and coded automatically according to common rules

Two separate lists containing respectively about 1500 to 2200 foods and 150 to 350 mixed recipes most frequently consumed in the different EPIC countries were pre-entered in the software. During the interview, each item recalled is automatically searched, described, quantified and checked using pre-entered common rules.

2) The software was developed to be user-friendly and convenient for use in large populations of different linguistic, socio-cultural, ethnic and geographical origin

The EPIC-SOFT interface was developed using the same basic design for the versions in all countries, and translated into local languages. In addition, the general structure of EPIC-SOFT was designed to guide and control the interviewer by standardizing, across countries, the pathways to be followed during the 24-hour diet recall interview.

3) The quantity of the food as finally consumed (e.g. cooked and/or without inedible part)

Whatever way the food/recipe is quantified during the interview, the system automatically converts the food quantities "as reported" to "as finally consumed", using pre-defined algorithms and standard food-specific coefficients (e.g. raw-to-cooked, density or edible part coefficients) which can easily be updated.

4) Systematic quality controls have to be performed throughout the interview procedure
The EPIC-SOFT system checks systematically for all information reported by the subject and entered by the interviewer so that possible errors and suspicious answers, missing information and outlier values, can be detected and clarified with the subject during the interview.

5) Standardized procedures for maintaining the EPIC-SOFT databases
Like any open-ended method, the databases of the computerized 24-hour diet recall method need to be updated regularly so that new foods, recipes and other information reported by the study subjects can be added. To maintain a high level of control and standardization of the EPIC-SOFT databases and to facilitate updating, it was decided, in the EPIC context, that only one version will be available per country and that any modifications to the EPIC-SOFT files will be centralised at IARC. In addition, a four-step hierarchical structure involving the interviewers, centre co-ordinators, country co-ordinator and international co-ordinator (IARC) was set up to share the work involved in standardizing the collection, update, and export of the EPIC-SOFT 24-hour diet recalls and ensure controlled transfer of modifications required to the common or country-specific EPIC-SOFT files from the bottom level (interviewers) to the top (IARC). Various semi-automatic tools and guidelines were developed at IARC to ensure that the above tasks are highly standardized.

6) The storage, method of retrieval and export of dietary data has to be standardized
Other software programs (EPIC-SOFT Recompute and Export) were developed to recalculate automatically the individual food (or nutrient) intakes collected with the 24-hour diet recalls according to the latest modifications made to the EPIC-SOFT standard files (e.g. food standard unit, edible, density, raw-to-cooked standard coefficient files). Before performing statistical analyses, it is particularly important to ensure that the final food and nutrient intakes were estimated from the most up-to-date EPIC-SOFT version. This program also checks for incompleteness in the 24-hour diet recalls by indicating precisely the missing items (e.g. missing food or recipe, missing coefficient, missing food portion). In addition, this software allows the 24-hour diet recall interview data to be exported in a common export file, which facilitates the storage, exchange and pooled analyses of the EPIC-SOFT data.

ADVANTAGES OF THE EPIC-SOFT PROGRAM

1. The Concept of standardization already exists
EPIC-SOFT results from the development of a new concept of standardization of the 24-HDR interview procedure at the international level. It took about 3 years and more than 20 person-years to develop the theoretical concept of standardization, the software program and the EPIC-SOFT versions for the seven countries initially involved in EPIC. Four other versions were developed later. This general concept of standardization is reported in detail elsewhere (Slimani et al., 2000). Although some further improvements may be made to the EPIC-SOFT program and additional modules are necessary to ensure the computerized maintenance of its databases, the work already done can serve other purposes and can easily be applied to other study contexts.

One of the main characteristics of this concept is that the food and recipe lists are classified in food (sub-) groups common among the national EPIC-SOFT versions which constitute the backbone of the entire concept of the standardization of the software. The rules to set up the food and recipe lists, describe, quantify and check them are indeed defined according to the (sub-) group to which the common classification food or recipe belongs. These rules of standardization are stored in the so-called "*common files*", whereas the "*specific files*" (food and recipe lists, lists of standard units,..) ensure that the system has the necessary flexibility to capture the dietary information specific to each country.

2. Computerized versions already exist and are in use in 11 European countries
Eleven versions of the EPIC-SOFT program already exists already in 11 versions in France, Italy, Spain, Germany, The Netherlands, Greece, United Kingdom, Sweden, Denmark, and more recently Norway. A further

version (in French only) exists for Switzerland, which does not participate in EPIC.

3. The entire information collected from the subject is stored and easily retrievable
One of the characteristics of the EPIC-SOFT program is that ALL the original information reported by the subject is stored in a systematic and easy retrievable way.

4. EPIC-SOFT provides checked, completed and comparable dietary data
The final information available in EPIC-SOFT provides complete and checked information, already classified according to a (sub-) group classification system comparable across countries. Thus, when data are updated for missing information and exported according to a common format, it is possible to perform immediate pooled data analyses, at the (sub-) food group level.

5. The software is user-friendly and has been tested in different cultural situations
EPIC-SOFT and its different versions have already been used in different cultural settings to collect about 37,000 24-HDRs. Overall we observed no major problems in its use among the 90 interviewers involved in the 23 EPIC centres participating in EPIC. Further improvements could however be made to the interview and data maintenance procedures.

6. *Flexible system*
Due to the intrinsically flexible structure of EPIC-SOFT it is possible to make changes easily to the common rules applied to standardize the overall procedure of the 24-HDR interview, and to develop further national versions. However, depending on the developments required, more time and financial support are needed.

7. *Short interview duration*
The interview duration is comparable across countries. It takes about 30 to 35 minutes to conduct a 24-HDR interview whatever the country. This does not, however, include the time required to update incomplete interviews, which varies according to the amount and nature of the information missing, and the completeness of the initial food and recipe databases implemented in the EPIC-SOFT versions. This time is compatible with most of the logistical and practical constraints of large nutritional studies.

8. Encouraging preliminary results on the capacity of EPIC-SOFT to provide standardized 24-HDR measurements
Preliminary results based on an analysis of variance among the 90 interviewers involved in the study (Slimani et al., 2000), show that the percentage of interviewers with a mean energy intake within ± 5% or ± 10% of the country mean energy intake represents respectively 71.4% and 98.2% in men and 74.3% and 94.3% in women. The difference never exceeds 5% when centre and country mean energy intakes are compared, even though no extreme energy intake values were excluded. Other unpublished results suggest a strong gender effect on under-reporting energy intakes which is, however, unlikely to be attributable (only) to a methodological problem. Further evaluations on the reliability of the dietary intakes obtained with EPIC-SOFT using urinary markers as reference measurements (nitrogen, potassium) will be available soon.

CURRENT DISADVANTAGES/LIMITATIONS FOR THE USE OF EPIC-SOFT OUTSIDE THE EPIC CONTEXT

1. The preparation of new national EPIC-SOFT versions is centralised at IARC.
All the programs needed to check and link the 58 common and country-specific files together, and implement them in the EPIC-SOFT software are, for the time being, centralised at IARC. In addition, so far the supervision of this work has been carried out by IARC staff.

2.   Maintenance of the EPIC-SOFT databases
One of the current difficulties of using EPIC-SOFT outside the EPIC context is related to the problem of database maintenance. Various tools and guidelines were developed at IARC to ensure the standardization of EPIC-SOFT database maintenance. However, due to lack of resources, it was not possible to develop programs to automate these procedures entirely. Further programs need therefore to be developed to make EPIC-SOFT database maintenance totally independent of the logistics of EPIC.

3.   Limited number and non standardized nutrients in the current EPIC-SOFT version
In the current EPIC-SOFT versions the number of nutrients available is restricted to total energy and macro-nutrients. In addition, these nutrients are not standardized across countries but based on national food composition tables. The temporary and country-specific nutrient databases currently available in EPIC-SOFT are used only to identify and correct gross possible under- or over-estimation when the subject is still present. The pooled analyses of the calibration data at the nutrient level will be recalculated when final standardized EPIC food composition tables are available.

4.   Developed for use among adult populations only
EPIC-SOFT was developed for use among the middle-aged European populations involved in EPIC. Food and recipe lists, dietary habits and interview techniques specific to other population-groups (e.g children, teenagers, different ethnic groups) are therefore not currently available in EPIC-SOFT.

5.   EPIC-SOFT is not compatible with Microsoft (R) Windows NT (R)
EPIC-SOFT is a program written with Clipper language on MS-DOS.
The minimum hardware requirements to run it are:
   - PC with Windows version 3.11 or MS-DOS version 3.x
   - 386 processor
   - 2 MB in RAM memory
   - 5 MB available on the hard disk
Although this language of development and the minimum requirements may seem obsolete, it is efficient enough to collect and process the data of the 24 hour recalls.
The main disadvantage of EPIC-SOFT is that it cannot run on Windows NT. There is a problem of compatibility between the use of the protection key and Windows NT, which is now the operating system used by most people. So we could consider improving EPIC-SOFT to make it compatible with Windows NT but we should also assess whether this development is really necessary knowing that EPIC-SOFT runs perfectly on Windows 98.

FURTHER DEVELOPMENTS/IMPROVEMENTS NEEDED TO USE EPIC-SOFT OUTSIDE THE EPIC CONTEXT
At that stage of the discussion, one would like to indicate in broad but exhaustive terms, the different areas of development needed to make EPIC-SOFT independent of EPIC logistics. Further discussions are needed to clarify who will be the potential users of EPIC-SOFT further and what is the most cost-effective strategy for developing it further and making it available to other users.

The additional areas of development which may be envisaged on EPIC-SOFT are :
   1.   Develop further EPIC-SOFT versions for countries not involved in EPIC;
   2.   Develop and implement standardized food composition databases in EPIC-SOFT;
   3.   Develop additional programs to update/maintain the EPIC-SOFT databases independently of current EPIC logistics;
   4.   Adapt the EPIC-SOFT databases to other study populations not initially involved in EPIC (children, teenagers, foreign populations,…);

5.   Reprogram EPIC-SOFT to be compatible with Microsoft (R) Windows NT (R).

1.   *PREPARATION OF A NEW EPIC-SOFT VERSION*
The general procedure for preparing a new EPIC-SOFT version is the following:

1.   Verify that the rules (summarised in the common files) correspond to the needs of new countries.

2.   Develop the food and recipe lists according to the common criteria decided, and classify them according to the common (sub-) group classification system. Guidelines exist already, and the food and recipe lists available from the EPIC countries are useful examples to start with when setting up new lists.

3.   Prepare all the country-specific files for food and recipe lists respectively (e.g. facets/descriptors, quantification methods, probing).

4.   Translate common EPIC-SOFT screens and related instructions/functions.

5.   Prepare/select the additional tools needed to quantify foods or recipes, according to standardized criteria (e.g. shapes for bread slides, HHMs and related pictures, food pictures).

6.   Translate the documents needed for the training courses and during the interview (EPIC-SOFT, RECIPE MANAGER and RECOMPUTE/EXPORT user's manuals, introduction/instructions on how to use the EPIC-SOFT picture book).

Most of the work of preparing country-specific files should be done locally by one or two persons with a good knowledge of nutrition, in close collaboration with a person expert in the standardization rules applied in EPIC-SOFT. This person will provide supervision and technical assistance during the preparation of a new EPIC-SOFT country-specific version.

So far the programs used to check the common and country-specific files and implement them in the EPIC-SOFT software were developed outside of EPIC-SOFT, and used exclusively at IARC. Further developments will be needed if the preparation of new EPIC-SOFT versions is to be more independent of EPIC logistics.

2.   *FOOD COMPOSITION TABLES*
Despite improvements in the comparability of food composition tables (FCTs) in recent years, promoted by national and international initiatives (Institutes in charge of national food composition tables, INFOODS, EUROFOODS-ENFANT/COST-ACTION99), there are still considerable differences between national food composition tables (Deharveng et al., 1999). Since no reference European food composition table for use in large multi-centre studies exists, it was decided to develop an *ad hoc* standardized EPIC nutrient databases to be used for the pooled analyses of the EPIC data. The overall concept of standardizing these EPIC food composition tables is developed elsewhere (Slimani et al., 2000). One of the characteristics of this concept is the proposal to build up nutrient database tables, using the already standardized food intakes collected with EPIC-SOFT as the vertical entry of these "*new matrixes*" independently of the national food composition tables. The main advantage of this approach is to overcome the large heterogeneity in the food lists observed across current national food composition tables (number of items, level of details), considered as one of the principal causes of lack of comparability across European FCTs. This project is currently on-going and consider the possibility to extend it to countries not participating in EPIC. The EPIC project on the development of standardized nutrient databases across European countries involved in the study will be presented in more detail within the working group co-ordinated by A. Møller. The project of developing standardized nutrient databases should logically precede the actual implementation of the nutrient databases in EPIC-SOFT.

In order to reach this objective, the following issues need to be addressed :
- Finalize the preparation of the new matrixes (i.e. aggregated list of food items reported in the 24-HDRs)
- Finalize the criteria for standardizing FCTs
- Finalize the database management system (DBMS) to compile FCTs
- Compile the standardized FCTs according to the new country-specific matrixes
- Develop the programs to include and ensure the maintenance of standardized FCTs in EPIC-SOFT (i.e. NUTRIENT MANAGER programs)
- Implement standardized FCTs in EPIC-SOFT

3.   MAINTENANCE OF THE EPIC-SOFT DATABASES

The open-ended nature of the 24-HDR method implies a dynamic system where any new food or recipe, or other changes in the standard EPIC-SOFT files need to be updated regularly. This will be obtained only with strictly controlled procedures. So far these procedures were all centralised at IARC, using partially computerized approaches. Additional modules need to be developed to ensure automatic maintenance of the 58 EPIC-SOFT *common* or *country-specific* databases, independently of EPIC logistics :

- The common EPIC-SOFT files are the backbone of the standardization of the 24-hr diet recall interview between the EPIC countries. If we want to maintain the overall concept of standardization of EPIC-SOFT across versions and over time, changes to these files should be protected and restricted to authorised persons/institutions. These changes should be made after official requests and with the approval of the participating countries. However, these may be limited. Our experience in EPIC was that we received no requests to modify the common rules, except to add new photos for Nordic countries which joined EPIC later.

- The country-specific EPIC-SOFT files are the flexible part of the software which contain the dietary information specific to the country. More flexibility can be foreseen in the maintenance of these databases. To a certain extent, this maintenance could be performed locally by the users, under strict conditions.

EPIC-MANAGER contains the programs with the different modules to update and maintain the EPIC-SOFT files. Three different modules can be identified:

  a.   RECIPE-MANAGER : This software contains all the programs to maintain the recipe files. Although RECIPE MANAGER is already partially used to update standard recipes in the EPIC context, the programs are not totally finalized:

  b.   *FOOD-MANAGER :* This software contains all the programs for maintaining the food files. These programs are not developed yet, but the general concept for updating these EPIC-SOFT files is partially defined on paper.

  c.   *NUTRIENT-MANAGER :* A third module (NUTRIENT-MANAGER) also needs to be developed to ensure the maintenance of the nutrient databases to be implemented in EPIC-SOFT. The update of the nutrient database, like any other EPIC-SOFT food file, is already planned in the conceptual development of the EPIC-MANAGER. However, considering the complexity of this module, it is not yet decided whether the nutrient databases should be included in EPIC-SOFT or available in a separate but compatible database management system (DBMS). This for the following reasons :

  1.   the type and number of food + facet/descriptor combinations depend on individual answers given by the subjects during the interview;

2.   the need to aggregate these combinations into a restricted food list to be matched with available FCTs;

3.   FCTs are themselves dynamic files which need to be updated and maintained across countries.

The final decision between these two possible options (i.e. link between the food and nutrient database and calculation of nutrient intakes, inside or outside EPIC-SOFT) and their specific implications for the programming and future use of EPIC-SOFT still need to be carefully considered. These discussions will overlap with those on the conceptual and practical standardizing of food composition tables and their use outside the EPIC project.

4. ADAPTING EPIC-SOFT VERSIONS TO STUDY POPULATIONS NOT INITIALLY INVOLVED IN EPIC

Depending on the needs, it should be checked whether the current EPIC-SOFT versions are adapted to study populations other than those involved in EPIC (e.g. populations of different age, socio-cultural levels or ethnic groups) and whether some further changes are needed in the databases (e.g. food and recipe lists, probing questions…).

5. MAKE EPIC-SOFT COMPATIBLE WITH MICROSOFT (R) WINDOWS NT (R)

Further programme to make EPIC-SOFT compatible with Windows NT may be considered, but should not be seen as a top priority.

6. OTHER POSSIBLE IMPROVEMENTS TO EPIC-SOFT AND RELATED PROGRAMS

In addition to the developments mentioned above, a certain number of relatively minor improvements could be made to EPIC-SOFT or its related programs :

On EPIC-SOFT:

- *Note file*

Improve the note file to facilitate search, use and management (i.e. to make it possible to sort the information reported in this file according to different criteria : type of message reported automatically by the system; country-specific codes or abbreviations used by the country to indicate that a message, error or missing information has been checked or corrected).

- *Standard recipe file*

Make it possible to recompute the standard recipes. For the moment, if modifications (e.g. add/delete ingredient, change portion sizes) are made to the originally entered standard recipes, the system is not able to retrieve physically the place of each ingredient.

- *Nutrient database*

Add more nutrients to the existing file which, for the time being, contains only Energy, Protein, Carbohydrates, Fat and Alcohol. However, refer to chapter 3 for additional comments about this file.

- *Vitamin/mineral supplements*

Add a standard unit and nutrient database for supplements

- *Possibility to enter several 24-HDR measurements per individual*

Not an available option for the time being

- *Other :*

Other requirements may be expressed by the country users based on their practical experience with EPIC-SOFT (and related programs)

On the RECOMPUTE program:
- Separate and detail the message errors
- Make it possible to change the food and recipe names in the interview files
- Make it possible to export interviews according to different criteria (e.g. subject code, date of interview,)

PRELIMINARY TIME AND COST ESTIMATES FOR THE PREPARATION OF A NEW COUNTRY-SPECIFIC EPIC-SOFT VERSION (*)

Definition	Localisation	Personnel	Time (months)	Cost per Month (US $)	Total Cost for each new EPIC-SOFT country-version (US $)
Development of country-specific files	Country	1.5 dietician(s)	12	2817	33804
Supervision of the work	Coordinating centre	1 nutritionist	5	3894	19470
Implementation of the new version in the EPIC-SOFT program	Coordinating Centre	1 computer technician	0.4	3570	1428
Total direct costs					**54702**
Overheads x 13%					7111
Total					**61813**
Additional Costs (**) Picture-books	Country	1 per interviewer		75/unit	Depend on the number of interviewers involved
Protection keys to be installed on each PC in order to use EPIC-SOFT		1 per PC		75/unit (~)	

NOTES :

(*) Staff costs are based on IARC/WHO standards. These average estimates will however largely depend on whether already existing versions can be used as the starting point for preparing new EPIC-SOFT versions (e.g. the British version to develop a new Irish version). In addition, the time and cost needed to prepare a new national EPIC-SOFT country-version may be increased if additional modifications are required such as :

-    Additions/changes to the common files (new facets/descriptors, new situations not identified so far, which need further adaptations to the existing files or further programming)
-    Need to add new photo series to the EPIC-SOFT picture-book
-    Adapting the EPIC-SOFT databases to other study populations not initially involved in EPIC (children, teenagers)

(**) Approximate Costs : to be discussed – does not include the cost of training courses and overheads

(~) With a volume discount

PRELIMINARY TIME AND COST ESTIMATES ON THE DEVELOPMENT NEEDED TO MAKE EPIC-SOFT INDEPENDENT OF EPIC LOGISTICS (*)

Definition	Localisation	Personnel	Time (months)	Cost per Month (US $)	Total Cost (US $)
To work essentially on the actual programming of EPIC-SOFT.	Coordinating centre	1 computer technician (Free lance or with temporary contract)	18	2817	50706
Supervise the computing development and work on the conceptual development	Coordinating centre	1 computer technician	6	3570	21420
Supervise the entire project and work on the conceptual development (**)		1nutritionist (IARC staff, P2)	6	6367	38202
Total direct costs					**110328**
Overheads x 13%					14343
Total cost					**124671**

NOTES :

(*) All staff costs are based on IARC/WHO standards. At this stage it is difficult to make a precise estimate, as it depends largely on the difficulties and options needed particularly on NUTRIENT MANAGER. These estimates do not include the cost of completing the standardized food composition tables to be implemented in EPIC-SOFT and which is charged in another separate project.

(**) This estimate covers only the cost of supervising the conceptual and computing development to make EPIC-SOFT independent of EPIC logistics. It does not include the cost of supervising and ensuring the maintenance of the EPIC-SOFT databases over time and at the international level.

CONCLUSIONS AND FUTURE DISCUSSIONS NEEDED:

This report shows that the EPIC-SOFT program is already available for 11 European countries and could relatively easily be extended to other non EPIC countries, if resources are available. EPIC-SOFT was designed to obtain standardized 24-HDR interviews, and tools are already available to export them according to a common format in order to perform pooled data analyses at the food (sub-) group level. However, additional developments are required to obtain standardized nutrient intake estimates, and make the maintenance of the EPIC-SOFT databases independent of EPIC logistics.

The need to develop standardized food composition tables is, however, not specific to EPIC-SOFT, and addresses a more general problem of lack of such tools for large nutritional studies, whatever the dietary methods used. In addition, the conceptual approach proposed in EPIC to obtain standardized food composition tables relies strongly on the dietary data collected with EPIC-SOFT, although this concept could be extended to other non EPIC countries. It is therefore important to extend further discussion on the possible use of EPIC-SOFT outside EPIC also to the food composition table project, presented so far as a separate issue. This may have substantial implications for the future development and use of EPIC-SOFT in large European multi-centre studies. In addition, combining these two projects (i.e. EPIC-SOFT and food composition tables to obtain standardized estimates at the food (sub-) groups and nutrient level), will increase the likelihood of having a complete standardized dietary package perfectly adapted to the current needs of large multi-centre nutritional studies.

If general agreement is found on the usefulness of making EPIC-SOFT available to a large spectrum of users, to invest further to make it independent of EPIC logistics and to link the EPIC-SOFT and food composition table projects together, it will be necessary to discuss a number of practical, methodological, political and logistical issues on how to carry out such a project in practice. In view of the increasing requests to use the EPIC-SOFT program, it is likely that the number of potential users would largely exceed the EFCOSUM project. At first, it is important to identify the different institutions and research centres interested in such a project, their specific needs and how they wish to interact on the project. It will therefore be important to enlarge the discussion and envisage giving a wider dimension to the project than initially thought. This may also be a way to increase our chance of obtaining support as the best and most cost-effective strategy to have in the near future a complete, standardized dietary interview package for large nutritional surveys in Europe.

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Annex B-13

Selection of relevant dietary indicators

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One of the aims of the European Food Consumption Survey Method (EFCOSUM) is to define a set of dietary components which are relevant determinants of health in Europe. These dietary components are intended to serve as nutrition indicators in the European Health Monitoring Program and as such should be limited in number, relevant for health and practical for all involved countries with respect to data gathering and comparability of data.

Epidemiological and clinical research in the field of nutrition has identified several important dietary factors relevant for the development of chronic diseases. For many major factors there is general consensus among scientists with respect to their role in disease etiology. This consensus is reflected in international reports and nutrition action plans, where major nutritional factors relevant for health in Europe are defined. These include a report on Health and Nutrition prepared by the French Presidency of the European Union (French Presidency, 2000), which refers to the report from the project Nutrition and Diet for Healthy Lifestyles in Europe (EURODIET, 2000) and reports from The World Health Organization, Regional Office for Europe (WHO, 2000a, WHO 2000b).

Diet and health

Cardiovascular disease (CVD) is the main cause of death in the European Union and it is estimated that more than a third of cardiovarscular deaths of people under the age of 65 are attributable to diet (Rayner & Peterson, 2000; Ferro-Luzzi & James, 1997). The most important dietary factors are those that affect serum cholesterol levels. Thus, diets high in **saturated fatty acids** but low in foods of plant origin, increase the risk of cardiovascular disease, while diets high in **fruits and vegetables** but low in saturated fat are protective. Also diets including a weekly **fish** meal are associated with lower cardiovascular risk (Deckere et al., 1998) while **sodium** rich diets contribute to hypertension and stroke (Sacks et al., 2001; Tuomiletho et al., 2001)

Cancer accounts for 29% of all deaths of men and 22% of women in the EU (French Presidency, 2000) and it is estimated that between 30 and 40% of these can be attributed to dietary factors (Doll & Peto, 1981). Excess **energy and alcohol** intake are risk factors for cancers of the mouth, pharynx, larynx, oesophagus and liver, while high intakes of **fruits and vegetables** are associated with reduced risk of cancers of mouth, pharynx, oesophagus, stomach and lung (WCRF/AMCR, 1997). Other factors still need clarification, such as the relationship between dietary fatty acids and cancers, as well as the possible protective role of fruits and vegetables in cancers of the colon, breast and prostate.

Prevalence of obesity and overweight are rapidly increasing among all age groups in Europe, both children and adults alike. Consequently diseases resulting from excess body fat, not the least diabetes type 2, are expected to follow this development, and become an ever increasing burden on society and health care (WHO, 1998). Diabetes prevalence is already rapidly rising in Europe and it is estimated that at least 80% of diabetes type 2 are due to obesity and overweight. Lack of physical activity in daily life combined with **energy dense, high fat diets**, contributes to increased weight gain and obesity in most societies.

Osteoporosis and the associated bone fractures among post-menopausal women and older men are predicted to become an increasing burden on society as a result of increasing age of European populations. Physical activity and sufficient **calcium and vitamin D** from childhood to old age are preventive factors against osteoporosis (EU

Commission, 1997).

While the relative importance of nutritional deficiency diseases have diminished in European populations in recent decades, certain nutrient deficiencies are still of concern. This includes **iron** deficiency, which is prevalent among young children and women of child bearing age in most European countries. **Iodine** deficiency is also a health problem in many European countries involving 16% of the European region (Delange et al., 1993). Lack of both these micronutrients affects the health and well being of large number of people. Iron deficiency anaemia is associated with impaired immune function and diminished learning capacity in children and decreased physical fitness and work capacity in adults (WHO, 1989). Iodine deficiency is the most important preventable cause of mental retardation and only a few countries in Europe are free of iodine deficiency. Iodized salt is an effective public health measure to introduce iodine in the general population but few European countries require universal iodination of salt. **Folate** is also a nutrient of special concern as a clear link has been established between folate intake of mothers and the occurrence of certain birth defects, especially spina bifida (MRC, 1991). Biochemical indications of folate insufficiency are found in a large proportion of adults with evidence of increased risk of cardiovascular disease. Green leafy vegetables are a particularly rich source of folate as well as some fruits and bread whereas in some countries cereal products are enriched and therefore are an important source. Some European countries encourage all women of child bearing age to take folate supplements as a preventive measure against spina bifida in their offspring.

Diet indicators for health monitoring in Europe

The choice of dietary indicators must be governed not only by their relevance for health but also by the practicality of obtaining reliable and comparable data in European countries. Such considerations limit for example the feasibility of selecting many nutrients mentioned above in spite of their importance for health. This includes intake data of vitamin D, folate, sodium, iron and iodine, all of which are of important health significance but are difficult to measure in the diet in a comparable way between countries. Information on vitamin D in food composition tables is often incomplete, folate values of foods are not comparable in European databanks due to different laboratory methods for determination, and use of iodized salt and iron fortified foods make intake estimates difficult for these nutrients. Finally, sodium intake is difficult to measure from food consumption data, as sodium content of otherwise similar foods varies greatly according to amount of salt used in preparation and at the table.

However, all of these nutrients can be estimated with the use of biomarkers. It should therefore be considered to include biomarkers of these selected nutrients as dietary indicators instead of dietary intake data. Other important nutrients, while still posing problems and needing harmonization and standardization cross countries, lend themselves better for comparison using intake data. These include total energy, total dietary fat, saturated fatty acids and ethanol. While total energy is not an useful indicator by it self (body composition is preferred), energy intake is needed to calculate the contribution of saturated fatty acids as well as total fat to energy intake (total fat refers to total lipids). While dietary calcium has a role in the prevention of osteoporosis, priority is given to information on physical activity (will be included as an indicator in EUPASS project). Consequently, calcium is not included in this minimum set of relevant variables.

Foods or food groups may in many instances be easier to compare between countries than nutrients. Some foods or food groups may even give more relevant health information than single nutrients. Fruits and vegetables are in this category, as more data are available concerning the importance of fruits and vegetables in the diet than for single constituents in these foods. As consensus is lacking is lacking on the beneficial effects of fruit juice on health, it was decided to exclude these beverages with the exception of freshly squeezed fruit juice. To be specific, nuts, seeds and olives are not included in the fruit group, and pulses and potatoes are not included in the vegetable group. While certain other food groups contain constituents with positive health aspects, including vegetable oils, meat & meat products, dairy products etc, priority was given to fish (including shellfish) as well as bread, both

being foods with great significance for health. Epidemiological studies have shown that populations that consume fish on the average once or twice per week have lower risk of cardiovascular disease and consumption of bread is considered as an indication of the proportion of carbohydrate in the diet.

At the EFCOSUM meeting in Athens, September 9th 2000 and Brussels, March 24th, working group 1 suggested, in order of priority, the following list of diet indicators for health monitoring in Europe. The selection is based on aspects from the report from the French Presidency as well as the arguments listed above.

1. Vegetables
2. Fruit
3. Bread
4. Fish
5. Saturated fatty acids, E%
6. Total fat, E%
7. Ethanol (g/day)

Biomarkers should be considered for the following nutrients:
8. Folate
9. Vitamin D
10. Iron
11. Iodine
12. Sodium

Energy has to be assessed in order to calculate %E from total fat and saturated fatty acids.

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Annex B-14

Single vs. repeated 24-hour recall

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24-hour recall: general issues
Food section: open-ended

Contact: face-to-face interview, telephonic interview

Common issues:

❑ Accuracy
   depending upon
      • individual's reliance of memory (Marr, 1979)
      • detail in food description (Scott Stryker et al., 1991)
❑ Precision = suitability in describing food/food component intakes distribution
   depending upon
   • sample size
   • repeatability
both influencing Within variance/ Between variance ratio

Survey tools:
❑ Survey forms
❑ Collection of ancillary information (sex, age, geographical variables, socio-economic variables, physical activity, etc.)
❑ Food description criteria
   for
      • Link with food composition data
      • Link with regulatory information
      • Link with concentration levels of variable food components
      • Food grouping

❑ Standardized data entry
❑ Well-trained field workers

Remarks. According to the classification of methods proposed by Pekkarinen (1970) dietary recall is included in "interview method" (p. 158), while according to Marr (1971) it is classified as "past intakes recalled" (p. 117). Some authors considered "dietary recall data" also data collected by administering a Food Frequency Questionnaire (FFQ) (Wilkins and Bunn, 1997).
In the present paper, 24-hour quantitative dietary recall is discussed.

Comparison of single vs. repeated 24-hour recall
Intra-individual variability represents the major problem in analysing the distribution of food and food component intakes. On the other hand, it is the inherent aspects of "usual intake" that habitually varies day by day for each

individual.

The problem is to capture daily variability to gather all consumed foods (and consequently nutrients and other food components) and contemporary to estimating the variability between subjects (intakes distribution). In fact, "one-day recall […] does not give correct data on normal food consumption of the individual, since the menu of the recall day may be atypical and have too great an effect on the results." Conversely, […] "when the sample is large enough, chance errors like this *(rarely consumed foods)* are levelled out and the method gives fairly reliable data on the food consumption of the whole group. The one-day recall is most profitable when the sample is large and the diet relatively monotonous, about the same from one day to another. If the diet is varied and weekly variations are large, a one-week recall survey is not sufficient to provide reliable data on the normal food consumption." (Pekkarinen, 1970, p. 159).

In the simplest context, sample size is currently estimated by using the confidence interval for the statistic estimating the population mean that is distributed as an $N(\hat{\imath}, \dfrac{s^2}{n})$ for sample enough large (n>30):

$$n = \left(\frac{z_a s}{d}\right)^2$$

where

$$\ddot{a} = \bar{x}\,\frac{k}{100}.$$

$$\acute{o}^2 = \mathrm{Var_{TOTAL}} = \mathrm{Var_{INTER}} + \mathrm{Var_{INTRA}} + \mathrm{Var_{OTHER\ EFFECTS}}$$

The relative weight of intra-inter-individual variability of energetic macro-nutrients was studied by Beaton et al. (1979) in an experimental design (3 interviewers, 3 days, 6 interviews per each subjects) that pointed out the irrelevance of other sources of variation like sequence, interviewers (well-trained and standardized) effect and day of the week effect (except for women). Seasonal effect was not tested, while the weight of clerical errors on food coding and data entry and changes in food composition data were considered.

Consequently, when the whole process of data generation is well controlled, the formula that can be used is

$$\acute{o}^2 = \mathrm{Var_{TOTAL}} = \mathrm{Var_{INTER}} + \mathrm{Var_{INTRA}}$$

where variance due to other components is included into the residual one (intra-individual) estimated by applying the analysis of variance (Beaton et al., 1979, p. 2554).

In such conditions, the number of day (*d*) necessary to estimate the average intake for a given individual 95% of the time derives from

$$\ddot{a}_0 = \frac{1.96\,CV_0}{\sqrt{d}}$$

The sample size (*n*) and the number of days (*d*) are inversely related. In fact, defining $\ddot{a}_I$ the deviation of the mean for a group of *n* individuals from the true, but unknown, mean for the population, the 95% confidence limits, expressed as percentage deviation, may be calculated as (Beaton et al., 1979 p. 2555)

$$\ddot{a}_{I} = 1.96 \sqrt{\frac{\left(CV_{I}\right)^{2}}{n} + \frac{\left(CV_{0}\right)^{2}}{nd}}$$

In the design of large surveys, cost considerations are to be included in deciding the procedure. Authors suggested to use

$$d = R \sqrt{\frac{C_{1}}{C_{2}}}$$

where R is the ratio of intra- to intervariation coefficients, C_{1} is the cost of recruiting a new subject into the study and C_{2} is the cost of conducting and analysing a single dietary interview for a subject included in the study.

By considering precision only, Willet calculated the number of days necessary for a vector of nutrients (total fat, cholesterol, sucrose, vitamin A). The values range from 4 (total fat) to 26 (vitamin A) for unadjusted nutrients and from 1 (total fat) to 26 (vitamin A) for energy-adjusted nutrients (Willet, 1990, p. 45).

Because of practical impossibility of conducting such a large number of interviews (Willet, 1990, p. 45), other considerations must be taken into account in choosing the number of repetitions. At this regards the paper by Morgan et al.. (1987) suggested that "the method including an initial personal interview for 24-hour recall followed by three telephone interviews for 24-hour recalls over a 1-year period and the method including four telephone interviews for 24-hour recalls for 1-year period provided food energy intake data comparable with the data collected with other methods and with less effort or cost."
Other authors studied the possibility of using the telephone to interview (adult) people about their 24-hour food consumption mainly because it allows to reduce costs (Casey et al.., 1999; Buzzard et al.., 1996).

Conclusions

The short analysis presented here allows to identify the necessity of repeating the 24-hour recall over a 1-year period to either estimate usual nutrient and energy intakes or evaluate changes along time (Buzzard et al.. 1996, Jonnalagadda et al.., 2000). The number of days must be selected according to the desirable precision and expected costs as well as the type of contact (face-to-face interview, telephonic interview). Personally, I think that for conducting nation-wide surveys the 4 interviews method is sufficient.
Additionally, stratification by specific national factors and season effect should be considered in planning studies.

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Annex B-15

Improvement of intake assessment using currently available data based on individual food consumption surveys

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The existing national food consumption surveys on an individual level, which are not designed on the same basis, cannot be used directly to monitor nutrition or food intake at a European level. Despite of that, regarding the importance of food consumption monitoring as a basis for both nutritional and safety assessment, it seems important to find urgently a way to improve the comparability of national data bases. The results of such comparisons would be used as a calibration method or as a first step, preliminary to a more accurate national estimate.

The current procedures for risk assessment in the field of nutrition and food safety are based on a stepwise approach with crude estimates at an international level and a more refined assessment at the national level. For the time being, intake data are the pivotal element to assess both the covering of nutritional requirement and the exposure to food additives and contaminants.

The aim of the present paragraph is then to provide general guidelines for the comparison of food intake data using the currently available information. Such a comparison will not be conducted in the EFCOSUM project but could be recommended to the European Commission as a future work.

The parameters influencing the comparability of dietary surveys are:
• the population participating (age group or whole population)
• the age of the survey
• the way of data collection: Food Frequency Questionnaire, recall or record
• the duration of the survey
• the food categorisation system
• the food composition table currently used

At first, considering the results of the COST action 99, it was observed that important differences exists in national food composition databases in Europe. In the general framework of the EPIC study, a pan-European food composition database will be available in 2002, nevertheless, it seems rational for the present guidelines to focus the comparison of the different surveys on a food intake level rather than at a nutrient intake level. The results from this work would be used at a latter stage for further comparison, using one or an other of the available national food composition database or specific maximum permitted levels for chemicals.

Annex D contains a description of all food consumption data bases. An analysis of this table shows that within the 20 European countries participating to the project, 45 different food consumption surveys are available. Even if the aim of the proposed exercise consists in a crude comparison, several pragmatic assumptions need to be made in order to avoid to increase the uncertainty of the results. These assumptions can permit to select the more comparable data in a transparent way:
• Only one survey from a considered country, will be take into consideration. This survey will be selected as the most representative and the most recent one.
• The current exercise will apply only to intake data from adults, representatives of the whole adult population of a country.

- In order to take into consideration the modifications of behaviour of the population and based on a pragmatic approach, the surveys conducted before 1990 will not be considered for the purpose of the present exercise.
- The surveys based on Food Frequency Questionnaires will not be compared in the same way.

Considering these parameters, 15 surveys remain available. The survey from Croatia was conducted only with children, the Norwegian and the Swiss surveys were based on FFQ and both the Belgian and the Portuguese studies were conducted before 1985 and therefore can not be taken into consideration.

Within the remaining databases, 7 were collected following a *recall* methodology, 7 are based on a *record* and 1 is based on *Dietary History (4 week recall and FFQ).* The duration of the surveys varying from 1 day to 1 month. These different methodologies can be assumed to provide similar results if the comparison is based only on the first day of data collection (the use of the first day was preferred by the group of experts to a day selected randomly or a mean of the days, because in those cases a bias could affect the comparison between the 24h recall studies and the longer surveys).

The next step to consider, to find a common basis for a comparison of food intake surveys, is the food categorisation system which was used for data collection. A recent workshop on food identification (COST action 99, Paris, December 1999) emphasized the problem of the level of food description which should be published at an international level to permit intercomparisons. Based on the study of different food classification systems (Eurocode 2, WHO GEMS regional diets, FAO food balance sheet, DAPHNE 1, TNO classification, British NFS survey and French national food consumption survey), the experts proposed a simplified classification baptised "EURO FOOD GROUP" containing a list of 33 food groups. This classification is listed in annex B (paper Ireland) and is at that time the most appropriate for the purpose of an international comparison.

After exclusion of under-reporting subjects of every national survey using the same assumption, The result of such a combination of different data would provide the mean amount of food of each category which is eaten per day and per individual in Europe. In order to improve this first result, it is possible to consider the percentage of consumers of each of the 33 broad food categories on a 24 hours basis. This parameter can be extracted from the national studies in which it is included for a more detailed level of categorisation. The combination of the mean intake with the percentage of consumers can provide, using a multiplication factor, a good estimate of the high percentiles of the distribution of the food consumption curve (90th or 95th percentile).

In practical terms, a comparison of 15 surveys from 15 different European countries (10 within the EU) could be conducted on the food consumption of 33 food categories consumed on a 24 hours basis. Such a comparison could permit to describe the differences between average food intake and portion size across Europe and using the percentage of consumers, provide a good estimate of the high consumption levels.

Conclusions - Recommendations

The proposed harmonization of existing data in Europe can be anticipated as sufficiently precise for a crude estimate of exposure assessment at a community level.

Even if this type of data would be insufficient to fully quantify the exposure, it would be used to prioritize the actions related to nutrition and food safety in different ways:

- At first, a description of the different national European diets on the same basis and at an individual level, could highlight the major differences within the different countries, in terms of occurrence of foods consumed, mean consumption per eating occasion and percentage of consumers. Such a calibration could be used to make a link between the epidemiological studies conducted in member states and to prioritize the new actions related to food and public health.
- This harmonization could also result in a more precise level of predicted exposure, than those from the FAO

Food Balances. This could be used by the European Commission to simulate the impact on national food pattern of European regulation changes i.e. (for example) for the harmonization of rules for fortification of food commodities or for setting maximum residue limits for chemicals in foods.

- Another usage of this exercise would be to monitor the food consumptions on a common basis and to describe, at least in relative values, the observed evolutions.
- At last, considering that both in the United States of America and in Australia, the surveys are conducted on the same duration (24-hour recall), a comparison of food ingestion and percentage of consumers would be extended to these countries. Such a comparison could have important consequences to compare public health effects related to food consumption in developed countries.

Annex B-16

Sample size estimation for dietary surveys
Short presentation of principles based on available literature

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The estimation of sample size: introduction

The question of the estimation of the sample size is always an essential step in the planning of a sample survey. In order to avoid a too large sample and unnecessary expenses, the estimation of the sample size is often the estimation of a minimum sample size necessary to achieve a precise goal.

There are two main steps in the determination of the sample size: the choice of the parameter or item to be estimated and the specification of the precision desired.

The choice of the items to be estimated

Most of the time, the parameter to be estimated is a mean or a proportion, for example a mean intake of a nutrient or a food or a proportion of consumers. In the major books on sampling (Hansen et al., 1953), (Cochran, 1977) these two cases are described. The choice of the parameters of interest and of the desired precision allows the calculation of the sample size. The choice of means or proportions as parameters of interest (instead of percentiles for instance) makes the calculation of the sample size easier because of the binomial or normal distribution according to the central limit theorem (Jolliffe, 1995).

Very often, several different parameters are to be estimated which leads to as many desired sample sizes as there are different parameters to be estimated. Two cases are possible:
- the estimated sample sizes for each parameter are not very different from one another and the largest one can be chosen,
- the sample sizes needed for some parameters are very different and the choice might be made to accept a lower precision for some parameters (for instance for a mean intake of a micronutrient).

Parameters of interest other than means or proportions can be chosen. In clinical trials for example, the aim is to test a difference between groups. The result of the test is the parameter of interest and the power of the test, i e one minus the probability of the type II error (not to refuse the null hypothesis although in reality it is false) gives the desired precision of the test and determines the sample size (Bailar & Mosteller, 1992).

The specification of the precision desired and the methods of estimation of the sample size

Concerning the estimation of a mean or a proportion, the determination of the sample size necessary to achieve a predetermined precision is linked to the variance of the estimator in the whole population.

In the case of the mean estimate, one can wish to get either a relative error (for instance +- 10%) or an absolute error (for instance +-1 mg for a nutrient intake) with a confidence level of 0,05.

When the sampling rate is small, which is the case for national dietary surveys, the sample size does not depend

on the size of the population.

If we choose a relative error, the sample size is linked to the coefficient of variation CV.

(1) $n = (z(\alpha)/r)^2 . (CV)^2$

where CV is the coefficient of variation for the real population, $z(\alpha)$ the value of the normal deviation (z-score) corresponding to the α probability and r the relative error accepted (for instance 10%).

If we choose an absolute error , the sample size is linked to the variance S^2.

(2) $n = (z(\alpha)/\alpha)^2 . S^2$

where S^2 is the variance for the real population, $z(\alpha)$ the value of the normal deviation (z-score) corresponding to the a probability and α the absolute error accepted (for instance 1 mg).

The case of non simple random sample
Very often, the sample is not a simple random one. For instance, there are often two sampling units: the household and the individuals within the household. In this case, we have to take into account the design effect of the plan (Kish, 1965).

The case of a stratified sample
In the case of a European dietary survey, there will necessarily be a stratification of the sample by countries. We will have to determine the optimum allocation of the sample in the various strata or countries.

When the cost of the survey per individual is the same in each country, the 'classic' allocation of the sample for a country is proportional to the product of the population size, Ni, by the standard deviation of the interest variable Si, for the same country. It is called the Neyman allocation (Neyman, 1934).

(3) $n_i = n\ N_i . S_i\ /\ \Sigma\ N_i S_i$

n_i is the size of the sample for the country i.

Other allocations can be chosen with other criteria: for instance, the minimum sample size for each country to allow detailed statistical analyses country by country.

The case of a surveillance or monitoring system
In this case, the determination of the precision desired depends on the anticipated trends of the parameters (mean intakes, proportion of consumers) and of the time period between two surveys.

Conclusion
If a new dietary survey would take place on a European level, we should get the following information to estimate the sample sizes:
- The list of parameters of interest (mean intakes of food groups, nutrients, rates of consumers of food groups),
- The expected values of these parameters,
- The coefficient of variation or the standard deviation of these variables in previous comparable studies (for instance in previous 24 hours recall if the new project is a 24 h recall),
- The anticipated (or previous) trends of these variables, the time period between two surveys,

- The definition of the sampling method and the identification of a design effect (cluster sampling, stratification),
- A choice of the method used for the optimal allocation of the sample size between countries (Neyman allocation, other).

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