Example of guidelines for study organisation and planning of the survey based on the PILOT-PANEU project

1 The content of this Appendix is used with permission of the PILOT-PANEU project. (Ambrus et al., 2013)
1. **Study organization and planning of the national dietary survey**

A well designed and prepared study plan and implementation programme are the basics of the successful dietary survey. The Study Plan shall include as a minimum:

- the objectives of the study;
- target population including the number of subjects interviewed and the principles of stratification;
- time periods to be covered;
- description of the survey management and organization of the survey process (from planning to reporting);
- description of measurements to be taken;
- methods of dietary data collection;
- time schedule of the survey overall;
- study personnel and training requirements;
- protocols and questionnaires;
- supplementary documentation (including issues related to ethics; quality controls and a risk management strategy);
- methods of data recording, processing and statistical evaluation;
- personnel, equipment and financial resource requirements;
- communication plan

The age limit indicated in the EU Menu guidance and the supporting documents may be different in various countries. All relevant country specific regulations shall be clarified and taken into account while planning the study.

The main study phases are presented in Figure 1.
**Objectives and responsibilities of institutes conducting the dietary survey**

Based on the updated EFSA guidance (EFSA, 2014) and the finding of the children’s pilot (PANCAKE) (Ocké et al., 2012) and adults pilot (PILOT-PANEU) (Ambrus et al, 2013) EFSA is collecting harmonised European-wide food consumption data. The EU Menu methodology recommends the use of food diaries for children and the 2 x 24 hr recall CAPI/CATI method for adolescents and adults using a dietary survey software tool to assist with the data entry.

The institute responsible for the organization of the country specific dietary survey (Survey Coordinator Institute, SCI) will be responsible for applying the EU Menu methodology at national level. The main purpose of the EU Menu methodology is to provide EFSA with reliable data for the assessment of consumers’ exposure to contaminants in food. Similarly, the individual food consumption data collected by a country should be suitable for the assessment of short term exposure at national level.

The main tasks of the responsible organization to be undertaken include but are not limited to:

- preparation of a preliminary study plan;
- evaluation of the availability of acceptable methodology and tools to be used;
- preparation of the detailed study plan and related documentation;
- evaluation of the requirements of human resources, technical backup for data collection, equipment needed for data collection, study sites (home/study centres), provision of vehicles/transportation, communication requirements and other miscellaneous needs;
- estimation of budget and evaluation of funding possibilities;
- compilation of an action plan for the study process.

According to the current position of IARC, the use of the GloboDiet methodology (former EPIC-Soft methodology), including the web-based platform and all its related tools, guidelines and procedures, is subject to a bilateral agreement between IARC, the sole owner of the methodology, and the potential user taking into account the proprietary rights of IARC. In brief, the country specific supporting data...
will be part of the GloboDiet methodology, while the owner of the consumption data is the institution sponsoring the survey unless further agreements govern the right of the utilisation of the data. EFSA and future potential users of the GloboDiet methodology are advised to carefully clarify the preconditions of the application of the methodology in order to avoid any hindered obstacle of the implementation of the food consumption survey.

Once the proper survey tool is selected, the study coordinator institute/study director (SCI/SD) shall prepare a detailed Study Plan (SP) taking into account the principles described and supporting documents provided in this manual, the experience gained in previous national surveys and the country-specific features which may affect the successful implementation of the programme.

As part of the preparation of the SP, the first step is the decision on the age groups (e.g. infants, toddlers, children, adolescents, adults and elderly) and gender of individuals to be included in the programme, their social and economical background, and regional differences. Naturally each main group can be subdivided if more detailed information on food consumption is desired. The number of aspects of distinguishing individuals will exponentially increase the number of strata, and consequently the total number of individuals to be interviewed in the survey. Furthermore, it should always be kept in mind that the main purpose of the EU-Menu is to provide EFSA with reliable data for the assessment of consumers’ exposure to contaminants in food. Similarly, the individual food consumption data collected by a country should be suitable for the assessment of short term exposure at national level which would ideally require valid data from a minimum of 130 individuals from each stratum. The total number of individuals targeted will significantly affect the total cost of the survey. Therefore, the careful balancing between the level of details in consumption data desired (the number of strata) versus the minimum requirements for obtaining information which fit for the purpose and the total cost of the study is very critical, and is one of the most difficult decision to be made as part of preparing the SP for the survey.

Based on the Study Plan the requirements of human resources, technical backup (computer program for data collection, vehicles, computers, communication and miscellaneous equipment, etc.), site facilities shall be accounted for the estimation of the budget.

Once the budget has been approved, or simultaneously with the approval process, the action plan for the preparation and implementation of the study shall be prepared. These are the main components of the action plan (Conti et al., 2008) but not limited to the followings.

- Getting the permission of Ethics Committee.
- Signing agreement of cooperation of external partners taking part in the elaboration and or implementation of representative random sampling or providing the necessary information for that.
- Getting agreement for the use of a data collection tool, either national or international (e.g. with IARC for use of the GloboDiet tool for recording food consumption data, if it is planned to be used).
- Adaption of the data collection tool for national use:
  - Translation of user manual for the data collection tool, thesaurus, and part of the Software;
  - Preparation of country specific files;
  - Training on the use of the program.
- Translation/adaptation/preparation of working/supporting documents (protocols, questionnaires, documents for administration of the survey).
- Arrangements for secure and confidential management and anonymous handling of personal data and survey results, which should comply with the country’s Data Protection Act or equivalent.
- Selection of interviewers and supporting field staff.

The PANCAKE pilot study pointed out also that the recruitment of large number of experienced interviewers for the dietary interviews throughout the country may be a challenge, especially when no official network of dieticians is available in the country. Furthermore, the PANCAKE project
highlighted that the coordinator of a dietary survey needs to be experienced in similar work and have very good organisational and communication skills, because co-ordination, motivation and monitoring the fieldwork is very demanding. It is important to purchase the necessary technical equipment (computers and software) for the survey interviewer because all such technical equipment, at least in the case of a large-scale survey, should be under the control of the survey organisation. Interviewers should not be allowed to use their own computers to perform any survey-related tasks. In addition, based on the PANCAKE experience, another factor to be evaluated at an early stage is whether public transport can be used or whether cars need to be organised for the survey team (e.g. because of long distances between one study area and another (Ocké et al., 2012)).

**Ethical and legal aspects of a national dietary survey**

Each study on human beings has to be approved by local or national ethics committee. The following documents should be typically submitted for getting approval:

- study plan,
- description of the study registry of personal information,
- invitation letter, consent form of invited participants including parents or guardians for children and adolescents;
- age specific information leaflet to the participants, questionnaires,
- methods for anthropometric measurements and other protocols (Annex 2),
- statistical methods used for the evaluation of the results,
- method of compensation of participants,
- description of the main and relevant activities of the lead/coordinator institute,
- professional curriculum vitae of the study director and key study personnel.

In some countries the ethics committees can demand detailed information concerning studies that will be carried out among children. For instance, parents or a teacher must be allowed to be present when the children are interviewed.

It is advisable to clarify the specific requirements of relevant Committees in advance, and to take into account the relatively long time (3-10 months in case of the PILOT-PANEU study) for obtaining the permission for conducting the study.

After getting the Ethics Committee’s approval, the study coordinator institute can request information required to design appropriate sampling plans from the available data source (Figure 2). The sample request defines the information to be collected for each subject such as name (surname, first name), birth date and complete address. Depending on the content of the national population registry, communal code and native language can be included in the sample information.

It is recommended that the frame of cooperation between the provider of the data collection tool and study director including the key staff of the survey should be agreed and specified in the agreement of using the tool and connected methodology.
2. Adaptation of the data collection tool and connected methodology

Data collection tools

The EU Menu methodology recommends the use of food diaries for children with a completion CAPI/CATI interview and the 2 x 24 hr recall with a CAPI/CATI methodology for adolescents and adults applying a software tool that complies with the requirements specified by EFSA.

Firstly, a suitable survey tool should be selected and the survey coordinator institute/survey director (SCI/SD) should prepare a detailed survey plan (SP) taking into account the principles described for the use of the data collection tool, and supporting documents provided in this manual. The experience gained in previous national surveys and the country-specific features which may affect the successful implementation of the data collection tool should also be taken into account in the planning.

The adaptation of the dietary software used for data collection may include, among others, the preparation of:

- files including customised country-specific food list and recipe data;
- country-specific customization of dietary interview tool;
- translation of relevant documents to national language(s);
- training on the use of data collection tools.

In order to prepare the dietary software for data collection in the EU Menu, country specific databases need to be prepared at national level before the survey starts. It is recommended that the national food list with standard recipes and standard portion sizes are used for data collection and included in the software before the survey begins. Each country can use relevant national data obtained from previous dietary surveys, national food composition databases and country-specific market data to collect the variety of food items and descriptors for the food list. It is important to update the available food list according to the actual market supply. The food names and recipes in the food list should be listed in national languages and in English names. The foods should be described using the list of FoodEx2 descriptors provided by EFSA. Information on the brand and packaging of the foods may be collected during the interviews. A food portion list based on the FoodEx2 classification system has been matched with an indicative maximum portion size for each basic FoodEx2 code. This list should be customised to national common portion sizes to be used as a quality control measure when evaluating reliable portions either during the data collection phase or during the data cleaning phase.
During data input, each item should be automatically searched, described, quantified and checked using pre-entered common rules. The standardised level of description of the foods using the FoodEx2 descriptors should be incorporated in the data collection software. In addition, the software should guide and control the interviewers with real time quality checks following an interview protocol (EFSA 2014, Appendix 5.3.1). For quantification of consumed food and drinks, household measuring devices, food shapes and portion size pictures should be evaluated and updated if necessary. When foods are quantified during the interview, the software must be able to automatically convert food quantities “as reported” to “as finally consumed” (e.g. cooked and/or without inedible part), using pre-defined algorithms and standard food-specific coefficients (e.g. raw-to-cooked, density or edible part coefficients) which can easily be updated. Therefore it is recommended that the software includes yield and retention factors for the recipe calculations. In the final data the amounts consumed of composite dishes needs to be reported “as raw” and “as consumed”. Therefore, if not incorporated in the software, these transformations need to be produced after the interview, before the data submission.

Systematic quality controls have to be performed throughout the data input procedure. The system should check systematically for all information reported by the subject and entered into the program so that possible errors and suspicious answers, missing information and outlier values can be detected and clarified with the subject during or after the survey. It must be possible to re-run accuracy and consistency checks after merging into the European database.

Maintenance procedures for the different databases must be ensured. Like any open-ended method, the databases 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 standardisation of the different databases and to facilitate updating, it is important that only one version is available in each country and that any modifications to the country-specific files are centralised at country level and at European level.

The program must be able to provide output files with valid population food, energy and, if possible, macronutrients intake data in electronic format. These output files must be functional to perform statistical analysis. The software must allow storage, output and export of the different databases in a standardised way. The software should also allow the data to be checked for accuracy and consistency and to be compressed and encrypted for transfer via the internet. The data transfer and management system must ensure the security and confidentiality of the data.

It is recommended that for extraordinary cases, i.e. unexpected technical difficulties, there is a back-up option of a paper-based questionnaire that the interviewer always carries with them. The data collected during the interview should always be backed up onto a central server in case anything unexpected should happen with the lap-tops for the interviews. Technical support should be available for the interviewers of the survey and for the maintenance of the central server that holds the information gathered during the survey. Paper based questionnaires and the list of survey participants should be kept in a separate place with limited access (i.e. a locked cabinet) to avoid any infringement with regards to the personal data of the survey participants.

Preparation of portion size estimation aids

The pilot PANCAKE and PILOT-PANEU projects took the EFSA 2009 guideline for portion size estimation into account and developed more specific guidelines and tools for creating the PSMA’s to be applied in the pan-European dietary survey setting.

Portion size measurement aids that match the guidelines described in the portion size estimation protocol of the EU Menu survey should be used. In case such PSMA’s are not available at country level, the pilot PANCAKE project developed a picture book prototype and an online tool to help develop country specific picture books.
The picture book should include the common foods, country specific foods as well as picture series of country specific glasses, cups and bowls, in total around 45 picture series. For foods not included in the picture book, it is recommended that other quantification tools are made available, i.e. country specific household measures, standard units or abstract shapes. These tools need to be country and age specific and have to be developed based on knowledge about foods on the national market, food preferences and using weighted records identifying ranges of portion sizes for different foods and recipes.

3. Preparation for the field work

The main steps of preparation for the food consumption survey comprises of:

- selection of sampling regions including rural and urban areas representing different parts of the country concerning economical and social conditions according to the level of stratification specified in the SP;
- selection and evaluation of facilities to be used for the interviews according to local needs and the timetable of the field work;
- assessment of the number of interviews which can be conducted on one day at a given site.

The number of interviews completed in one day depends on the place of the interview and the availability of the selected subjects. Further on, it depends on how well trained and experienced the interviewer is, how detailed the interviewee’s knowledge about the foods consumed is, etc. The schedule of the interviews and the number of interviewing teams shall be decided accordingly.

The process is illustrated in chronological order in Figure 2.

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**Selection of study regions for obtaining representative sample**

The individuals selected for the interviews are called sample, which should be representative of the populations of the country as well as possible. The living conditions and the consequent food consumption may substantially vary among particular parts of a country due to differences in economical developments, sources of major income (agriculture, industrial production or service), nationality and religion of the majority of the inhabitants in the regions. Such differences should be
taken into account as far as possible in preparing the SP and the regions where the study will be conducted should be selected accordingly to assure representativeness of the sample.

The number of selected regions depends on their diversity within the country and it can be best decided based on national statistical data in cooperation with the Central Statistical Office.

**Sampling preparations**

The sampling plan depends on the number of strata distinguished within the survey and the number of individuals to be interviewed from one stratum. The sampling plan can be based on national population registry, census data or other registry of citizens. The most appropriate data source depends on the systems in individual countries. Sometimes information from more than one source is needed. The data provider(s) should be selected by the SC.

The sampling request to be submitted contains the following information: the number of persons to be taken into the sample by sex and age group and by other stratification variables. The approval obtained from the Ethic Committee should also be attached where needed.

In many countries the national protection of individuality requires that the person cannot be identified from the study material. Thus it is a normal procedure to keep the personal information (name, address, social security id etc.) separate from the study information. The usual solution to this is to handle separately the personal information as confidential material, and the individuals are identified by unique codes which would only be used in all record sheets and entering food consumption data in the computer during the interviews.

The methods of selection of representative samples from different age groups may be different.

**Selection of interview sites**

Conducting the face-to-face interviews (field work) may be carried out by visiting participants in their homes or in the schools of school-aged children, or inviting the subjects to a survey office or examination centre. Depending on the local conditions the two methods may be applied in combination. In some countries participants may be unwilling to allow survey personnel into their home.

**Scenario 1.** If the interviewers visit the homes of the participants, no interview rooms will be rented. The travelling of interviewers is organized with estimated reserve time. Data management and data cleaning is performed at the SCI.

The benefits of home visits are:

- no travel costs for participants;
- easy access and relaxed environment for participant;
- availability of information on consumed foods (respondents will be able to check information on packaging, recipes, etc.).

The disadvantages include:

- less effective implementation of survey due to the additional travel requirements of the interviewers;
- special arrangements for transport of equipment;
- problems with privacy and potential distractions if other family members are present;
- potential risk of safety of the interviewers.

**Scenario 2.** Study office shall be setup for the study period temporarily for the visits and interviews of the participants. The study office should provide a pleasant disturbance free environment, comfortable sitting arrangements for the 2 interviewers and the interviewed person, and should be situated at an easily accessible and well-known location near the participants’ residence. In order to increase the response rate, the study office shall be open during the day and after working hours, and the duration of the
study should be sufficiently long for giving certain flexibility for timing of the interviews depending on the availability of the participants.

The study coordinator shall carefully evaluate and optimise the maximum distance that an invited participant should travel and/or the travel time requirement depending on the local conditions. The appointments for the interviews shall be decided taking into account the working hours, study or other regular commitments of the participants. Travel expenses (if not reimbursed), inconvenient appointment time and extended travel time would increase the rate of refusal.

The study office can be rented from the local health centre or from other organizations in the city centre. Sufficient number of rooms must be reserved to provide a separate room for each interviewer team, ensure privacy of the interview, and a separate waiting room with entertaining reading materials which could include guidance documents on good kitchen and household practice to assure safe handling and storing food. However, information materials on healthy or slimming diet should be avoided as they might influence the information provided on food consumed on previous day.

Selection and training of study personnel and interviewers

The study personnel should preferably consist of at least one nutritionist, dietician or related health professional assisted by a second person who should also be properly trained before the study begins. The assistant may be a graduate or final year student in nutritional science, social science, food chemistry, food technology or food safety. The interviewers can be selected depending on the particular conditions in the country and the age and composition of the targeted population included in the survey.

The interviewer should be precise and accurate with positive empathic attitude during the interview, and should speak the language of the interviewed person.

The interviewers and study personnel involved in data management and evaluation of the results should be trained in the contents, rules and techniques of the data collection and application of the software and methodology. The training of the study personnel shall be organised by the SCI.

It is recommended to have training in two phases. The first session should be centralised for training the trainers in order to harmonise data collection. The interviewers conducting the survey should take part in the second phase provided with the customised country-specific version of the dietary software and questionnaires, protocols and training materials in local language(s).

The typical duration of the training is three to five days, but it may be different depending on the background and experience of the interviewers.

The training shall be provided by nutritionists or dieticians experienced in dietary surveys, familiar with the food consumed by the target population and fully familiar with and proficient in the use of EPIC-Soft or the alternative computer program. The proper use of EPIC-Soft software requires sufficient practice which has to be incorporated to the training programme. It is recommended that before training of the local study personnel, the trainers should take part in specialised training, provided by IARC or experienced professionals, on the use of software and interview techniques.

The training programme should include but not be limited to:

- presentation of the objectives of the study and the methods to be applied;
- explanation of the importance of the study and the utilisation of the data collected;
- methods for contacting, visiting or receiving the interviewee;
- communication and personal behaviour for establishing open and relaxed atmosphere for the interview, and avoiding conflict;
- familiarization with and use of the protocols and questionnaires, and administration of the interviews with interview record forms;
- composition of typical foods consumed by the target population;
- logistics of food database, food descriptors and presentation of quantification tools;
• assessment of the amount (mass) of consumed food based on the replies obtained by applying household measurements and or using the portions shown in the picture book;
• use (calibration) of equipment applied for anthropometric measurements;
• use of EPIC-Soft including interview recording, data management (export-import, back-up, restore);
• practical exercises including the whole interview process with conducting face-to-face and telephone interviews under various circumstances including subjects of different personal attitude, foods of different composition, entering new recipes, and performing anthropometric measurements;
• practical examples for recording information obtained to facilitate preferable complete harmonization between interviewers in recording relevant food items;
• practicing procedures in role playing exercises in the presence of instructor and then with volunteer interviewees covering the whole interview;
• quality control of review results.

Additional topics may be included taking into account the professional background and experience of the study personnel.

**Provision of suitable equipment and documentation**

The interviewer team shall be provided with:

• vehicles or suitable utensils for carrying the equipment needed for the anthropometric measurements and conducting the interview;
• official authorization issued by the SCI for performing the interview;
• mobile phones containing the telephone numbers of interviewees and study coordinator and other contact points deemed to be necessary under given conditions;
• portable computers equipped with mobile Internet connection, supplied with the consumption data recording software containing country specific data files, picture book, and files of protocols, and questionnaires. Each computer used for the survey shall have a unique identification code which is required to manage the interview data. The proper functioning of the computer shall be checked every morning. It is advisable to provide the local offices with spare computer(s) for assuring that the interviews can be conducted according to the agreed schedule;
• picture book including country specific food items with typical densities or volume weights. Food specific densities or volume weights will also be needed for the quantification of all additional food items for which the portion size consumed will be determined with selected picture series being in the picture book;
• suitable equipment for performing anthropometric measurements;
• Record forms

**4. References**

