EXTERNAL SCIENTIFIC REPORT

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Slovenian national food consumption survey on children (infants and toddlers)

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Abstract

The Slovenian national food consumption survey on children was part of the third Slovenian national dietary survey - SI.Menu 2017/18. A dietary study was especially needed for infants and toddlers, since no national food consumption data for this population group was yet available in Slovenia. The methodology of the survey followed the EFSA EU Menu Guidance and specifications in the contract. Individuals were randomly selected from the Slovenian Central Register of Population following a two-stage stratified sampling procedure. Dietary survey sample was at population level representative of gender and age classes (three months to three years old). The participation rate to the survey was 67%. A fully completed data was collected for 637 participants of whom 294 were infants and 343 were toddlers. Data collection period was divided into four quarters (3-monthly samples) and equal distribution of all week and weekend days was employed. Information on food consumption was collected with two non-consecutive 24-hour dietary recalls (using the OPEN dietary software) by interviewers. Recall was complemented with a short food propensity questionnaire. In addition, information concerning breastfeeding, feeding practices, milk formulas, food allergies, and food supplements was collected. Food items consumed were coded according to the FoodEx2 classification. Body mass and height/length were measured. Collected data for this sensitive population group will be very valuable for national risk assessments, nutritional studies and for the development and evaluation of nutrition and health policies.

Key words: Slovenia, food consumption survey, dietary intake, infants, toddlers, children, EU Menu

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Summary

The Slovenian Dietary survey "SI.Menu 2017/18", is a third national dietary survey at individual level and for the first time provide detailed information on the food consumption, nutrient intakes and nutritional status of Slovenian children population from three months to three years old. The project started in December 2014 and ended in June 2019, the fieldwork was conducted from March 2017 to April 2018. At the end of the survey a fully completed data was collected for 637 participants of whom 294 were infants and 343 were toddlers.

Individuals were randomly selected from the Slovenian Central Register of Population following a two-stage stratified sampling procedure. A total sample consists of 1,006 selected individuals, of which 946 were found eligible. With many promotion activities included in this survey, the participation rate for the survey was 67%.

Dietary assessment was performed by open-ended food diary with written instructions for two non-consecutive one-day (24h) records. The food diary was completed one to two days after the instructions at the first home visit and on the next day, the parent/caretaker participated on computer-assisted telephone interview (CATI) with the trained interviewer. At the second home visit, usually the next day after the second recording, trained interviewer used face-to-face interview (using computer-assisted personal interviewing – CAPI) to complete data entry. For breastfeeding, the frequency was collected. Responsible persons (e.g. personnel in kindergartens) were asked by parents/caretakers to give precise information on food consumed and on the place and time of the meal for children in the day care or kindergartens. Additional data on socio-demographic characteristics, birth data, health status and food allergies, breastfeeding and feeding practices, exposure to sunlight and smoking were collected within a general questionnaire. Information on consumption of food supplements was collected both in the dietary record and in the food propensity questionnaire (FPQ). Anthropometric information (body weight and body (standing) height or recumbent length) were collected for all selected persons using actual measurements performed by the trained interviewers following a standardized protocols.

Open Platform for Clinical Nutrition (http://opkp.si) was applied in a survey as existing national dietary software and was upgraded for the aims of the survey to support 24h recall interviews as well as food diaries. It is an open-ended app and allows food and beverages consumed during the survey days to be entered (multi-pass method). Consumed amounts of foods were estimated using a national picture book, complemented with household measures and portions indicated in standard recipes. The picture book contains six different portion sizes for 46 different food products or simple recipes. Consumption data was complemented with a FPQ to collect the usual frequency of consumption of specific foods (and food supplements) in the last 12 months. Additional non-dietary data was collected with a face-to-face questionnaire using a computer-assisted personal interview.

For the fieldwork, a subcontract with company, specialized for interviewing, was signed. Only those with nutrition background or with strong background in interviewing techniques were selected as interviewers. Several quality control measures were taken during different phases of the project to guaranty a high quality of collected data. Systematic quality controls were performed throughout the data input procedure.

The main results of the survey will be presented in a statistical publication available on the website (http://www.nijz.si/). The food consumption data will be under certain conditions available also for other users. As the survey is also included in the EU Menu project, the food consumption data coded according to the FoodEx2 classification will be included and available in the EFSA Comprehensive European Food Consumption Database.

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

A long-term objective of EFSA is the acquisition of a harmonised pan-European Food Consumption database within the framework of the EU Menu process "What's on the Menu in Europe?" (EU Menu).

In October 2009, the EFSA Expert Group on Food Consumption Data (EGFCD) endorsed the Guidance of EFSA on "General principles for the collection of national food consumption data in the view of a pan-European dietary survey"[1]. The main objective of this Guidance was to recommend general principles for the collection of dietary information that can be used to estimate dietary exposure to food borne hazards and nutrients considered by EFSA's Scientific Panels and Units. The methodology used in the national food consumption survey is expected to follow the general principles described in the 2009 EFSA Guidance. The most important requirements are reported here below. For some of the requirements, the present call presents differences with respect to the above-mentioned Guideline and the requirements of the tender specifications must be followed. The main changes are mainly due to the results of the pilot and methodological projects supported by EFSA in the last years. EFSA is planning to publish on EFSA's web-site an updated version of the EFSA Guidance on the EU Menu methodology within 2014[2]. This will contain additional information, but the basic methodology requirements described in the present call will not change. The methodology described in the Guidance of EFSA and complemented in the present call for tender based on the results of the recent pilot and methodological projects is defined here as the EFSA EU Menu methodology.

- The piloting activities have included the following projects: In December 2009, EFSA started the Article 36 project (CFP/EFSA/DATEX/2009/02) "Pilot study for the Assessment of Nutrient intake and food Consumption Among Kids in Europe" (PANCAKE), to develop and test tools and procedures for the collection of individual food consumption data for infants, toddlers and other children up to 10 years of age. The final report, protocols and questionnaires produced by this project were published on the EFSA website in September 2012 (Ocke et al, 2012).
- In December 2011, EFSA started the Article 36 project (CFP/EFSA/DATEX/2010/02) "Pilot study in the view of a Pan-European dietary survey – Adolescents, adults and elderly" (PILOT-PANEU), to develop and test similar tools and protocols for the different adult population groups. The report, protocols and questionnaires produced by this project were published on the EFSA website in November 2013 (Ambrus et al, 2013).
- Further, EFSA has collaborated with the International Agency for Research on Cancer (IARC) through a negotiated procedure contract (NP/EFSA/DATEX/2010/01) in order to develop and adapt the EPIC-SOFT dietary software according to the needs of EFSA and to ensure that this software can be used by EU Member States for their dietary surveys within the context of the EU Menu process. The final report of this project called EMP-PANEU was published on the EFSA website in June 2013 (IARC, 2013).
- In August 2012, to get a broader view of the dietary tools available for dietary surveys, EFSA started the procurement project "Dietary Monitoring Tools for Risk Assessment" (Mandate number M-2012-0027). This project carried out a review of dietary assessment tools mainly available in Europe, evaluated 11 European tools and tested in collaboration with EFSA six tools in a standardised ring-

[1] European Food Safety Authority; General principles for the collection of national food consumption data in the view of a pan-European dietary survey. EFSA Journal 2009; 7(12):1435. [51 pp.]. doi:10.2903/j.efsa.2009.1435. Available online: http://www.efsa.europa.eu/en/efsajournal/pub/1435.htm

[2] The guidance of EFSA has been updated in December 2014 and is available as Guidance on the EU Menu Methodology at http://www.efsa.europa.eu/en/efsajournal/pub/3944

trial setting and provided a critical analysis of data accumulated through this project. The final report of this project will be made available on the EFSA website within 2014[3].

- Since 2011, EFSA has supported 14 dietary surveys in 10 Member States, as part of the EU MENU process. The first three supports to national dietary surveys were provided by means of the calls for tender CFT/DCM/2011/02, CFT/DCM/2012/01 and CFT/DCM/2013/02. So far both children and adults are covered by contracts with eight Member States, namely France, Estonia, Spain, Belgium, Latvia, The Netherlands, Cyprus and Portugal; only adults are covered by a contract with Greece, and only children are covered by a contract with Romania.

The aim of this procurement procedure is to award direct service contracts to organizations from EU Member States, and from Norway and Iceland which have a governmental mandate to carry out a dietary survey at national level in the period from 2014 to 2019 and a national dietary survey has not been carried out within the country in the last five years for the planned target group and Under the resulting contracts the contractor(s) should either adapt or develop the methodology to be used in these surveys according to the EFSA EU Menu methodology. The dietary data collected through the contracts should be available for EFSA's scientific activities without restrictions on its use.

The objectives of the contract resulting from the present procurement procedure are as follows:

- objective 1: to either adapt or develop the methodology to be used in the national food consumption survey according to the EFSA EU Menu methodology and to prepare and transfer to EFSA the national protocols and related documents, pilot and carry out the data collection.
- objective 2: to prepare and transfer to EFSA the food consumption data and related information collected during the survey according to the format required by EFSA.

This contract was awarded by EFSA to: National Institute of Public Health of the Republic of Slovenia as Consortium leader and coordinator of the Project.

Contractor: National Institute of Public Health (NIJZ) Ljubljana, Slovenia (contractor and consortium leader), Jožef Stefan Institute (IJS) Ljubljana, Slovenia (partner 1), Nutrition Institute (NUTRIS) Ljubljana, Slovenia (partner 2), University of Ljubljana, Biotechnical Faculty (UL BF) Ljubljana, Slovenia (partner 3), University Medical Centre Ljubljana, University Children' s Hospital (UKC PeK) Ljubljana, Slovenia (partner 4).

Contract title: Service contract "Support to National Dietary Surveys in Compliance with the EU Menu methodology – fourth support" Lot 1 – "The children's survey"

Contract number: OC/EFSA/DATA/2014/02-LOT1-CT02

2. Description of the protocol of the survey

The SI.Menu 2017/18 children survey focused on infants (3 – 12 months of age) and young children (1 – 3 years of age). The project had its Project policy, Scientific and Steering Committee and was divided into five Work Packages, with each responsible for fulfilling its specific objectives.

The various phases of SI.Menu 2017/18 children survey are shown in Table 1. The survey followed the EFSA Guidance on EU Menu methodology (EFSA, 2014) and specifications of the call for tender "Support to National Dietary Surveys in Compliance with the EU Menu methodology- fourth support". The SI.Menu 2017/18 on infants and young children was a cross-sectional study.

[3] The final report of the Dietary Monitoring Tools for Risk Assessment project has been published and is available at: https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/sp.efsa.2014.EN-607

Table 1: Time scheme of SI.Menu 2017/18, children survey

Phase	2014	2015	2016	2017	2018	2019
Preparation of the methodology framework, consortium meetings						
Adaptation and/or development of the survey methodology, national protocols (WP1 & WP2)						
Adaptation and development of dietary software and supporting tools according to the EFSA EU Menu methodology (WP2)						
The pilot survey (WP3) Selecting and training of interviewers (WP3)						
Activities to increase response rate (WP4) Data collection, supported by dietary web-based application (WP4)						
Preparation of the database for EFSA and database of other collected information (WP5)						
Final report and databases in EFSA reporting format (WP5)						

2.1. Study population and exclusion criteria

The study population of the SI.Menu 2017/18 on children was defined as all children aged from three months to three years old with residence in Slovenia at the time of the survey. The sample was stratified according to age and both genders in two groups - infants (from 3 to 11 month) and young children (toddlers) (from 1 to 2 years old). Both groups were stratified also according to the size and type of settlements (6 classes) and according to the statistical region (12 regions).

Selected persons were systematically excluded from further implementation of the interviews if they were found to be ineligible:

a) institutionalized population (hospitalized or live in different types of institutions),

b) individuals residing abroad and

c) infants and toddlers with known metabolic disorders, other possible irregularities for insufficient weight gain, e.g. heart defect, meningo-myelocele, known chromosome anomalies, inborn and acquired illnesses, infections.

In the case of acute sickness of a child (or parents/caretakers) during the survey, the interview was adjusted or moved to another date.

2.2. Sampling frame

National Statistical Office selected the individuals by using Central Register of Population Slovenia (CRP), which serves as a sampling frame for majority of population-based surveys in Slovenia.

The register contains several variables which are needed for the sample preparation such as Personal identification number (PIN), name, gender, age, year of birth, address, municipality, statistical region, size of settlement, degree of urbanization; weight of selection probability is defined during the selection procedure.

The sample selection was spread over 52 weeks and performed in seasonal waves (four quarters means 3-mounth samples seasons) in order to use the most actual version of the CRP to ensure the compatibility of age groups with the target population and avoid subjects who had died or moved

between the date of selection and the date of interview. This was especially important for infants in order to capture the necessary age groups in every relevant season.

2.3. Sampling method and design

The subjects of the SI.Menu 2017/18 children survey were selected according to a two-stage, stratified sampling procedure. The sample size consisted of 1,006 selected individuals aged from three months to three years old, stratified according to the size and type of settlements (6 classes), according to the statistical region (12 regions) and age groups (Figure 1).

In general, Slovenia uses the same sampling frame for all probability samples and similar sample designs. Sample frame is based on Central Register of Population and divided into strata as described above, and further on divided in around 10.000 primary sampling units (PSU) with 200 inhabitants on average (but varying from 30 inhabitants to around 300 inhabitants per PSU). Within two stage stratified sample design, the PSUs are selected with probability proportional to size, and within PSU the fixed number of persons is selected, what enables the equal probability of sampling for all units (at this point, neglecting different probabilities of selection due to age groups what was calculated and balanced later on).

At the first stage primary sampling units (PSU) were selected with the probability proportional to size (PPS), where size of PSU is defined as weighted average of number of persons in target age groups. At the second stage, certain number of persons in the target population was selected according to interclass correlation coefficients gathered in other population surveys like Slovenian Household Budget Survey, where also consumed quantities of food and drinks are measured. About 8-10 persons per PSU were selected. Given that subjects were selected with different selection probabilities due to different age groups, weights were defined at this stage of sample selection.

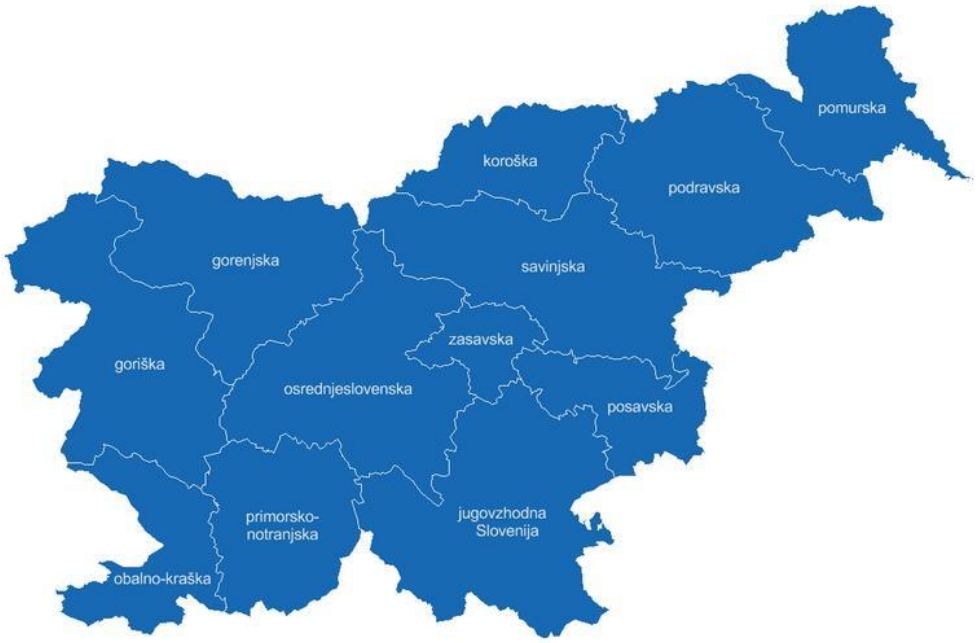

Figure 1: Statistical regions in Slovenia, SI.Menu 2017/18

2.4. Sample size

The sample size based on minimum sample sizes for age groups proposed by EFSA and was enlarged taken into account expected realistic participation rate (min 60%).

In total, 1006 children were recruited:

- Infants (from 3 months to below 12 months old): 470 individuals;
- Toddlers (from one year old to strictly below 3 years old): 536 individuals.

2.5. Strategy to achieve an adequate response rate and the initial sampling size

As the participation to the survey was voluntary, it was expected that some of the selected individuals would not participate, either because we would not be able to contact them (ineligible and non-contacted units), they would refuse to participate or fail to respond due to other reasons. All interviewers had to achieve at least five personal contacts with the selected subjects. If none of these five contacts were successful, the subject was recognised as non-respondent. Substitutions were not applied. The interviewer met each respondent at least once to provide information on the complete dietary survey, supporting questionnaires and perform the anthropometric measures.

In case of low response rate at a specific PSU, more experienced interviewer was sent to double check the situation. Besides, in case of soft refusals, additional contacts were made by another interviewer.

Prior to the fieldwork period, an invitation/advanced letter, with detailed information on the study characteristics and the motivational text, was sent by post to all selected individuals. There was additional information at the back of the invitation/advanced letter such as legal background, information on data confidentiality, overview of data from previous or likewise surveys to show how the collected data will be used. Telephone number and e-mail address were available for additional questions.

Within two weeks after the reception of the invitation letter the parent/caretaker of the selected person was contacted by the interviewer. If the participant was not at home at the time of the visit, the interviewer left the notice with the date of the next visit, the interviewer's telephone number, the telephone number of the interview agency (with available working hours) and the e-mail address for additional questions. At least five contacts had to be made for each selected individual before they were classified as non-contactable. This first contact was intended to set a date for the interview at the participant's home at a convenient time.

After the first successful personal visit at the participants' homes, all participants got a small incentive to be motivated to finish the survey (glass water bottle, bib, headphones, umbrella, ice bags). The value of the incentives was of maximum five euro. Incentives were very well accepted; at the time of this survey, the majority of parents/caretakers chose glass water bottle or bib.

A national press release announced the start of the national food consumption survey in 2017 to gain publicity in the general Slovenian population. All consortium partners assisted in these activities. They were also asked to raise awareness of the survey on the local level by newspaper articles, digital newsletters, advertisement on the municipality website or social media, etc. All information related to the survey were also available on the NIJZ website.

The response burden was decreased as much as possible by dividing the time spent with the selected person equally over the two face-to-face contacts and by shortening some parts of the questionnaires based on the pilot survey.

At the end of the survey a fully completed data was collected for 637 participants of whom 294 were infants and 343 were toddlers. Five participants, two infants males, two infants females and one toddler male had only one day 24h-recall. The final status and response rates of respondents according to age and gender in SI.Menu 2017/18 children survey is presented in Table 2.

Table 2: Number of subjects in the SI.Menu 2017/18, children survey

	Infants		Toddlers		All children		Total
	Girls	Boys	Girls	Boys	Girls	Boys	
Number Of Units In The Sample	225	245	267	269	492	514	1006
Number Of Contacts	225	245	267	269	492	514	1006
Eligible Units	214	231	251	250	465	481	946
Number of fully completed (questionnaire + Diary/ 24h recall)	136	158	181	162	317	320	637
Response Rate	63.5%	68.4%	72.1%	64.8%	68.2%	66.5%	67.3%

The response rates according to quarters of the survey (see Table 3) clearly showed that the lowest response was during the summer time, when most families leave for a holiday.

Table 3: Response rates in in the SI.Menu 2017/18, children survey, according to the quarters of the survey

	1st quarter (spring)	2nd quarter (summer)	3rd quarter (autumn)	4th quarter (winter)
Infants	73%	60%	67%	74%
Toddlers	68%	59%	60%	76%

2.6. Legal and ethical aspects

The National Medical Ethics Committee of the Republic of Slovenia accepted the survey protocol in July 2016 (KME 0120-337/2016). The survey collects sensitive personal data, therefore survey was included in the Annual Programme of Statistical Surveys for 2016 (Nr. R3.2.05.01.12), available in Slovenian at: http://www.pisrs.si/Pis.web/pregledPredpisa?id=DRUG4163, which serves as a legal framework.

Written informed consent was obtained from the parent(s)/guardian(s) of selected individuals at the first home visit.

3. Dietary survey tools

3.1. Food propensity questionnaire

As recommended by EFSA and by the PANCAKE project a FPQ was used. The FPQ consisted of eight food groups (cereals and cereal products, milk and milk products, fruit and nuts, vegetables and potatoes, meat and meat products / fish and protein substitutes, fats and fatty foods, sugar / sweeteners / sweet foods, beverages) and food supplements. In each food group, the frequency of consuming the most typical representatives of this group and of food items that are rarely consumed by infants/toddlers was asked. Some food items were identical with SI.Menu 2017/18 on adolescents and adults to achieve comparability with the survey carried out in 2007/2008 (Gabrijelčič et al, 2009).

In the case of food supplements, we introduced some common ingredients (vitamins, minerals, omega 3 and omega 6 fatty acids, plant extracts, probiotics / prebiotics, propolis, algae), but the question was also open. In total, 67 food items were included in FPQ. The frequency response options for the food list were never, 1-3 times per month or less, once per week, 2-3 times per week, 4-6 times per week, 1-2 times per day or more.

The FPQ was included in the general questionnaire and parents/caretakers used special cards with possible answers that it was easier for them to answer.

3.2. Dietary record

For children an open-ended paper-based food diary with written instructions for two non-consecutive one-day (24h) record has been structured by usual food consumption occasions – before breakfast, breakfast, meal before lunch, lunch, after lunch meal, dinner, after dinner meal and additional occasions. The design of the food diary followed the recommendations of the EFSA Guidance and of the PANCAKE project. The information on the place and time of the meal are included.

During the first home visit, trained interviewer explained to parent/caretaker how to record where, what and how much their child had consumed during the recorded day. The food diary had to be completed one or maximum two days after the instructions. On the next day the parent/caretaker participated on a telephone interview with the trained interviewer, where the records were checked and the data was entered in the dietary software, namely "OPEN app", see 3.2.3.

There were minimum seven days and maximum three weeks in between the first and the second food dietary record, and the observed days had to be the same as in the first record (working day or weekend day). At the second home visit, usually the next day after the second recording, trained interviewer used face-to-face interview to complete data entry and to check both dietary records to ensure that detailed information about the food items consumed was captured.

For breastfeeding, the frequency was collected. In order to evaluate the quantity of breastmilk consumed we used the data from Paul et al. (Paul, 1988). In this regard, we took into account that the collected data on the frequency of breastfeeding does not indicate whether all the meals are intended for feeding or even the soothing of the baby. Therefore, in the case of a 3 -month-old fully breast-fed infant, we used the amount of breastmilk in g per meal according to gender by Paul et al for 6 meals for breastfeeding frequencies between 6 - 8, in the case that the reported breastfeeding frequency was above 9 we added one meal more. In babies aged between 4 and 6 months, we used the amount of breastmilk in g per meal according to gender by Paul et al for 5 meals for breastfeeding frequencies 6 -8, in the case that the reported breastfeeding frequency was above 9 we again added one meal more. The estimated energy value for breast milk was 68kcal / 100g.

A section on food supplements was also included in the food diary. Responsible persons (e.g. personnel in kindergartens) were asked by parents/caretakers to give precise information on food consumed and on the place and time of the meal for children in the day care or kindergartens.

3.2.1. Food description

All foods, beverages and food supplements consumed were recorded per food consumption occasion (before breakfast/ breakfast/ mid-morning snack/ lunch/ mid-afternoon snack/ dinner/ after dinner /between meals). For each food consumption occasion, the place and time of consumption were recorded.

All composite dishes were disaggregated and described at the ingredient level. The disaggregation was based on information provided by the subject (if self-made) or by means of 742 standard recipes. Different facets and descriptors were used to describe dietary items (i.e. foods, recipes and food supplements) in more detail. Facets characterise different aspects of the dietary item.

For food description and codification purposes, the FoodEx2 codification system has been used (EFSA, 2015). Foods have been classified at raw (edible part) and at ingredient level. The software includes an open database in which 2401 codified food items are included. In the case that a new item was reported, it was codified and included in the database.

3.2.2. Determination of portion sizes

Consumed amounts of foods were estimated using a national picture book, complemented with household measures, portions indicated in standard recipes and with known packaging sizes as weights or volumes. The last have been converted to weights based on the food/beverage densities.

The SI.Menu 2017/18 picture book is composed of pictures from the PANCAKE pilot study and pictures from Slovenian national menu. After the pilot study some food items were added, the order of the pictures has been changed and the table of contents has been included.

In the picture book 46 different food products or simple recipes are represented by a series of pictures (photos of reference foods with their actual gram weight). Each of the series included six different portion sizes. These pictures were used not only for estimating the food that is illustrated, but also for other food with similar density, size and shape. This was explained in the picture book (available at: http://www.nijz.si/sl/slikovno-gradivo-s-prikazom-velikosti-porcij).

This picture book validation according to the method of conceptualization was carried out in May 2015 with 31 female and 23 male participants at Biotechnical Faculty in Ljubljana (Vede et al., 2016). Validation has proved to be successful as there were only two unacceptable picture series. The second part of the research included the addition of picture series to existing PANCAKE food picture book intended for Slovenian national food surveys. Eleven picture series with six portion sizes were prepared for this purpose. The selection of food items was adjusted for the Slovenian population. Determination of portion sizes and photography conditions was done in compliance with PANCAKE guidelines. It was concluded that design of specific food picture book for Slovenian population is necessary and that properly validated picture series significantly reduce the errors in food intake assessment. Weight data of 57 food items from manufacturer's information or commercial units and around 50 household measures (spoon, cup, glass, etc.) were included in the picture book (NIJZ, 2017).

The interviewers used the picture book with quantified food items (in grams) and the participants used the picture book with the numbers (1-6) by the food items (without grams).

3.2.3. Dietary software

The Open platform for clinical nutrition (OPEN) (http://opkp.si) is a computerised 24-hour recall program that has been developed and is maintained by the Jozef Stefan Institute (consortium partner) included in several national and EU-funded nutrition-based projects: EuroFIR NEXUS, RFID Farm2Fork, Diets2, EuroDISH, ISO-FOOD, PD_manager, SAAM and QuaLiFY.

The OPEN has been extended by the mobile app "EUMenu", which uses food composition data maintained in the OPEN database. The OPEN food composition database complies with "Food data structure and format standard" (BS EN 16104:2012) and includes Slovenian food composition data on meat and meat products as well as food composition data on plants (Korošec et al., 2013). Missing food composition data have been borrowed from other European and USDA food composition databases.

OPEN has embedded a database of generic foods and food supplements. It also provides food composition data on traditional recipes and recipes that are frequently consumed in Slovenia. For each recipe, OPEN provides a list of ingredients (with their quantities), its yield factor and portion size. The OPEN database also stores compositional data on many branded foods purchased in Slovenia. For branded foods, OPEN provides food composition data for nutrients that are available (in most cases, data for branded foods include data for energy, protein, fats, carbohydrates, sugar, fibre and sodium).

OPEN also enables an easy inputting of new foods, food products and recipes. If there was a lack of time during the 24h recall interview, the interviewer described a missing food in a comment field and the missing data was added to the database after the 24h recall interview and considered before reporting to EFSA. If the participant was able to describe the missing dish (recipe) in details, the interviewer either entered the new dish into OPEN directly or into the comment field (by specifying the ingredients, quantities, portion size). Otherwise, when the participant was unable to describe the missing dish in details, we considered a general recipe to specify the dish with respect to ingredients, their quantities and portion size. Many foods and all the recipes hold an information about household measures/portions. The reported food and recipe data was indexed by FoodEx2. OPEN has been scientifically validated (Koroušić Seljak et al., 2013; Bizjak et al., 2014; Benedik et al., 2015) and applied

in the cross-border (Slovenia–Italy) cooperation project PANGeA: Physical Activity and Nutrition for Quality Ageing (2007-2013) (http://www.pangeaeu.org).

The OPEN app was designed to support 24h recalls as well as food diary. It allows its usage in a local mode, where no internet access is available. A user may be an interviewer or an administrator. While an interviewer may access only a limited set of profiles, one for each interviewee, an administrator may control all the profiles (all the interviewees), create new profiles, generate reports etc. Collected data is regularly stored on the IJS server, whenever an access to internet is available. Data quality checking measures are integrated into the app. If the meal or daily meal energy intake exceeds the recommended daily intake, a user is alerted about that. If mandatory data, such as place of consumption, time of consuming etc., is missing, the interview (24h recall) cannot be completed. A report, which conforms to the EFSA methodology requirements, can be easily exported directly from the app. This feature is enabled only for administrators.

3.3. Other information

3.3.1. Questionnaires

Additional data on socio-demographic characteristics, birth data, health status and food allergies, breastfeeding and feeding practices, exposure to sunlight and smoking were collected within a general questionnaire.

3.3.1.1 Socio demographic information

In the general questionnaire, socio-demographic and socio-economic information was collected with regard to age and marital status of the parent/caretaker, households size, rural/urban area, educational level (of the parent/caretaker), type of employment, maternity leave (yes/not) and self-reported material standard (of the parent/caretaker).

The employment status of the parent/caretaker was classified according to the eight social classes and educational level according to the nine education-class scheme (Eurostat, 2007).

3.3.1.2 Physical activity

No data on physical activity was collected.

3.3.1.3 Birth data

Questions regarding gender, age, body weight and body length at the time of birth, head circumference at the time of birth, the way of giving birth (vaginal / caesarean delivery), duration of pregnancy were also part of general questionnaire.

3.3.1.4 Breastfeeding and feeding practices

Additional information was collected with regard to breastfeeding (yes/no, exclusively or partially, usage of milk formula if not breastfed) and feeding practices of the selected person. Feeding practices included questions about the approximate month of child's age when the consumption of selected food items and beverages started (water, tea, fruit juice, bread, pasta, potatoes, rice, vegetables, fruit, milk and milk products, meat and meat products, eggs, marine fish, marine products, fatty food, nuts, sweet breakfast cereals, honey, sugar, salt, sweet products). Additional information was obtained from the mothers of selected persons regarding their dietary habits (usual dietary habits, use of food supplements, fortified foods, soft drinks, alcohol, energy drinks and sweeteners).

3.3.1.5 Lifestyle and health

Questions on health (for selected person (child) and for mother of the child) and the presence of allergies to food of the child were included in the general questionnaire. A questionnaire also collected information regarding health characteristics such as dieting due to health problems or weight

management, self-perceived health and prevalence of a list of nutrition related diseases diagnosed by medical doctors.

In addition, questions regarding exposure to sunlight and tobacco smoke at the time of the survey and in the last 12 months (for toddlers) were added at the end of general questionnaire.

3.3.2. Measurement of body weight and height

Anthropometric information (body weight and body (standing) height or recumbent length) were collected in SI.Menu 2017/18 survey for all selected persons using actual measurements performed by the trained interviewers following a standardized protocols considering also the instructions from PANCAKE projects.

Participants' weight and height/length were measured at their home in light clothing (dry diaper) and without shoes. In the case of children older than two years, the body weight was measured to the nearest 0.1 kg using a calibrated digital scale (Tanita BC-730, Japan). The height was measured with a measuring mat to the nearest 0.5 cm with the head positioned in the Frankfort horizontal plane. In the case of infants and children less than 24 months old, the measuring mat was used to measure the recumbent length. The body weight was calculated from the measured weight of parent/caretaker and child together (in lap) and body weight of parent/caretaker alone, measured to the nearest 0.1 kg using the same calibrated digital scale. The measurements were performed preferably at the first home visit.

3.3.3. Food supplements

Information on consumption of food supplements was collected both in the dietary record (consuming in the time of the survey) and in the FPQ, which asks about consumption in the time before interview. Food supplements were defined for parents as products intended to provide additional nutrients or give health benefits and taken in liquid, powder, tablet or capsule form. They can be sold as food supplements or medicines (e.g. vitamin D and vitamin A for infants < 12 months are also prescription medicines in Slovenia).

In the dietary record parents wrote down the details of any supplements they gave to their children on each diary recording day e.g. name of the product, technological form – tablets, drops and the quantity consumed (e.g 1 tablet/day). It was impossible to collect the unit weight of the consumed food supplement by the interviewer at the time of the home visit; therefore, as much information as possible about the product was collected during the visit (including the brand name and photo of the product) and then obtained the data from Database of Food Supplements in Slovenian market. In the case that the unit weight was not available we used the average weight for different types of food supplements as determined by EFSA (EFSA, 2018), taking into account the reported consumption (number of drops, tablets, capsules).

In the FPQ for children the information about the frequency of consumption of nine types of food supplements (vitamins, minerals, omega 3 and omega 6 fatty acids, botanicals, probiotics and prebiotics, colostrum, propolis and other bee products, algae, others) in the time before interview was collected. The frequency options were: never, a few days, regularly/about 1 month, regularly, more than 3 months. The FPQ further asked about the specific vitamins and minerals containing in food supplement.

In the general questionnaire, the use of food supplements in the last 12 months was obtained also for mothers of selected persons. The questions were the same as in the FPQ in SI.Menu 2017/18 survey on adults.

4. Administration of the interview

4.1. Selecting the examination site

Face-to-face interviews and anthropometric measurements were performed preferably at the participant's home. In the case that participant refused to perform the interview at home, an alternative suitable site was allowed.

4.2. Content and organization of the survey visits

The SI.Menu 2017/18 children survey consisted of the following steps:

- The first contact (at the doorstep)

- The first interview (1st home visit), CAPI

- A telephone call for completion interview, CATI

- The second interview (2nd home visit), CAPI or CATI.

Figure 2 illustrates the organisation of the data collection of the selected individual (infant or toddler).

1st INTERVIEW (Home visit)		
Tools	**Actions** (Time: app. 40 – 60 min)	**Outcomes**
Motivational and supportive materials, incentives	Presentation and motivation for conducting a survey	Consent to the survey (signed statement)
Notebook with uploaded SurveyToGo app. to perform general questionnaire	CAPI – computer assisted personal interview	Collected data from general questionnaire, including FPQ
Mass scale, measuring tape	Anthropometric measurements: body height/length and body mass	Collected anthropometric information
Food diary with instructions (paper form) Picture book for the estimation portion sizes (paper form) Letter for kindergartens, if needed	Instructions for completing the food diary	The agreed date for a telephone call for completion 1st food diary

Telephone call		
Tools	**Actions** (Time: app. 20 min)	**Outcomes**
Notebook with uploaded OPEN app. to perform food diary Phone Picture book for the estimation portion sizes (paper form)	CATI – computer assisted telephone interview	Collected data from 1st food diary
		The agreed date for a telephone call for completion 2nd food diary

2nd INTERVIEW (Home visit or telephone call)		
Tools	**Actions** (Time: app. 30 min)	**Outcomes**
Notebook with uploaded OPEN app. to perform food diary Picture book for the estimation portion sizes (paper form)	CAPI – computer assisted personal interview	Collected data from 2nd food diary, checked and confirmed
Notebook with uploaded OPEN app. and SurveyToGo app.	Controlling entered data in OPEN app and answers in SurveyToGo app.	Checked and completed data for each respondent

Figure 2: Organisation of the data collection in SI.Menu 2017/18 children survey

4.2.1. First contact

Participants were invited in the SI.Menu 2017/18 by an invitation letter together with an information leaflet. Within two weeks after the reception of the invitation letter the parent/caretaker of the selected person was physically contacted by the interviewer at their doorstep. At least five contacts had to be made for each selected individual before they were classified as non-contactable. This first contact was the opportunity to check the receipt of invitation letter, to explain further the survey and to determine the eligibility of the selected person. First contact was intended also to set a date for the interview at the participant's home at a convenient time.

4.2.2. First interview

The first interview took place at the participant's home. Face-to-face interview was performed with parents/caretakers of selected persons (preferably with mothers). After the obtained consent for participation, interviewer went on with general questionnaire through a computer-assisted personal interview (CAPI). During the interview participants received a showcards supporting the complex questions (e.g. FPQ and questionnaire on health).

Depending on the mood and daily rhythm of the child, anthropometric measurements were done using scale and measuring mat. All results were directly entered into the software.

After the general questionnaire, the parent/caretaker received information on how to fill in the food diaries and a picture book to be used during the interview. If the toddlers are in the kindergarten the daily menu was requested from the parents/caretakers or kindergarten institution. In addition, the kindergarten caretakers were asked to fill up the food diary about the actual amount of consumed food. Portion sizes were estimated by a combination of picture book and household measurements with their actual gram weight (spoon, cup, glass, etc.).

At the end of the first home visit, a date/hour for a telephone call for the first completion food diary was agreed.

4.2.3. Second interview

The second interview started with the completion of the second food diary through the telephone with the help of the OPEN application. Together with parents/caretakers, the interviewer reviewed and confirmed the general questionnaire and both food diaries and entered the data in the software. A date for a second interview and a home visit was scheduled.

4.2.4. Interviewing and checking questionnaires

All interviewers were provided with a notebook containing the necessary software to perform the food diary (OPEN app) and general questionnaire (SurveyToGo® software, a computer-assisted interviewing system), a two different versions of picture book for determining portion sizes during the 24-hour recall, extensive methodological guidelines and the showcards helping with the possible answer categories for the CAPI questions. Interviewers were also provided with a bag containing scale and measuring tape for anthropometrical measurements as well as practical incentives for respondents.

With the CAPI technique of the interview the responses to the questionnaires were directly entered into a portable computer. This technique enables automatic controls and redirections within the questionnaire. Anthropometrical measures were also registered with the CAPI system during the first home visit.

Fieldwork was organised in accordance with internal procedures and the contract signed with the sub-contracting company conducting the interviews. The work of each interviewer was continuously checked and their payment relayed on the completeness of collected data for each individual participant. Subcontracted company for performing the interviews foresaw these quality assurance controls. Weekly reports on response rates were prepared (including the numbers of eligible and non-eligible persons, soft and hard refusals, non-contacts, etc.). Besides, data collected with CAPI interviews and 24-hour recalls were weekly checked to assess their completeness or inconsistencies.

There were also nominated supervisors for the survey that control the fieldwork. They checked approximately 15% of conducted interviews per each interviewer. Respondents were informed in advance that the control of the interviewers' work is foreseen. If the control showed any deviations for a particular interviewer, a 100% control were conducted for this specific interviewer. The control included specific oriented questions.

4.3. Recruitment and training of the staff

4.3.1. Selection of the fieldwork staff

Interviewers with experience in face-to-face interviewing with similar content (e.g. health, nutrition) have been preferred. In the selection process of interviewers, those with a background in human nutrition, dietetics or food sciences (minimum B.Sc.) or with strong background in interviewing techniques have been favoured as specified in the call for tender. Interviewers had to sign a contract with the company conducting the interviews. For each PSU (initially) 8-10 interviewers were selected, resulting in total of 30 interviewers.

Interviewers were recruited separately for different regions of Slovenia. All interviewers have been selected with the help of consortium partner and subcontracted company. The NIJZ as project leader authorised all selected interviewers.

4.3.2. Training

All interviewers received a collective two-day training performed a few days before the start of the fieldwork period. Selected interviewers were trained by professionals in human nutrition and interviewing techniques from NIJZ and consortium partners, as well as from sub-contracting agency, which has a lot of experience with interviews and surveys in Slovenia.

Interviewers were provided with an extensive interviewer guideline describing general survey information, the protocol for home visits and telephone calls, the content of the questionnaires, the anthropometrical measuring protocol and the user manual for the CAPI questionnaire. For "OPEN", Jozef Stefan Institute (consortium partner) created a separate detailed manual.

The training program included:

- basic interviewer's skills,
- presentation of the content of the questionnaire,
- presentation of CAPI technique and SurveyToGo tool,
- food diaries instructions and 24h-recall methodology,
- handling with the OPEN app,
- performance of anthropometric measurement,
- workshop with practical examples.

After three quarters of the fieldwork, we carried out a refreshing one-day training, where we presented the previous course of the survey and distributed practical gifts to the interviewers. They provided valuable information of their experiences on the survey from the field.

New interviewers recruited during the course of the fieldwork received the same training, but on an individual or smaller group basis.

5. Quality assurance

Quality assessment principles were effectively implemented to continuously improve the quality of deliverables. Previous to the survey, as a part of the quality assurance, a pilot study was done to test the methodology, questionnaires and tools. The sample for the pilot survey was selected "on-purpose" to achieve different population groups according to age, gender and education / functional literacy. The pilot survey was carried out under a strong supervision of survey methodologists and nutritionists, responsible for methodology of the survey. Based on pilot results, the final version of the dietary survey design and supporting tools were prepared.

The following measures were taken to ensure the quality principles of the project:

5.1. Organization of the survey

- Tasks, competences and responsibilities of all personnel were well defined
- Highly motivated, qualified and responsible personnel participated in each step of the survey
- Tasks were organised in five Work Packages, employed in different time periods
- The specific management structure ensured the partners to exchange views and solve potential problems as well as follow the progress of the project and take decisions
- Each member of the core group of the consortium has defined internal project working group, responsible for the implementation of the project tasks at partner level. They had regular meetings
- All partners were obliged to report to the coordinator on the progress of the project at least every six months
- Scientific Committee consisted of one researcher from each partner with one additional member from the core group
- Steering Committee consisted of one senior representative from members of core group and representatives of Ministries
- Communication and specific meetings between different working groups, Scientific Committee and Steering Committee were arranged when needed
- All prepared deliverables were checked according to the quality control and assessment plan by Scientific Committee to guarantee for their quality and their timely submission to EFSA.

5.2. Sampling

- The sampling protocol selected ensured representativeness by gender and age classes
- Response and non-response rate was controlled
- A professional institution (Statistical Office of the Republic of Slovenia) prepared the sample from the CRP in Slovenia.

5.3. Field work

- Only interviewers with a background in human nutrition, dietetics or food sciences (minimum B.Sc.) or with strong background in interviewing techniques have been favoured
- Fieldwork was handled in accordance with internal procedures. Weekly reports on response rates were prepared (including the numbers of eligible and non-eligible persons)
- The database was checked regularly to assess the basis quality controls and completeness of data
- The supervisors were nominated for the survey. They checked approximately 15% of conducted interviews per each interviewer.

5.4. Data entry

- Dietary software "OPEN" was upgraded to support 24h recall and food diary methods
- Systematic quality controls were performed throughout the data input procedure to avoid missing collecting of mandatory information and foods that are easily forgotten to be recorded during interviews
- Automatic control checks were performed for daily energy intake, which had to be within expected range for different age and gender groups
- Screen warnings appeared when there were inconsistencies or partially erroneous data.

5.5. Data cleaning of the food consumption data

- Two team members from NIJZ with high nutrition knowledge regularly checked to assure quality criteria in this project
- A supervisor, nutritionist, checked all interviews according to the quality control and assessment protocol, looking for inconsistencies, for example:
  - very high or very low consumption amounts
  - reporting of foods that are expected to be thermally treated as raw (e.g. raw pasta, raw meat)
  - reporting of foods which are normally assumed to be prepared with liquid (e.g. instant porridge and cocoa powder without milk)
  - dishes defined as undefined dishes (no exact recipe)
  - food items unrelated to the interviewee's age (whole nuts, spicy food in children under one year old; infant formula in adults, etc.)
  - the same food is eaten several times a day (eg. the same fish or the same meat)
  - respondents who identified themselves as vegetarians or vegans consumed meat etc.

5.6. Anthropometric measurements

- A protocol for collecting anthropometric data was followed
- Repeated measurement if it seemed incorrect (perceived error in SurveyToGo tool)
- Quality control of devices: instruments were calibrated and validated.

5.7. Food consumption amounts

Consumed amounts for every food item and individual consumption were checked for detecting odd data (very low or high amounts for a specific food item). Food weight or volume data was compared with standard or commercial portions, recipes, recommendations, etc.

5.8. Energy intake

Energy intake was checked as a final control, which had to be within expected range for different age and gender groups.

6. Data management

The data management process was designed bearing in mind that the reliability of the collected information should be ensured from the field work, carried out by the interviewers, to the final users of the consumption data. Collected information, both by phone or by face-to-face interviews, was transferred online to the host system and was systematically backed up.

Each user (interviewer or administrator) of the OPEN app had a personal identification and password. Moreover, different levels of accessibility were established: e.g. interviewers were only allowed to the data entry level, supervisor had all power. Code numbers were assigned to each respondent and personal data were allocated in separate files than those containing other information. Each instrument of data collection: Survey questionnaire, 1st and 2nd 24h recall, 1st and 2nd Food Diary generated an independent data base, which could be only combined together through the respondent code.

All food consumption and related data were checked (skip checks, validation checks, consistency checks etc.) and cleaned, and are stored on OPEN web server and in the NIJZ server according to internal acts (The life-cycle of NIJZ databases; The protocol of data processing). All data in the database was stored according to all the variables available, coded according to the data model.

Food consumption and related (transmission) datasets were provided to EFSA according to a common data model defined by EFSA and through Data Collection Framework. Before that, all foods and facet descriptors were coded according to the FoodEx2 food classification and description system. Data were divided in three files: Subject, Food and Consumption file.

7. Dissemination and publicity

The main results of the SI.Menu 2017/18 survey on children will be available for general and professional public in statistical publication, which will be published on the website (http://www.nijz.si/). As the survey is also included in the EU Menu project, the food consumption data coded according to the FoodEx2 classification will be included and made available in the EFSA Comprehensive European Food Consumption Database.

Original dataset will be available for the national risk assessment agency and for any other potential users for research and statistical purposes under certain conditions. An agreement with researcher / research agency on data transmission will be required. General terms and conditions for the use of those data are available on NIJZ web page.

The consortium partners were committed to develop ways to increase use of the data by external researchers in order that this rich resource may be put to full use. As indicated above, the set of conditions ensures that data are correctly interpreted and takes a disciplined approach to its use at all times. In order to maintain a comprehensive archive as a resource for internal and external use, careful monitoring of the use of data and related publications is necessary through certain procedures.

8. Special issues/challenges

No special issues arose during the survey, therefore, it was not necessary to implement any of major deviations. However, different challenges listed in Table 4 had to be faced and were solved without any disruption of the survey progress. Most of the challenges were foreseen thanks to previous experience of similar surveys and projects.

Table 4: Main expected challenges and issues in the SI.Menu 2017/18 dietary survey

	Special issue/challenge
Work Package	
Adaptation and development of the survey methodology according to the EFSA EU MENU methodology	Time consuming Cooperation was needed with many other institutions
Adaptation and development of dietary software and supporting tools according to the EFSA EU MENU methodology	Mapping of Slovenian foods to the FoodEx2 classification (although most of food items are already connected with FoodEx2 codes) Software updates during the fieldwork
Methodological guidelines for interviewers training and the pilot survey	Difference (dis-advantages) between interviewers with and without nutrition background Interviewers with nutritious background should or should not participate in any dietary or health advice giving
Preparation of the sample, collecting the data from fieldwork	Response rate achievement Outsourcing (although we have good experience with some previous surveys) Sample points (100 households represents one sample point, not enough new-borns, one mother and two children) Length and complexity of the interview Emerge conditions (floods, bad weather)
Data preparation and harmonisation to the EFSA	Datasets validation (corrections in datasets….)

Conclusions

The SI.Menu 2017/18 survey on children for the first time collected food consumption data at national level for this sensitive population group. The survey provided extensive and valuable information regarding breastfeeding, feeding practices and nutrient adequacy during these periods. SI.Menu 2017/18 on children provides data that can inform researchers about the food and nutrient intakes of young children. Furthermore, the food consumption data will be useful for national risk assessments and the development and evaluation of nutrition or health policies, especially for evaluation of Slovenian new food and nutrition action plan. The results of the SI.Menu 2017/18 survey will be also valuable for the preparation of national food-based dietary guidelines.

Slovenia applied to EU Menu project as consortium, consisting of several partners from academia, institutes and hospitals. It turned out that this way of work is highly effective and as a consortium continues research on food and nutrition and applies on national and European scientific projects. Being part of EU Menu project was also an opportunity for our national dietary software provider, which have

enabled us to harmonise our project with EFSA requirements. Due to the limited number of dietary experts, this project was an opportunity to create a national network of experts.

At European level, the participation of the SI.Menu 2017/18 survey in the EU Menu project has been very beneficial because of the high level of standardisation of the survey methodology and its quality assurance. Although the coding of the food consumption according to the FoodEx2 classification after data collection required an extra effort, the inclusion of the Slovenian consumption data in the EFSA Comprehensive European Food Consumption database is considered valuable for future dietary exposure assessments at the European level.

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Glossary / Abbreviations

CAPI	Computer assisted face-to-face interview
CATI	Computer assisted telephone interview
CRP	Central Register of Population in Slovenia
Diets2	Dieticians ensuring education, teaching and professional quality
EFSA	European Food Safety Authority
EU	European Union
FoodEx2	Food classification and description system developed by EFSA
EGFCD	EFSA Expert Group on Food Consumption Data
EPIS-Soft	Software developed to conduct 24-h dietary recalls in the European Prospective Investigation into Cancer and Nutrition (EPIC) Study
EuroDISH	Studying the need for food and health research infrastructures in Europe
EuroFIR NEXUS	The EuroFIR Food Platform: Further integration, refinement and exploitation for its long-term self-sustainability
FPQ	Food Propensity Questionnaire
GQ	General Questionnaire
IARC	International Agency for Research on Cancer
IJS	(Inštitut Jožef Stefan) Jožef Stefan Institut
ISO-FOOD	Era chair for isotope techniques in food quality, safety and traceability
NMEC	National Medical Ethics Committee
NIJZ	(Nacionalni inštitut za javno zdravje) National Institute of Public Health of the Republic of Slovenia
NUTRIS	(Inštitut za nutricionistiko) Nutrition Institute
OPEN	Open platform for clinical nutrition, developed by IJS
QuaLiFY	Quantify Life Feed Yourself
PANCAKE	Pilot study for the Assessment of Nutrient intake and food Consumption among Kids in EU
PANGeA	Physical Activity and Nutrition for Great Ageing
PD_manager	Parkinson's Disease management project
PeK	(Pediatrična klinika) University Medical Centre Ljubljana, University Children´s Hospital
Pilot- PANEU	Pilot study in the view of a Pan-European dietary survey - Adolescents, adults and elderly
PIN	Personal identification number
PPS	Probability proportional to size
PSU	Primary sampling Unit
QuaLiFY	Career Coaches for Low - Qualified Adults project

RFID- Far2Fork	European project funded through the CIP ICT PSP programme
SAAM	Supporting Active Ageing through Multimodal coaching
SI.Menu	Slovenian (SI) national dietary survey (Menu)
UL BF	(Biotehnična fakulteta) University of Ljubljana, Biotechnical Faculty
UL PF	(Pedagoška fakulteta) University of Ljubljana, Faculty of education
UM FZV	(Fakulteta za zdravstvene vede) University of Maribor, Faculty of Health Sciences
UP FVZ	(Fakulteta za vede o zdravju) University of Primorska, Faculty of Health Sciences
WP	Work Package