EXTERNAL SCIENTIFIC REPORT

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Spanish National dietary survey in adults, elderly and pregnant women

Agencia Española de Consumo, Seguridad Alimentaria y Nutrición

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Abstract

ENALIA2 is a dietary survey conducted in Spain to collect food consumption data and other information about eating habits and physical activity on adults (18 – 64 years old), elderly (65 to 74 years old) and pregnant women. Data on 1033 individuals were obtained in line with the EU Menu guideline to be included in the EFSA Comprehensive European Food Consumption Database. In this sense the survey followed the EFSA "Guidance recommendations on the General principles for the collection of national food consumption data in the view of a pan-European dietary survey". The project was funded through an EFSA procurement and was included in the EU Menu Project. The participation rate was 53.4% in general population and 80.1% in pregnant women. No major deviation from the guidance or technical specifications was required.

Key words: Spain, dietary survey, food consumption, adults, elderly, pregnant women, EU Menu

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Summary

ENALIA2 is a dietary survey conducted in Spain to collect food consumption data and other information about eating habits and physical activity on adults, elderly and pregnant women. It began in summer 2013 and finished at the end of 2015. The methodology followed the EFSA guidance recommendations on the "General principles for the collection of national food consumption data in the view of a pan-European dietary survey".

The food consumption survey was carried out at individual level by means of the 24-hours recall, including two non-consecutive days (at least 14 days in between) and complemented with a Food Propensity Questionnaire.

The survey included 900 adults and elderly and 133 pregnant women (oversampled). The project was awarded with an EFSA contract and was included in the EU Menu Project.

Following the referred guidance and specifications in the contract, study subjects were selected according to a random multistage sampling procedure. One computer assisted telephone interview and a second computer assisted personal (face- to- face) interview at the home of the participants were organised. Interviewers were specifically trained in conducting dietary interviews. The sampling procedure was designed considering the variability between seasons, day of the week and territoriality. Anthropometric data and physical activity information was collected at the interviewees home. Specific tools, already developed for the previous ENALIA survey, in children and adolescents, were implemented in ENALIA 2. Nevertheless, some questionnaires were adapted to the new groups of population, following PANEU project recommendations.

In order to classify and code food items, in terms of harmonisation, the EFSA FoodEx2 classification system was used.

Data recording and management were done with a previously developed application, ENIA SOFT first implemented in ENALIA survey.

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1. Introduction and objectives

In Spain there was a lack of recent food consumption data. For that reason, AECOSAN carried out a survey in Spanish children and adolescents (ENALIA) following European criteria, supported by EFSA, and included in the EU Menu project.

Not comparable food consumption data collected by using the same methodology were available on adult and elderly population. In order to solve this situation, AECOSAN organised a food consumption survey on this group of population. As there is also little information about food consumption in pregnant women, this group was oversampled in the survey.

Data were obtained in a consistent way regarding other EU countries, to be included in the EFSA Comprehensive European Food Consumption Database. In this respect, the survey follows the EFSA "Guidance recommendations on the General principles for the collection of national food consumption data in the view of a Pan-European dietary survey" (EFSA, 2009).

ENALIA 2 is a survey, carried out in Spain, at individual level, with the objective of collecting accurate food consumption data in adults, elderly and pregnant women. It was funded by EFSA, through an open call, in 2013 as part of the EU Menu Project. In that way a contract was signed between EFSA and AECOSAN.

This contract implies to carry out the survey following EFSA specifications, to send the required reports and the final data transmission to be included into the "Comprehensive European food consumption database".

The study began in winter 2013 and finished at the end of 2015. The sample included 900 individuals with ages between 18 to 74 years old, randomly chosen from all 17 autonomous communities in Spain and 133 pregnant women that were oversampled.

1.1. Background and terms of references 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" (EFSA, 2009). 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.

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), coordinated by RIVM (The Netherlands), 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 of this project was 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" (PANEU), coordinated by the Hungarian Food Safety Office to develop and test similar tools and protocols for the different adult population groups. The final results are described in the final report of this project published on the EFSA website in November 2013 (Ambrus et al, 2013).

The Guidance of EFSA on "General principles for the collection of national food consumption data in the view of a pan-European dietary survey" is scheduled to be updated in 2014 based on the outcomes of the above-mentioned pilot studies1.

[1] 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

Further, since December 2010, EFSA collaborates 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)

The first and second support to national dietary surveys was provided by means of the calls for tender CFT/DCM/2011/02 and CFT/DCM/2012/01. Support for seven surveys from six Member States (Estonia, France, Latvia, Portugal, Spain, The Netherlands) was granted in 2011 and 2012

The aim of this procurement procedure is to award direct contracts to organizations from EU Member States, which have a governmental mandate to carry out a dietary survey at national level in the period from 2013 to 2018. Resources will be made available to support the adaptation of the methodology used in these surveys according to the EFSA Guidance document on the general principles for the collection of national food consumption data in the view of a pan-European dietary survey4. The dietary data collected through the activity 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 adapt the methodology to be used in the national food consumption survey according to the EFSA Guidance document on the general principles for the collection of national food consumption data in the view of a pan-European dietary survey,
- objective 2: to prepare and transfer to EFSA the national food consumption data and related information collected during the survey according to the format required by EFSA.

This contract was awarded by EFSA to: **Agencia Española de Seguridad Alimentaria y Nutrición**

Contractor: **Agencia Española de Seguridad Alimentaria y Nutrición**

Contract title: Support to National Dietary Surveys in compliance with the EFSA Guidance on General principles for the collection of national food consumption data in the view of a pan-European dietary survey"- third support.

Contract number: CFT/EFSA/DCM/2013/02-LOT 2-CT04

2. Description of the protocol of the survey

The survey was planned by a team composed by Demométrica, a private company, and AECOSAN staff, according to the EFSA Guidance (EFSA, 2009) and the contract requirements signed with EFSA. Previous experience in former surveys was also considered in both planning and management.

AECOSAN was responsible for designing tools, organizing and supervising each task in order to fulfil the contract requirements and deadlines. In addition, AECOSAN staff carried out quality control and food codification. The sampling design, fieldwork and data processing were done by the private company.

The sampling design, field work and data processing were done by Demométrica. This company has a broad experience in socio sanitary fields, including nutritional surveys.

The original timeline was followed. The project began in August 2013. The survey design and adaptation of the materials were done in March 2014. A pilot study was carried out in April and May 2014. The fieldwork and the food consumption data collection began in June 2014 and finished one year later.

The survey design followed the recommendations proposed in the EFSA "General principles for the collection of national food consumption data in the view of a pan-European dietary survey" (EFSA, 2009).

Dietary information was collected by means of two 24 h dietary recall, separated at least by 14 days.

In all population groups, the two 24h recall were complemented by a Food Propensity Questionnaire (FPQ), designed specifically for this purpose.

Other information collected:

- General information
- Physical activity
- Anthropometric data (height and weight)

The survey calendar was organized in such a way that the appropriate proportion of working days and weekend days was taken. Individuals were uniformly distributed over the four seasons of the year and the geographical distribution and urban and rural populations were also taken into account.

2.1. Study population and exclusion criteria

The study population was people living in households throughout Spain from 18 years old up to and including 74 years of age.

Following the EFSA Expert Group on Food Consumption Data (EGFCD) suggestion, the criterion of exclusion was the institutionalized population not resident in households which in the age range of 18 to 74 years old represent approximately 2% of the total population.

Pregnant women were over-sampled, thus a different sampling design from the general population was used.

Besides the groups set in the Guidance of EFSA (EFSA, 2009), we divided the 18 to 64 years old group in two subgroups a) 18-39 and b) 40-64 years old. The first subgroup included the youngest people and the great part of the women of childbearing age.

The total study population was consequentely divided in four groups:

a) Adults from 18 to 39 years old
b) Adults from 40 to 64 years old
c) Elderly, 65 to 74 years old
d) Pregnant women

2.2. Sampling frame

2.2.1. General population

The design of the main population-based cohort studies, carried out by the National Institute of Statistics (INE) in Spain, was followed.

Four sampling units were considered in this kind of multi-stage sample design:

a) Municipality (town/city)
b) Census section
c) Household
d) Person to be interviewed or sampling element

Census section (called "sección censal" in Spanish) is the last cluster or population division designed by INE. These are town partitions with a small number of households.

As the sampling variables were considered homogeneous within the census section, it was used as the primary sampling unit. Besides, the municipal census figures were available by municipality, district and census section, and they were broken down according to sex, age, nationality and place of birth.

A database of households with telephone was used to identify the households included in census sections, since there was no other available information. Considering that close to 80 and 90% of households have a telephone, the bias produced by the population outside the sample frame was considered quite small.

Only one person was selected from each household. When there were more than one person fitting the sampling requirements (age and gender), the participant was randomly chosen.

2.2.2. Pregnant women

Despite being possible to recruit pregnant woman for the survey, a difficulty to identify and capture this group of population in households was noted. To solve this issue, since most of the pregnant women visit midwives in primary care health centres, the recruitment was made throught these professionals. A census of these centres is available from the Ministry of Health, with just one midwife per health centre.

2.3. Sampling method and design

2.3.1. General population

It was followed a multistage cluster sampling method, with stratification of the sampling units in first and second stage, and post stratification for last stage units (subjects or sampling elements).

Sample distribution by geographical area and kind of municipality (by number of residents) was done by allocation proportional to the population.

Stratification criteria were :

- For census section and municipality:
  - Residence in regions. Groups were made of the 17 autonomous regions in Spain.
  - Residence in urban or rural areas. In this last criteria four strata were used:
    - Large cities more than 500.000 inhabitants
    - Cities from 100.000 to 500.000 inhabitants
    - Cities from 10.000 to 100.000 inhabitants
    - Towns less than 10.000 inhabitants

- For household/individuals:
  - Age, class, and gender, according to study population. Five strata formed by crosstabs of age (adults 18-39, adults 40-64, elderly 65-74) and gender (male/female)

2.3.2. Pregnant women

With the above described sampling frame (section 2.2.2) we used a two stage cluster sampling:

a) Health care centre/midwife
b) Pregnant women

Stratification criteria considered health centres instead of census section and municipality, attending residence in regions groups and in urban or rural areas:

- Residence in regions. Groups were made of the 17 autonomous regions in Spain.
- Residence in urban or rural areas. In this last criteria four strata were used:
  - Large cities more than 500.000 inhabitants
  - Cities from 100.000 to 500.000 inhabitants
  - Cities from 10.000 to 100.000 inhabitants
  - Towns less than 10.000 inhabitants

In every randomly selected municipality one Health Care Centre/midwife was selected. If in one municipalty there were more than one Health Centres present, one of them was selected by simple random sampling, with a constant allocation between three and four women for each midwife.

No pregnant woman was found using the general population sampling method.

Sample distribution along the survey followed identical pattern in both general and pregnant women population:

- In order to capture inter - seasonal variability in consumption patterns, subjects were uniformly distributed over the four different seasons
- The survey calendar was organized in order to capture an adequate proportion of weekdays (5/7) and weekend days (2/7) at population group level
- The week (beginning of month, end of month, intermediate) can offer differences in purchasing power and, by consequence, between food intakes. Therefore, sample was distributed uniformly over the weeks in the month.

2.4. Sample size

As EGFCD recommends, at least 260 subjects (130 males and 130 females) were included in each of the age classes defined above. Therefore, sample sizes were:

- 270 adults 18 to 39 years (140 males and 130 females)
- 266 adults 40 to 64 years (130 males and 136 females)
- 264 elderly 65 to 74 years (131 males and 133 females)
- Pregnant women were over-sampled and 133 subjects were included

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

Efforts were made to achieve the sample size and to minimize the non-response rate:

1. Recruitment process

a) **Initial contact with household**. It was made by phone. The pilot study showed that one previous phone call, to explain the instructions for completing the 24 hour recall features, was appropriate to improve the response rate. Experienced staff, trained specifically for this study, explained the survey main objectives and procedures. Individuals were then asked whether they wanted to receive more specific and detailed information. Finally, an up – coming letter by post was announced to those who showed interest in participating to the survey.

In the case of pregnant women the initial contact was done at the Primary Care Health Centres through midwives.

b) **Letter by post**. Including:

- A brochure with detailed written information on the study characteristics
- An institutional letter signed by the head of AECOSAN. This document underlined the importance of the study, besides asking for participation, on behalf of the Ministry of Health, Social Services and Equality.

According to previous experience, this letter was very important to encourage participation. The institutional character of the survey was confirmed and individuals got familiar to its content before giving their approval. In this way, in subsequent contacts, the willingness to participate increased significantly and, more important, the interest in filling up the interview correctly also increased. Taking advantage of this delivery by post a 24 hour recall template was also included in the envelope.

This template was not used to collect data. The aim was only to help the interviewees, especially the older ones, to clearer understand what to answer to a 24 hour recall.

c) **Third contact with household**. A second telephone call to confirm the consent to participate and to conduct the general questionnaire was made few days later. The aim of this third contact was to conduct the general questionnaire to the entire selected sample, regardless of the disposition to participate and then to analyse the characteristics of those who did not answer. Participants were invited to express any doubt in order to receive as many explanations as necessary.

2. Other encouraging strategies

- A free enquire service by phone (from 9 to 21 hour) was offered in the letter by post to solve any doubt about the purpose of the survey, the company, what were the data going to be used for, personal data protection, etc.
- Advertisements on the Ministry of Health, Social Services and Equality and AECOSAN web pages and newspapers were used, thus more people knew about the survey
- An inexpensive gift (an apron) was given to those who finished the survey (any payment or economical compensation was completely forbidden).

The achieved response rate (media ratio) was 53.4% for general population and 80.1% for pregnant women. No statistically significant differences in the response rate per gender and geographical region in each season and at the end of the fieldwork were identified.

1498 individuals of the general population were invited to participate. The general questionnaire with socio-demographic questions was completed by 933 subjects (response rate of 62.3%). The first 24 hour recall was filled in by 824 subjects (55.0%) and both two 24 hour recall by 800 individuals (53.4%).

166 pregnant women were contacted, 144 completed the first 24 hour recall and 133 both first and second 24 hour recalls (response rates of 86.7 and 80.1%, respectively).

Appendix A - describes more specific sampling distribution and response rate results according to season, gender and age.

2.6. Legal and ethical aspects

Ethical principles for medical research involving human subjects (WMA Declaration of Helsinki) were considered. Moreover, participants were informed that personal data gathered in the survey will be treated as confidential and kept in automated data files authorised according to the Spanish law of personal data protection.

3. Dietary survey tools

The adaptation and design of different tools was made following PANEU Project recommendations (Ambrus et al, 2013).

3.1. Food propensity questionnaire

The Food Propensity Questionnaire (FPQ) included specific food/beverages interesting for their nutritional value or potential risk. Besides, food groups, such as fruits and vegetables, were also included. In addition, questions on the intake of food supplements were considered.

FPQ included 50 questions about food groups and selected food items (salt, processed baked goods…) and 14 questions related to food supplements. Food items or groups were selected based on the one hand, on PANEU FPQ (Ambrus et al, 2013) and, on the other hand, on recommendations given by AECOSAN staff working in different areas of food safety and nutrition.

Other questions related to the consumption of organic (bio) products and food hygiene practices were in this FPQ questionnaire. These questions were previously included in the general questionnaire, according to the PANEU recommendations, but were moved after the pilot, because they fitted better among food related questions.

3.2. Dietary recall

A 24 hour dietary recall for the previous 24 hours was used. Information on food consumption per day, per meal and in between meals was recalled.

The recall was conducted using specific software (described in section 3.2.3) in computer-assisted interviews by trained interviewers and by nutritionists/dieticians with Associate Degree in Dietetics and Nutrition.

Participants, helped by the 24 hour recall template, were asked about the different eating occasions, place and time of the meal. Interviewers also made specifics questions on food items that could be easily forgotten, such as bread, water, oil, etc.

In order to assess chronic exposure, dietary information was collected for two non-consecutive days with at least two weeks interval between them.

3.2.1. Food description

For food description and codification purposes, the FoodEx2 classification system of EFSA (EFSA, 2015) was used. It was already implemented in the previous ENALIA survey. Browser and catalogues were regularly checked, following up EFSA's system updates, and applied in the Spanish food list.

Composite dishes[2] (e.g. paella, casserole) were disaggregated into their ingredients according to standard recipes. Foods were classified at raw (edible part) and at ingredient level.

Industrial products (i.e. cakes, sausages etc.) that do not fall under the composite dishes category of FoodEx2 were not disaggregated.

When it was necessary for describing the item in FoodEx2 system in the best way, facets were added to the main code, such as preservation process (e.g. canned, smoked, etc.), qualitative information (e.g. light, lactose free, gluten free, etc.), etc.

The software included an open database with 1020 codified food items. This number includes the previously codified plus the new items that appeared along the survey. When a new item appeared, it was codified and included in the database. 794 items were reported to have been consumed during the survey.

3.2.2. Determination of portion sizes

Consumed amounts of food were estimated by means of a Spanish picture book, complemented with household measures and standard recipes.

In the picture book 53 different food products and simple recipes were represented by series of pictures. These pictures were used not only for estimating the food represented, but also others with similar size and shape, e.g. legumes, fruits or vegetables. This condition is explained in the photo series and it is taken into account in weight calculations. Depending on the product, each of the series included from 4 to 6 different portion sizes.

[2] General principles for the collection of national food consumption data in the view of a pan-European dietary survey (EFSA, 2009)

1.4.1. Food description

In general, it is important that foods consumed are described in detail and that industrially produced composite foods or home-made dishes, such as a ready-made frozen pizza or a home cooked beef stew, are disaggregated as much as possible into their main ingredients at a level that can be reported by the subjects.

The picture book was validated (perception) for the ENALIA survey (Marcos Et al, 2015), by the parents of the participating children, and its applicability was verified in the ENALIA 2 pilot. It was available as digital image during the interview and it was uploaded to AECOSAN website.

A database has been built containing weights of each of the portions represented in the atlas. Depending on the product, data of weight of more than 200 different household measures or commercial units (spoon, glass, pinch, handful, drops, bottle, can, slice, etc.) were also included. Finally, some food weights were available from manufacturer's information (tins, beverages, pre-packaged foods, etc.).

3.2.3. Dietary software

ENIA-Soft is a software designed for data collection during 24 hour recall dietary interviews, besides other information. The first software version dates back to 2001; since then, it was used in several surveys (among others, in the ENRICA research - National Survey on Cardiovascular Risk- in 2007-2008). It was adapted to fulfil this project objectives, especially concerning to food codification and quantification. The current version was validated during the pilot phase of the ENALIA survey on children and adolescents.

The software guides the user during data collection, facilitating the homogenous collection of information.

Considering that quantification is a key factor for the accuracy of food consumption data, the software has integrated the picture book, standard recipes and the database with all food weights and household measurements. The pictures were used for the correct identification of the dishes, which were then disaggregated into their ingredients according to standard recipes. It was possible to adapt a standard recipe to the ingredients that are really present in the dish.

The food list, with coded items, was included in the software, which was also prepared to collect any new food or recipe not initially included in the database with the possibility to incorporate it afterwards.

In addition, ENIA-Soft includes a database with the energy and macronutrients food composition. Therefore, it is possible to calculate energy and some nutrients intake which allows a quality control of the interview.

This software has the ability to collect:

- General questionnaire, where all information about the home and socio demographics is kept
- Food Propensity Questionnaire
- Dietary 24h recall
- Anthropometry, collection of information regarding weight, height and other measurements
- Physical activity

ENIA-Soft is equipped with an on line update system. The backup copy of the databases provides security from the harmful data lost.

3.3. Other information

3.3.1. Questionnaires

Socio demographic information

A general questionnaire included questions such as the place and date of birth, country of origin, academic level, and profession.

Moreover, questions about health status are included: special diet, any drug, prescribed or not, chronic or acute diseases, etc.

Physical activity

The level of physical activity of the people participating in the survey was measured using the International Physical Activity Questionnaire (IPAQ) (Hagstromer, M. et al., 2008).

3.3.2. Measurement of body weight and height

Trained staff collected body weight and height data at the home of the interviewee. The tools used were validated in previous studies in Spain.

Height and weight were measured using protocols adapted from Measurement Protocols in Recommendations for the Health Examination Surveys in Europe (Tolonen, 2013). The examination results were saved in the study database using ENALIA-soft.

A validated stadiometer was used to measure height. It was measured in centimetres (accuracy 0,5

cm).

Participants were weighed in kilograms using a validated digital weight scale (accuracy 0,1 kg).

3.3.3. Food supplements

Besides data on food supplements collected during the 24 hour recall (name, brand name, strength and amount taken), the food propensity questionnaire also included one section to collect information on their consumption.

Tables 1 and 2 describe the percentage of consumers obtained from the FPQ.

Table 1: Percentage of vitamins and minerals supplements consumers (through the FPQ)

	Vitamin mineral supplements Consumers	
	n	**%[(a)]**
General population	110	13.3
Pregnant women	132	91.7

(a): Related to population
Vitamin A, Vitamin D, Vitamin A+D, vitamin C, Iron, Calcium, and multivitamin and mineral supplements

Table 2: Percentage of vitamins and minerals supplements consumers by age and sex (through the FPQ)

	General Population						Pregnant women	
	Men		Women		Total			
	n	%[(a)]	n	%[(a)]	n	%[(a)]	n	%[(a)]
18 – 39 years old	20	54.1	24	32.8	44	40	--	--
40 – 64 years old	5	13.5	18	24.6	23	21	--	--
65 - 74 years old	12	32.4	31	42.5	43	40	--	--
Total	37		73		110		132	91.7

(a): Related to consumers

4. Administration of the interview

4.1. Selecting the examination site

Face to face interviews and anthropometric measurements were done at the participants' home. No remarkable incidents were observed.

4.2. Content and organization of the study visits

The organization of the interviews and visits prioritized the achievement of an adequate response rate and it is partially described in section 2.5.

The individual survey began once individuals confirmed their agreement to participate, after the initial contact by phone and the letter by post. This letter also included the general questionnaire and the first 24 hour recall. Then, the process was organized according to the following phases:

a) First phone call (general questionnaire)

b) Second phone call (first dietary recall)

c) Third phone call (to set the visit at home)

d) Home visit

4.2.1. First contact

A phone call was done to conduct the general questionnaire. Participants also received a thorough explanation of what the 24 hour recall was and recommendations to avoid forgetting consumption events and taking note of the place of the meal.

During this phone conversation, a date was set to perform the first 24 hour recall (even though it would be preferred not to warn the interviewee to avoid bias, our experience showed that otherwise it was very likely not to find the interviewee at home).

The average length of this phone call was eight minutes.

4.2.2. First interview

Despite EFSA's guidance (EFSA, 2009) recommendation to have the first interview carried out at home, ENALIA survey and ENALIA2 pilot study showed that refusals were lower if the first dietary

interview was made by phone and the second at home, because people were then more confident, the access to homes was easier and fewer refusals were made.

It was also noted that one previous phone call was necessary to explain the instructions to complete the 24 hour recall features.

The first 24 hour recall interview was done using CATI (computer – assisted telephone interviewing). The specific ENIA-soft was used for data registering. At the end of this interview, of 20 minutes average length, an appointment was set for the home visit after 14 days.

4.2.3. Second interview

The second 24 hour recall interview was made at the interviewee's home. As mentioned before, the access to participants' homes was easier after previous phone conversations. In addition, prior to the home visit, a reminder phone call was made.

During this visit:

- Weight and height measurements were performed
- A computer-assisted interview was carried out to complete the 24 hour recall
- The food propensity questionnaire was completed
- The physical activity questionnaire was completed

The interview lasted 42 minutes on average.

For this step CAPI technique (Computer-Assisted Personal Interviewing) was used.

4.2.4. Interviewing and checking questionnaires

a) Phone interview: General questionnaire, first 24 hour recall

During the phone interviews, done with CATI system, the supervision process was simultaneous with the work during all the process. Each and every one of the interviews could be listened to and viewed in a screen as they were performed. Interviews were also recorded and written reports were generated.

During this process the correct way of making questions was checked and causes of possible incidents were also controlled.

There was also an inconsistency-check plan in place that allowed the detection of mistakes in real time, warning the interviewer about possible mistakes or inconsistences in answers during the current interview. The interviewer could immediately see these warnings in the screen, he checked the situation and reposed the question.

b) Second 24 hour recall (CAPI), Food propensity questionnaire, Physical activity

Interviewers visiting homes were provided with laptops. Face to face interviews were carried out with the ENIA-Soft application.

c) Weight and height measurement

Weight and height were measured at the participants' home, as described in 3.3.2. Anthropometric data were registered in ENIA-Soft.

d) Checking and supervision

In addition to the supervision tasks, previously pointed out, the supervision plan included:

- In a random and continuous way the work of every interviewer was supervised

- At least 20% CAPI interviews were supervised by calling the participant to verify that the visit was done, the correct questionnaire was filled in and the anthropometric measurements were taken
- At least 15% of every interviewer work was supervised. When inconsistencies were detected in an interviewer work, the supervision increased and, if necessary, this work was repeated

If there was any doubt or mistake when revising the questionnaires, the participant was called again to check the answers and the interviewer work was also checked.

4.3. Recruitment and training of the staff

4.3.1. Selection of the fieldwork staff

Every interviewer had experience in conducting dietetic interviews computer assisted, phone or face to face interviews. At least 5 years of experience in CATI was also a selection criterion.

Interviewers were recruited from every geographic area. This allowed them to be regional language speakers, trained in local foods and dietary habits. In addition, interviews could be carried out in all the Co - official Spanish Languages if participants ask for it.

4.3.2. Training

The same staff that conducted the ENALIA survey in children and adolescents carried out the ENALIA 2 survey. Therefore, after having received training, they had a valuable experience in ENIA-soft and other tools, such as questionnaires and portion size measurements.

Nonetheless, they followed a specific training session (one day), on how to conduct interviews on elderly people, to be more helpful for this group of population.

5. Quality assurance

Previous to the survey, as a part of the quality assurance, a pilot study was done to test the methodology, questionnaires and tools.

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

- Organization of the survey
  - Tasks, competences and responsibilities of all personnel were well defined
  - Qualified personnel participated in each step of the survey
  - Communication between different teams and members was previously organized, but specific meetings were arranged when necessary
- Sampling
  - Sampling protocol ensuring representativeness
  - Response and non- response rate was controlled
- Field work
  - Trained interviewers: Only interviewers with previous experience participated
  - Calls were made by staff with experience in this type of work and trained for this specific study. Every phone interview could be listened on line by a supervisor

- Details on field work supervision are given in section 4.2.4.d

- Data entry
  - Some inconsistencies were considered in the software in order to avoid the collection of erroneous data
  - Screen warnings appeared when there were inconsistencies or partially erroneous data (height over 2 m, weight over 100 kg, etc.)
  - The software also included a system of identifications and codes that prevented from duplicities or from assigning the data to a different individual
- Data cleaning

A dietician checked randomly 70% interviews, looking for inconsistencies in food consumption data like the following:

  - Very high (e.g. 300g of breakfast cereals) or very low consumption amounts
  - Food items related to specific eating occasion (spaghetti for breakfast, breakfast cereal at lunch time)
  - The same food is eaten several times a day (e.g. the same fish or the same meat)
- Anthropometric measurements
  - A protocol for collecting anthropometric data was followed
  - Quality control of devices: instruments were validated
- 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 were compared with standard or commercial portions, recipes, recommendations, etc.

- Energy and macronutrient intakes

Energy and macronutrient intakes were checked as a final control. The estimated energy and macronutrient intakes were compared with standard requirements calculated for the age and sex of the subject. Ranges of energy and macronutrient intake by meal were set. Data out of the expected ranges were checked and a contact with the interviewee was made if any doubt arose.

6. Data management

The data management process was designed bearing in mind that the reliability of the information collected were ensured from the field work, carried out by interviewers, to the final users of the consumption data gathered in the survey.

- All the staff and field workers were affected by the Spanish law of protection of personal data
- Every user of ENIA-soft had a personal identification and password. Moreover, different levels of access were established: e.g., only interviewers were allowed to data entry
- Code numbers were assigned to each participant and personal data were allocated in separate files than those containing other information. Each instrument of data collection: General questionnaire, FPQ, 1st and 2nd 24hR, etc. generated an independent database, which can be only related by means of the participant code

- Even though only few people were allowed to make changes in data previously introduced, ENIA-soft, as a part of quality control, registered any change done in any datum (person, date, etc.)

- The software was provided with quality checks assuring that no data is missing and that it was not possible to have unknown quantities

- There were different codes for every intake: breakfast, lunch, dinner, between meals, etc.

- Food items were codified using two systems (ENALIA2 code + FoodEx2). As FoodEx2 codification follows an on-going implementation process, both systems were overlapped, preventing items from having inadequate codes due to FoodEx2 improvements

- Information collected during the interviews, either by phone or face to face, were on line transferred to the host system and systematically backed up.

7. Dissemination and publicity

The Ministry of Health, Social Services and Equality and Spanish Agency for Consumption, Food Safety and Nutrition web pages and newspapers were used for advertising with the aim that most population knew about the survey.

The results of the survey will be disseminated by means of presentations and short publications. Statistics in relation to food consumption data of the studied population will be included in the AECOSAN website.

It is foreseen that individual food consumption data, obtained in ENALIA2 survey, will be available for institutions involved in research, risk assessment, nutritional studies, etc. Terms of use will be bound to the signature of specific agreements.

8. Special issues/challenges

As in the previous ENALIA survey, some preventive actions were implemented, intending to minimize problems along the survey:

- The participant was not at home when visited; it was previously considered as a challenge, as it is explained during first contact (4.2.1)
- Variability in answers versus standard recipes; the dietary software included a number of standard recipes covering the variability of Spanish dietary habits. Nonetheless, the software allowed any change in non-essential ingredients of the recipes
- Variability in naming foods-Food dictionary; regarding the linguistic variability in the country many food items received different names depending on the region. It was solved by including in the Software a dictionary of foods previously revised
- Avoid easily forgetting foods; the software was structured with specific probes to help the respondent to remember all foods consumed throughout the day in the case of 24h recall. At the end of the interview there was a checklist with foods or snacks that might be easily forgotten (water, salt, snacking, seasoning,etc.)
- To avoid the possible bias due to different purchasing power along the month, the sample was distributed uniformly over the weeks.
- The survey showed a lower response rate in comparison with the observed in children and adolescents. The main reason for people refusing their participation was not being interested in the study. They explained about the lack of time for answering the phone. Evenmore, they were more reluctants to receive interviewers at home than parents in ENALIA. Nevertheless, it was not considered a matter of concern, as it was seen a participation rate over 53%, similar to the obtained in surveys in other European countries.

Conclusions

ENALIA2 is a dietary survey conducted in Spain to collect food consumption data and other information about eating habits and physical activity on adults (18 – 64 years old), elderly (65 – 74 years old) and pregnant women (oversampled).

AECOSAN considers very positive and fruitful the participation in the EU Menu Project. This is because of the technical experience gained in terms of methodological harmonization and the inclusion of the Spanish data in the EFSA Comprehensive European Food Consumption Database.

At national level, ENALIA2 survey has provided valuable food consumption data, because of the population groups it included, the standardization of the methodology and its quality assurance. These data will very useful, mainly for national risk assessment purposes and for nutritional studies. Besides, it is foreseen that they are used for some dietary recommendations for the most vulnerable population groups.

The main conclusions of this study are described below.

- Methodology
    - The survey followed the EFSA Guidance recommendations on the General principles for the collection of national food consumption data in the view of a pan-European dietary survey" (EFSA, 2009). No major deviation from the guidance or technical specifications was required
    - The adaptation and design of different tools were made taking into account PANEU Project recommendations (Ambrus et al, 2013). PANEU tools showed to be very useful
    - The previous experience of the company in conducting public health related surveys and national food surveys was very important for the management of the survey
    - Previous experience on ENALIA in children and adolescents and conclusions from the pilot study were essential for the development of the project
- Response rate
    - The achieved response rate (MEDIA RATIO) was 53.4 % in general population and 80.1% in pregnant women
- Consumed amounts
    - Consumed amounts were estimated using a validated Spanish picture book, together with household measures and portions indicated in standard recipes
    - Household measures and picture book showed to be very useful tools
    - The possibility of consulting the picture book in AECOSAN webpage showed to be very convenient and attractive for participants. Besides, calculations were very accurate
- Food classification system
    - Using Food classification system FoodEx2 implies a big effort and dedication. However, the opportunities that this system offers towards harmonization worth it.

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Abbreviations

AECOSAN	Agencia Española de Consumo, Seguridad Alimentaria y Nutrición Spanish Agency for Consumer Affairs, Food Safety & Nutrition
CAPI	Computer-assisted personal interviewing
CATI	Computer-aided telephone interview
EFSA	European Food Safety Authority
EGFCD	EFSA Expert Group on Food Consumption Data
ENIA-Soft	Ad hoc designed software for the data collection in 24 hour recall dietary interviews and one day diary
ENALIA	Encuesta Nacional de Alimentación en la población Infantil y Adolescente National food survey in children and adolescent population
FoodEx2	Food classification and description system
FPQ	Food propensity questionnaire
INE	Instituto Nacional de Estadística (National Institute of Statistics)
IPAQ	International Physical Activity Questionnaire
NDA	Panel on Dietetic Products, Nutrition and Allergies (EFSA)
PANEU	Pilot study in the view of a Pan-European dietary survey— adolescents, adults and elderly" (PILOT-PANEU)
WMA Declaration of Helsinki	Ethical Principles for Medical Research Involving Human Subjects

Appendix A – Sampling distribution and response rate

Table 3: Sampling distribution and response rate by trimester and stage of the study

	1st trimester[(a)]		2nd trimester[(b)]		3rd trimester[(c)]		4th trimester[(d)]		Total	
	n	%	n	%	n	%	n	%	n	%
Contacted	418		353		393		334		1498	
General questionnaire	237	56.7	236	66.8	253	64.3	207	62.0	933	62.3
1st 24 h. recall	219	52.4	220	62.3	212	53.9	173	51.8	824	55.0
2nd 24 h. recall	212	50.7	220	62.3	201	51.1	167	50.0	800	53.4

(a): Summer
(b): Autumn
(c): Winter
(d): Spring

Table 4: Sampling distribution and response rate by age group and stage of the study

	18 -39 years old		40 – 64 years old		65 – 74 years old		Total	
	n	%	n	%	n	%	n	%
Contacted	505		518		475		1498	
General questionnaire	314	62.1	309	59.7	310	65.3	933	62.3
1st 24 h. recall	278	55.1	272	52.5	274	57.7	824	55.0
2nd 24 h. recall	270	53.5	266	51.4	264	55.6	800	53.4

Table 5: Sampling distribution and response rate by age group, gender and stage of the study

	18 -39 years old				40 – 64 years old				65 – 74 years old				Total	
	Men		Women		Men		Women		Men		Women			
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Contacted	278		227		257		261		230		245		1498	
General questionn.	162	58.27	152	66.96	154	59.92	155	59.39	152	66.09	158	61.49	933	62.30
1st 24 h. recall	146	52.52	132	58.15	133	51.75	139	53.26	136	59.13	138	56.3	824	55.00
2nd 24 recall	140	50.36	130	57.27	130	50.58	136	52.11	136	56.96	131	54.29	133	53.40

Table 6: Sampling distribution and response rate by gender and stage of the study

	Men		Women		Total	
	n	%	n	%	n	%
Contacted	765		733		1498	
General questionnaire	468	61.18	465	63.44	933	62.30
1st 24 h. recall	414	54.12	410	55.93	824	55.01
2nd 24 h. recall	401	52.42	399	54.43	800	53.40

Table 7: Pregnant women. Sampling distribution and response rate by trimester and stage of the study

	1st trimester[(a)]		2nd trimester[(b)]		3rd trimester[(c)]		4th trimester[(d)]		Total	
	n	%	n	%	n	%	n	%	n	%
Contacted	33		40		46		47		166	
General questionnaire	30	90.9	37	92.5	44	95.6	46	97.9	157	94.6
1st 24 h. recall	27	81.8	33	82.5	39	84.8	45	95.7	144	86.7
2nd 24 h. recall	25	75.8	31	77.5	37	80.4	40	85.1	133	80.1

(e): Summer
(f): Autumn
(g): Winter
(h): Spring