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1 Project objectives

1.1 General project objectives

The overall objective of EFCOVAL was to continue the work initiated by EFCOSUM (Löwik and Brussaard, 2002) and to further develop and validate a trans-European food consumption method to be used for the evaluation of the intake of foods, nutrients and potentially hazardous chemicals within the European adult population. Starting point of EFCOVAL was the recommended method by EFCOSUM i.e. the collection of 24-hour recalls to obtain reliable and comparable data from European countries using the computer assisted interview program EPIC-Soft. The main activities of EFCOVAL focussed on three main objectives i.e. 1) the upgrade, adaptation, and validation of the repeated 24-hour recall method using EPIC-Soft; 2) expanding the applicability of the upgraded software program to younger age groups and for use in exposure assessment and 3) to improve the methodology and statistical methods that translate short-term dietary intake information to usual intake estimates. In this third objective also the issue of the quality of the data in order to give information on the error in the estimate was addressed.
Project execution

The EFCOVAL project was carried out by 13 institutes from 11 European countries. Activities of the project included validation and feasibility studies, desk research, plenary sessions and workshops. All participating institutes contributed to one or more specific objectives. The results of the activities contributed to papers which will be published in a special issue of the European Journal of Clinical Nutrition.

List of EFCOVAL participants and responsibles

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2 The upgrade, adaptation and validation of the repeated 24-hour recall method using EPIC-Soft

EPIC-Soft has originally been developed in the early nineties and needed to be more flexible for future use in the European context and required adaptation to modern computer systems. An inventory was made of problems experienced in applying the EPIC-Software in nutrition surveillance which was followed by the adaptation of EPIC-Soft, resulting in a software programme working under Windows conditions. Furthermore within EFCOVAL the concepts of a platform for the maintenance, setting and dissemination of EPIC-Soft (EPIC-Soft Methodological Platform) was developed.

The 24-hour recall within EPIC-SOFT has been developed and validated for the nine countries (Denmark, Greece, the Netherlands, Germany, France, Italy, Spain, and Sweden) of the IARC-coordinated EPIC study (Slimani et al. 2003). More recently, the software has been used and adapted for Nutrition Surveillance in a few countries (Netherlands, Belgium, Germany and Spain). In EFCOVAL we substantiated the validity of the24-hour recall used in EPIC-SOFT for the intake of foods and nutrients for Nutrition Surveillance purposes relevant to health and safety policy in Europe.

2.1 Starting point and progress towards objectives

2.1.1 Transfer of knowledge and support to implement the EPIC methodology

Most of the transfer of knowledge was performed during year 1 as basis for other activities within EFCOVAL. This transfer of knowledge included providing the EFCOVAL network with the pre-existing EPIC-Soft versions and its related tools for 4 out of 5 of the countries participating in the validation studies, as well as all the guidelines to use it and update its databases according to EFCOVAL specific needs.

In the first year of the project instructions for a training period and data collection using EPIC-SOFT ('Instructions for a training period and data collection using EPIC-SOFT'). A 'train the trainers' workshop was prepared and given. In the second year, a document with instructions on cleaning interviews, which is done during the data collection for the validation studies and this document was distributed in February 2008 ('guidelines for the coordinating dietician and data manager'(confidential)) and made available to the partners in the validation study. In the first two years of EFCOVAL, a document was prepared with instructions on linking the reported foods with data from the national food composition database for the countries that have performed a validation study in EFCOVAL ('instructions to match the EPIC-SOFT food occurrences to nutrient databases', (confidential)). Knowledge transfer on the training and data collection using EPIC-SOFT was also part of the two-day workshop preceding the closing conference of Efcoval, on 7 and 8 September 2009.

Although most of the transfer of knowledge was done during the first year of the project, a continuing transfer of knowledge of the EPIC dietary methodology was necessary during the second and third year of the project as well. During the 3rd year this was done outside EFCOVAL during the closing conference of EFCOVAL, on 7 and 8 September 2009 and several other international scientific conferences (as invited speakers) and other meetings. A secondary task was the revision of existing EPIC-Soft related documents (guidelines/courses/manuals) according to changes requested within the EFCOVAL project.

The EFCOVAL consortium prepared a scientific paper on
Potential and Requirements for a Standardized Pan-European Food Consumption Survey Using the EPIC-Soft Software, Ocké, M. C. et al. Eur. J. Clin. Nutr. (in prep.).
This paper summarizes the potential and limitations of EPIC-Soft as a dietary assessment tool for pan-European food consumption surveys. This is followed by a description of the requirements for national and international organisations that consider to initiate or to participate in a pan-European survey with EPIC-Soft

as dietary assessment tool. Moreover, possibilities and barriers for harmonization of national food consumption surveys in the view of pan-European food consumption monitoring are listed and discussed.

2.1.2 Upgrade of the EPIC-Soft program for pan-European dietary monitoring

The EPIC-Soft program has been initially developed to collect interactive and comparable dietary interviews among the 10 countries participating in the EPIC international epidemiological study (France, Greece, Norway, Denmark, Germany, Sweden, the Netherlands, the United Kingdom, Italy, Spain). However, additional developments and improvements are needed to adapt the software to specific requirements of pan-European monitoring surveys and make its maintenance independent of EPIC logistics.

a) Inventory of the additional requirements of trans-European dietary monitoring surveys (gathered from EFCOVAL consortium, other EPIC-Soft users and meeting with experts)

In order to gather exhaustive and relevant information on how to improve the EPIC-Soft program, an ad hoc "EPIC-Soft specifications questionnaire" was developed and circulated to different past, current and future possible users of EPIC-Soft within and outside the EFCOVAL network. The list of new specifications obtained through this questionnaire is summarized in an exhaustive report "EPIC-Soft new specification list".

b) Adapting EPIC-Soft to modern IT standards (i.e. technical update to Windows environment)

A complete reprogramming of the software application into a modern IT environment was done. Following an audit of a specialized IT SME, the software was moved from MS-DOS to Windows standard operating systems (XP, W7…) using the framework 2.0. The database management system was also completely reviewed and moved from DBase to the professional and freely available SQL server express 2005 or 2008. It is also possible to use the licensed SQL server 2005 or 2008. The outdated program language ("Clipper") was changed by C# language using Visual studio 2008 as development environment and object-oriented development tools.

The reprogramming considered a new architecture in tree layers: 1) the data layer, 2) the business layers and, 3) the user interface. This approach is expected to give more flexibility and should facilitate possible future adaptations of the software (e.g. addition of new specifications and/or functions, using it as a data entry tool, a web-based application). An international character set (languages "Unicode") makes it now possible to use special characters (e.g. Cyrillic, Chinese).

c) Development of the software specifications according to the existing structure and definition of the software (conceptual definitions)

Each new specification was evaluated and conceptual and technical solutions were developed during internal technical meetings at IARC and in collaboration with internal and external software developers. Once the technical solutions were developed, each new specification was evaluated according to pre-defined criteria including its degree of (technical) complexity, relevance and priority (mandatory vs. optional). Based on the outcomes of this evaluation, a proposal on the specifications to be implemented in EPIC-Soft was drafted. Two Task Force Groups (TFG), "End-user" and a "Database and Software developer", were established, who gave valuable input for finalizing the technical solution proposal and tested intermediate and end releases of the software.

d) Implementation of new functionalities to the software (computer programming)

For the technical implementation of the specifications, a specialized IT company and individual developers involved in the previous development in EPIC-Soft were recruited. All software development activities were coordinated by IARC. A series of new specifications was added to customize EPIC-Soft more easily and adapt it to specific study aims and needs. In total, 63 new specifications have been implemented to EPIC-Soft. The implemented specifications underwent several usability tests, where feed-back and comments from the two TFG were considered for further refinement and amendment of bugs.

e) Development of additional EPIC-Soft modules for independent maintenance of the country-specific databases and for centralized upgrading (conceptual definitions and computer programming)

Initially it was foreseen to develop a tool for the independent maintenance of the databases which were so far handled outside EPIC-Soft. In addition, we were committed to provide the conditions and the overall conceptual infrastructure to facilitate long-term maintenance and dissemination of the EPIC-Soft methodology. As a result of our internal methodological discussions, taking into account new knowledge acquired during the course of the project, it appeared that the development of a maintenance tool should be an integrated part of a web-based methodological platform (so-called EPIC-Soft Methodological Platform, EMP) proposed as the best cost-effective solution to ensure long-term management, dissemination and standardisation of the whole EPIC-soft methodology.
The available resources have therefore been put as a first priority into the conceptual development of a comprehensive web-based platform (EMP), which will not only include the EPIC-Soft application but a series of other modules, including the EPIC-Soft module for independent maintenance to support the access and use of the whole web-based EMP, particularly international study contexts.

Methods, results and discussion of the adapted EPIC-Soft software have been described in a scientific paper *Slimani N. et al Adaptation of the standardized computerized 24-hour dietary recall method EPIC-Soft for pan-European dietary monitoring. Eur. J. Clin. Nutr. (in prep.).*

2.1.3 Upgrade and test of the country-specific EPIC-Soft versions

For the five countries involved in the validation study, 4 updated country-specific EPIC-Soft versions were prepared BE, NL, N, and FR while a new version was prepared for CZ (i.e. the first EPIC-Soft version of an Eastern European country). All work was carried out during the first and second year of the project.
The update process included the development of instructions for the preparation of EPIC-Soft country-specific files (preparation/update of 60 databases) for the countries that performed a validation study in EFCOVAL.
A proposal on the changes for the databases to be used in the validation study was made. Final decisions for the EPIC-Soft versions in the validation study were taken in the first year. The most important changes were:
- Treatment of soups as recipes rather than foods
- Added facet on biological production
- New descriptors in facet flavour (especially raspberry and other berries)
- Systematic use of bread shapes to quantify the sizes of bread slides
- Use of photo booklets rather than full EPIC photo album

2.1.4 Validity of the 24-hour recall method using EPIC-Soft

The validation study was performed in 5 selected countries (BE, CZ, FR-South, and NL) already familiar with nutrition surveillance using the 24-hour recall method. The selection of countries was based on the following criteria: geographical position in Europe, possession of a national food composition database, experience with the performance of nutrition surveys, and the ability and willingness to participate in the testing of the new instrument in their country in the framework of the validation study. Because of cost-efficiency reasons, 4 countries already had a country specific version of EPIC-Soft. Two of these countries had a recent version of the program, and two other countries had a version that needed to be updated. One country (CZ) had not yet a country specific version of the EPIC-Soft program.

In every country included in the validation study two adult populations (men and women) with different food patterns were chosen, e.g. including two different age groups (45-65 years). The study validated the computerized two-day 24-hour recall using EPIC-Soft for comparisons of nutrient and food intakes with the use of biomarkers in 24 hr urine collections and in blood samples.

a) Collection of food consumption data and conversion into nutrients.
In the Netherlands food consumption data have been collected between April and July 2007. In Belgium, Czech Republic, France and Norway collection of food consumption data took place between October 2007 and April 2008. In total, food consumption data were collected from 599 subjects. Training of the

responsible person of each country who would train the dieticians for the recalls has taken place on 24-09-2007.

b) Collection of biological samples

In the Netherlands biological samples have been collected between April and July 2007. A blood sample of about 18 ml has been collected from each participant. Each subject has collected two 24-hour urine samples. The urines cover the same day of exposure as the 24-hour dietary recalls. In Belgium, Czech Republic, France and Norway collection of samples took place between October 2007 and April 2008. The final version of the "specimen collection, storage and transport protocol" has been send to the centres on 06-09-2007. The shipment of all blood and urine samples to Wageningen University was completed mid June 2008 by all partners.

Chemical analysis of the samples from the 5 countries and analysis of the calibration samples started in June 2008 and all analyses were finished by March 2009. We originally planned to measure (n-3) fatty acids in cholesteryl esters as biomarker of (fish) intake. However, it appeared that fatty acids have been measured in the phospholipid fraction of plasma in EPIC. We therefore decided to measure fatty acids in phospholipids in EFCOVAL instead of fatty acids in cholesteryl esters. Originally Dumas analysis was planned for urinary nitrogen. Because instability of the Dumas machine caused delay of the analysis and poor precision, we decided to analyse all samples by Kjeldahl.

c) Calibration with EPIC data.

Serum carotenoids, fatty acids in phopholipids, and urinary nitrogen and potassium have been measured in the EPIC and in the EFCOVAL study. To ensure comparability of the laboratory methods used in EPIC and EFCOVAL, a calibration study has been conducted with orphelin samples from 100 EPIC subjects. These will be analyzed for carotenoids and fatty acid patterns, both at IARC and in Wageningen. For calibration of urinary analyses of nitrogen and potassium, the laboratory characteristics are more favorable, and analysis of 45 samples in two labs (Wageningen, Cambridge) will suffice.

Exchange of SOPs and design of the laboratory calibration work plan was finished in April 2008. Simultaneous analysis of the calibration samples and EFCOVAL specimen has been completed by March 2009.

Analyte	Sample origin	Lab - Method		Number of samples
Urinary N	EPIC subject	MRC-Kjeldahl	WUR-Kjeldahl	45
Urinary K	EPIC subjects	MRC-Flame Photometry	WUR-K selective electrode	45
Serum carotenoids	EPIC orphan samples	IARC-HPLC	WUR-HPLC	100
Fatty acids phospholipids	EPIC orphan samples	IARC-GC	WUR-GC	100

d) Determination of validity

The complete data of the EFCOVAL validation study consist of two datasets and a codebook. The first EFCOVAL database contains 24h recall data per food per day per person and consists of 71,014 foods and 56 variables. The second EFCOVAL database contains information on all 392 variables per person per day for 600 subjects.

Methods, results and discussion have been described in two papers on the validation study; one on nutrients and recovery markers and the other one on foods and concentration markers.

Crispim, S. P. et al.(2010): Two Non-Consecutive 24 h Recalls Using EPIC-Soft Software Are Sufficiently Valid for Comparing Protein and Potassium Intake Between Five European Centres - Results From the European Food Consumption Validation (EFCOVAL) Study. Br.J.Nutr. 1-12.

Crispim, S.P. Biomarker-based evaluation of two 24-h recalls (EPIC-Soft) for estimating and comparing fish, fruit and vegetable intakes across five European centers: results from the European Food Consumption Validation (EFCOVAL) study. Eur. J. Clin. Nutr.(in prep.).

3 Expanding the applicability of the upgraded software program to younger age groups and for use in exposure assessment

EFCOSUM concluded that the collection of repeated 24-hour recalls using EPIC-Soft was suitable for subjects of 15 years and older. Children need specific methodology and are not (yet) fully covered. Based on desk research and expert meetings a trans-European methodology therefore was defined for assessing of usual daily intake of food and beverages in dietary surveys among children (EFCOVAL-CHILD).

The objective of trans-European food consumption monitoring is to provide information on the intake of foods, nutrients and potentially hazardous substances (food safety issues). However, EPIC-Soft was not developed for the latter. Within EFCOVAL attention was given to the adaptations of EPIC-Soft that are needed to collect information in such a way that food safety issues can also be handled. To achieve this objective the critical aspects of existing datasets for the assessment of dietary exposure to potentially hazardous substances were identified.

3.1 Starting point and progress towards objectives

3.1.1 Workshop on methodology and description of the recommended EFCOVAL-Child method

The main aim of the workshop was to define or recommend specific requirements to assess dietary intake among children aged 4-12 yrs. The workshop was held 24-25 May 2007 in Copenhagen, Denmark. In total, 27 persons from 13 European countries and USA attended the workshop. Besides the invited speakers and representatives from the EFCOVAL child project, invited experts, representing 7 different European countries, participated.
The workshop resulted in a comprehensive description on advantages and disadvantages of the two main dietary assessment methods (24h recalls and food records in relation to two age groups: 4-10 years and 11-14 years) and how to deal with problems and challenges. The age range was extended to 14 years, since the method, which is going to be validated among adults, was recommended in the EFCOSUM report from the age of 15 years.
After the workshop it was discussed which method to suggest for testing. The workshop did not reveal one obvious method to choose, but after some discussion, it was decided to suggest and test two methods for children aged 4-14 years:

- For school children: a method combining 2x24h recall and a food registration scheme (or booklet) for foods eaten away from home was suggested.
- For surveys on preschoolers: 2x1 day food record was suggested.

It was decided to use EPIC-Soft for data entry of the 24h recalls and also of the food records, if possible.

A scientific paper on the specific requirements needed to assess dietary intake of children with a trans-European method and presenting the suggested method of EFCOVAL-Child was written
Andersen, L. F. et al. Recommendations for a trans European dietary assessment method among children and adolescents. Eur. J. Clin. Nutr. (in prep.).

3.1.2 Feasibility and relative validation study of the recommended EFCOVAL child method

The recommended method was tested in a feasibility study in two selected EU countries (e.g. Denmark and Spain). The feasibility study resulted in recommendations for a pan-European approach.

For the feasibility study the EPIC-Soft versions of Denmark and Spain were updated.
The overall plan for pilot testing and validation was changed in the first year of the project .

Due to the challenges on the methods revealed at the workshop (e.g. how do we get reliable data on foods eaten away from home?) there was a need for focusing on the feasibility in the pilot testing, in order to be able to point out how to improve the method before conducting a final validation study in several European countries. In addition, conduction of a final validation study would benefit in awaiting the results of the validation study among adults. Financing of such a validation study was beyond the EFCOVAL project and should be applied for separately at the end of the EFCOVAL project.

Therefore it was decided to focus on the pilot testing in Spain and Denmark. The pilot needed to provide:

a. Concrete requirements for updating the EPIC-Soft for children
b. Concrete guidelines on the use of the method for the specific age group and
c. Description of the final validation study to be performed in a future project.

In order to fulfil the objectives of EFCOVAL child project and complete a relative validation/evaluation of the suggested method it was decided to include in the pilot study in Denmark an evaluation of the estimated energy intake against energy expenditure measured by the objective Acti-Reg measurement. Furthermore, the pilot testing results (selected food intake, energy intake and nutrient intake) were evaluated (only in DK) against results from 7 day food records, which is the method of the Danish national dietary survey.

The overall plan for pilot testing and validation was changed in the second year of the
It was decided that it was necessary to concentrate on one of the two methods, due to financial and time constraints.

Since the challenges of the method (for instance on estimating the foods eaten out of home) are most pronounced for the 24-hour recall compared to the food record method, it would be more scientifically interesting to investigate the feasibility of the 24-hour recalls. Therefore the EFCOVAL child partners decided the following plans for testing the method:

- To realise the Feasibility Study in Denmark and Spain (Basque Country) on the 2x 24h recall method using EPIC-SOFT among children aged 4-6, 7-9y and 12-14 y
- To realise the validation/evaluation including ActiReg in DK, within the feasibility study.

The updating of EPIC-Soft was completed in Spain in April 2008 and in Denmark in May 2008.
Data collection among both school children and prescoolers was completed in Spain in March 2009 and in Denmark in April 2009. In the final phase of the project, collected data were entered, processed and analysed.

Results were written down in scientific papers on feasibility and the validation study: one paper on feasibility of the method among school children, one paper on the relative validation/evaluation, and a short communication on the feasibility of the method among preschoolers. These papers will be included in a supplemental issue of the European Journal of Clinical Nutrition

Trolle E. et al. Feasibility of 2x24h recall combined with a food registration booklet, using Epic-soft, among school children Eur. J. Clin. Nutr. (in prep.).

Trolle E. et al. Evaluation of validity of the recommended method for a trans-European dietary assessment method among school children. Eur. J. Clin. Nutr. (in prep.).

Trolle E. et al. Feasibility of repeated 24h recall combined with a food registration booklet, using Epic-soft, among preschoolers Eur. J. Clin. Nutr. (in prep.).

3.1.3 Suggested small modifications to the EPIC-Soft for use in the validation study to explore the possibility of assessing exposure to one or more potentially hazardous substances

During the start of EFCOVAL an additional objective was defined. The consortium provided in the first project year suggestions for small changes to EPIC-Soft databases to be performed before the validation

study so that the food consumption data collected could be used in order to estimate exposure to a number of chemical substances. The feasibility of these changes was tested and the validation of one or more substances was performed in the validation study among adults. Six different categories of substances (and about 10 specific potential substances) were considered and intensively discussed. The decisions agreed were:

1. To perform small modifications to the databases used by EPIC-Soft (FADECODE.END and FDLIST.END) by adding some missing facets (07 Sugar content, 03 Cooking method) in some food groups and by harmonizing national food lists for offal's, crustaceans and molluscs food groups.
2. To use the field survey as a feasibility study for the assessment of dietary exposure to at least one flavouring substance (raspberry ketone) and of consumption of a limited number of organic products (fruit, vegetables, eggs and milk).
3. To use the field survey as an exploration study for the assessment of dietary exposure to raspberry ketone.

Because of these additional objectives, it was therefore decided that all partners involved in the validation study among adults (BE, CZ, FR, N, NL) would collect an additional amount of urine.

A small experiment aimed at testing the use of urinary excretion of raspberry ketone as a biomarker for dietary intake of raspberry ketone (with the case of a 'red fruit' flavoured yogurt), has been carried out in Italy. The trial was performed on one subject (adult female aged 32 years) who collected 24 h urines for 4 consecutive days. However, no raspberry ketone was found neither free nor after hydrolisation of metabolites. Conclusion: there was not enough evidence for using raspberry ketone as biomarker of flavouring foods.

3.1.4 Selection of a category of substances on which attention will be focused in the adaptation of EPIC-Soft.

Attention was given to a category of substances, and, within the target category a limited number (maximum 4) of specific food chemicals or families was selected in order to give practical examples all over the process of EPIC-Soft adaptations. The choice of a category has been driven by a number of considerations.
After in-depth discussion among all partners involved in the exposure assessment project, 'flavouring substances' were chosen as the target category.
Within the target category, 4 specific food chemicals were selected in order to give practical examples all over the process of EPIC-Soft adaptations. This was discussed and agreed among EFCOVAL partners in the first project year. The 4 selected specific food chemicals were:

1. Coumarin (contained in the natural flavour cinnamon);
2. Caffeine (added to cola drinks as a flavour enhancer and present in coffee);
3. Glycirrhizinic acid (naturally present in liquorice);
4. Raspberry ketone (naturally present or added to foods with raspberry taste or other berry taste).

An explorative study was performed for the assessment of dietary exposure to the four selected flavouring substances, using an adapted version of EPIC Soft databases. This activity resulted in the paper titled *'Dietary exposure to flavouring substances: from screening methods to detailed assessments using food consumption data collected with EPIC-Soft software. Crispim S. et al. Food Addit.Contam Part A Chem.Anal.Control Expo.Risk Assess.* **27,** 433-46.

3.1.5 Identification of critical aspects of existing data sets for food safety

A critical analysis of current use of existing databases by risk assessors who perform exposure assessment of the target category of substances was performed. Particular attention was given to the potential underestimation of exposure and to the adherence to existing international guidelines. Critical aspects of food consumption databases currently available for the exposure assessment of the target substances were identified by means of a survey among experts.
Scientists from all countries selected for the validation among adults (Belgium, The Netherlands, Norway, France and Czech Republic) were involved in this survey, together with other European countries including Italy and Denmark. To this aim a questionnaire on critical aspects of existing food consumption datasets in different countries was developed and administered to researchers responsible for the collection/analysis of

National food consumption data in each of these countries. Based on the output of this survey, a workshop involving experts in exposure assessment at European level was organised with the aim of collecting ideas and comments for the adaptations of EPIC-Soft for use in the assessment of dietary exposure to target chemicals. Experts in exposure assessment not involved in the project as partners were invited to the meeting as external consultants.

a. Administration and analysis of the questionnaire

The questionnaire was sent to 62 contacts in 29 different European countries and 27 persons from 16 different European countries filled the form and replied.
The completed questionnaires were analyzed and the results were used to perform a critical analysis of the current use of existing databases.
Based on the results of the questionnaire and on information retrieved from publications and websites, a table has been developed with information including year of the survey, population participating (age group), sample size, dietary assessment method (FFQ, recall, record), survey duration, reference of published results and previous use of the database for dietary exposure assessments. This information was complemented with that retrieved by the European Food Safety Authority (EFSA) in recent activities of the DATEX unit. The results of this work were included in a scientific publication.

Le Donne C. et al.(2010). Overview of Existing European Food Consumption Databases: Critical Aspects in Relation to Their Use for the Assessment of Dietary Exposure to Additives, Flavourings and Residues of Food Contact Materials. Int.J.Food Sci.Nutr 1-12.

b. Organization of the workshop

The workshop **"**Food consumption data needs for the assessment of dietary exposure to flavourings in the EU" was held on the 28th September 2007 in Rome jointly to the 3rd EFCOVAL plenary progress meeting, and involved both EFCOVAL participants and external experts. Its final objective was to collect ideas and comments for the adaptations of EPIC-Soft for use in the assessment of the dietary exposure to flavourings. To this aim the workshop dealt with exposure data needs for risk assessment and risk management of flavourings and with the current availability of occurrence data and consumption data.
The workshop summary report can be downloaded from the EFCOVAL website
See http://www.efcoval.eu/DietaryExposureAssessmentWorkshop.htm.

3.1.6 Inventory of requirement for the adaptation of EPIC Soft for use in the assessment of dietary exposure to target chemicals.

An inventory of requirements for the adaptations of EPIC-Soft was provided during the first year. This inventory was then improved, based on the output of the discussion among all experts invited at the workshop held in September 2007 in Rome. Since the use of the EPIC-Soft software makes it possible to collect information at brand level and the food items can be characterized at a high level of detail through the use of the facets that contain the descriptors, the main adaptations to EPIC-Soft databases suggested by the involved partners were to added news descriptors for the updating of the 'flavour/added component' facet in EPIC database in order to collect consumption data useful for the assessment of dietary exposure to the target substances.

Important information on the adaptations of the EPIC-Soft databases for food safety issues, such as the usefulness of the 'descriptors' related to the flavouring substances and the effective use of such 'facet', derived from the experience of interviewers during the field work. This type of information provide added value to the project.

During the final conference of the EFCOVAL project held in Utrecht, the main conclusion of the work has been presented: EPIC-Soft allows to characterize food items at a high level of detail through the use of descriptors; a better linking between occurrence data and food consumption data was obtained when the EPIC-Soft program was used after addition of specific "flavour" descriptors to the databases. This is likely to be possible also for other food chemicals. A number of activities are on going to enhance dietary exposure

assessments at EU level. The conduction of a pan-European food consumption survey appears highly desirable. If the 24 h dietary recall using EPIC-Soft program will be chosen as the method to be used in such a survey, priority substances for which dietary exposure assessment is needed should be clearly identified when the survey is designed and the databases should be adapted accordingly.

4 To improve the methodology and statistical methods that translate short-term dietary intake information to usual intake estimates

For policy makers unified and reliable data on food intake are crucial. The final goal of a pan-European dietary assessment tool is to provide policy makers with information they need to address with respect to food quality and food safety issues. In this cluster of projects the EFCOVAL consortium paied attention to the translation of the short-term dietary intake information to *usual* intake estimates in order to provide information on the prevalence of nutrient inadequacy and the prevalence of intakes of substances that exhibit thresholds of toxicity. Also, the issue of the quality of the data in order to give information on the error in the estimate was addressed.

4.1 Starting point and progress towards objectives

4.1.1 Development of an improved statistical tool.

The work was started by initially screening available statistical methods. Based on these existing methods, the theoretical foundations of the new method for estimating usual intake were successfully developed and represented at a workshop in the first year of the project. The new method "Multiple Source Method (MSM)"is characterized by a two-part shrinkage technique applied to residuals of two regression models, one for the positive daily intake data and one for the event of consumption. The method is applicable to nutrient and food intake including episodically consumed foods. Variation in intake that is explained by socio-demographic variables selected in advance is not affected by the method. The additional use of a food propensity questionnaire and other long-term consumption frequency information is possible. The method is suitable to estimate individual usual intake in the case of many repeated measurements and a long time period. It turned out that the mathematical foundation of the method is strong enough to handle different distributions of food and nutrient data and to construct proper population distributions.

The background, principles and testing of the method are written in a scientific publication.
Haubrock J. et. al. Estimating usual food intake distributions by using the Multiple Source Method: J. of Nutr. (submitted).

4.1.2 Testing the improved statistical method

As basis for the testing and validation work, the MSM algorithms were implemented using the SAS macro language. This implementation includes 3 macros equivalent to the major steps in the method, and two utility macros (data preparation, data transformation). The testing and validation work for the improved method was performed in the second and third year of the project. For testing data from EPIC Potsdam Calibration II study was used. All 39 food groups measured in this study were analysed using the improved method and published in the above mentioned paper of Haubrock et al. For further testing, data from EFCOVAL was used.

4.1.3 Development and validation of the improved software package.

A software package MSM was developed and tested by different EFCOVAL participants. Simultaneously, the first version of user's guide was written down and illustrated by real examples.
It was chosen to implement the MSM algorithms into the freely available statistical program package the R system. The program can be found at https://nugo.dife.de/msm/.

Furthermore, a scientific paper on the tool will be published in the supplement of the Eur. J. Clin. Nutr.

Harttig, U. et al. The MSM program: Web-based statistics package for estimating usually dietary intake using the Multiple Source Method.(in prep.)
The developed MSM method was compared with other frequently used methods to estimate usual intake distributions i.e. the Iowa State University method (ISU), National Cancer Institute method (NCI), and Statistical Program for Analysis of Dietary Exposure (Spade). Results of this study are included in a scientific publication.

Souverein O. et al. Comparing four different methods to estimate usual intake distributions through a simulation study and application to EFCOVAL validation study", (in prep.)

4.1.4 Estimate the uncertainty of dietary intake data

When establishing a guidance document, the goal was to elaborate a common approach for estimating measurement uncertainty (MU) in the field of nutrition. Because uncertainty is taking an increasing importance for nutrition-policy makers, it is compulsory to have a way to estimate the uncertainty of consumption data. This uncertainty can be combined to the uncertainty of chemical measurements, when estimating nutrient intake or contaminant exposure, but it can also be used by itself for risk management policies. Moreover, many techniques exist to collect food consumption data, such as dietary recalls, diet history, food frequency questionnaire, etc. Estimating the uncertainty for each of these procedures could be a possible way for ranking them and decide what is the most appropriate for a given purpose.
A document entitled "*User's guide for the estimation of measurement uncertainty (MU) of food consumptions (FC)*" has been prepared within the EFOVAL project. This document is presented following a classical guide as produced by standardization bodies, such as ISO. It describes how to apply the general procedure for the estimation of uncertainty when dealing with food consumption data. This procedure consists in four steps:

i) definition of the measurand;
ii) listing of possible sources of uncertainty;
iii) evaluation of standard deviations of uncertainty components or groups of MU components;
iv) estimation of combined uncertainty.

Important features were underlined:

- The assessment of the measurement model that recovers much importance in the case of food consumption data;
- The establishment of a cause-and-error diagram (fishbone diagram) that gives a graphical representation of all sources of uncertainty;
- The capacity to separately estimate the uncertainty of the various components and combine them.

Special attention was paid to 24-hour dietary recall (24HDR) because this type of measuring protocol has been used in EFCOVAL via the EPIC-Soft software. Actually 24HDR is used as a major practical example of application but a review for other measurement procedures also gives an overview of possible sources of error and uncertainty in measuring food consumption at different levels in a study population.

The proposed estimation procedure was applied to the specific case of data collected in the framework of the EFCOVAL validation study based on 24-hour dietary recalls. A manuscript entitled "*Quantifying Uncertainty in Intake Due to Portion Size Estimation in 24-Hour Recall For Dietary Surveys*" was coordinated by *Souverein O. et al.(in prep.)*. It illustrates that it is possible to piecemeal estimate MU. In this paper it is demonstrated that it is possible to quantify uncertainty due to portion size estimation in the usual intake distributions of vegetables, fruit, bread, protein and potassium. Portion size estimation was chosen because it is expected to be one of the largest sources of uncertainty.

5 Dissemination of project results

In the first year of the project the technical environment and hosting of the website was build and established. The website hosts all web-based activities for the EFCOVAL consortium for (secured) intra-as well as (public) internet communication of data and results: www.efcoval.eu. During the project both public and secured (partner) sites have frequently been updated with information regarding electronic newsletter, reports and announcements.

In total the EFCOVAL consortium prepared 5 newsletters during the project. All newsletters can be downloaded from the website and contain information about the project, summaries of some of the work performed and important meetings during the project. Furthermore, the overall results of the project were presented and discussed during the EFCOVAL closing conference held on 9-10 Sept. 2009 in Utrecht the Netherlands. The aim was to disseminate the results and its applicability for pan-European dietary monitoring was discussed. The closing conference was open for people interested in the results of EFCOVAL, from international and national organizations in nutrition and health, including authorities, industry and science. In particular, potential users of the EPIC-Soft program, including policymakers, representatives from governmental and scientific organizations in public health and nutrition were invited to attend the conference. About 80 delegates from 21 EU countries and some from overseas (US, Brazil) attended the meeting. On the second day (Thursday 10 Sept.) the overall findings of the EFCOVAL project were discussed with the audience and an expert panel. This panel included persons from EFSA, WHO, and experts on nutritional monitoring surveys in adults and children. The conference was closed by presenting the overall (preliminary) conclusions of the EFCOVAL project. A summary of this event can be downloaded from the website (link: summary closing conference). Furthermore, the overall conclusions and recommendations of the project will be published in the special issue of the European Journal of Clinical Nutrition.

De Boer E. J. et al. The European food consumption validation (EFCOVAL) project- conclusions and recommendation. Eur. J. Clin. Nutr. (in prep.).

In the two days preceding the closing conference, **on 7 and 8 September 2009**, a **workshop** on Pan-European Food Consumption Surveys - for Standardized and Comparable Transnational Data Collection was held for a limited number of participants. About 50 participants, from international organizations, universities, and research institutes in 18 European countries attended the workshop. About half of the participants were involved in the EFCOVAL project.

The aims of the workshop were: 1) to create support for pan-European food consumption surveys or for harmonization of national food consumption surveys; 2) to list and discuss possibilities and barriers for harmonization or for implementation of a pan-European food consumption survey; 3) to inform on the EPIC-Soft software for collecting 24-h dietary recalls and 4) to discuss potentials and requirements to use EPIC-Soft in the context of pan-European and national dietary monitoring.
The first day of the programme focussed on dissemination of information with regard to needs and requirements to harmonize food consumption data for Europe and on EPIC-Soft. The programme of the second day consisted of informal discussions related to the workshop aims. A summary of the workshop can be downloaded from the website (link: summary workshop EFCOVAL)

The main results of the project will be disseminated by means of a special issue of the European Journal of Clinical Nutrition. This supplement will contain 13 papers to be published in 2011. All papers included in this issue and mentioned in the current report are indicated by "*in preparation*".

6 Impact of the project

Due to the extensive network which was used to disseminate the results people from the fields of politics, statistics, nutrition are now aware of the adapted standardized computerized 24-hour dietary recall method EPIC-Soft for pan-European dietary monitoring. Several EU member states and EU institutes showed their interest in the program and the work performed in the project. In the 3rd reporting period additional initiatives to support a pan-European food consumption survey have commenced in parallel to EFCOVAL. Other EU institutions, including the European Commission Directorate General for Health and Consumers and the European Food Safety Authority (EFSA) expressed a high interest to use EPIC-Soft and related tools as the method of choice in a planned pan-EU survey. In March 2010, EFSA announced its planned implementation of a pan-EU survey under the proposed acronym “EU Menu” http://www.efsa.europa.eu/en/press/news/datex100212.htm

A pan-European survey could both serve (part of the) national needs as well as the pan-European needs for food consumption data, it is recommended to search for options of combined national and international financial support. As a first step in this direction, in February 2010, members of EFSA’s Advisory Forum signed a declaration supporting the establishment of a pan-European food consumption survey http://www.efsa.europa.eu/en/eumenu/docs/eumenudeclarationen.pdf

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