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Final list of certified FCDB compiler organizations and future plans for continuation of the certification scheme

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EUROFIR – NEXUS WP1.2.2

FINAL LIST OF CERTIFIED FCDB COMPILER ORGANIZATIONS AND FUTURE PLANS FOR CONTINUATION OF THE CERTIFICATION SCHEME

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ABSTRACT

The planned certification of food composition database (FCDB) Compiler organizations is a key part of the overall quality framework that was developed in EuroFIR NoE and further extended in Nexus (WP1). Task 1.2.2 requires assessment of up to a maximum 20 national FCDB Compiler organisations over 2 years and overall recommendations for continuation in the future. This report describes reviews of 16 FCDB Compiler organisations and summarises conclusions based on the reports. FCDB Compiler organisations have benefitted from the opportunity to review their data compilation processes and identify areas that could be improved and this information is important for their own organisation and management operations. The reviews have demonstrated the impact of EuroFIR developed guidelines for compilation processes and how FCDB Compilers have implemented quality management frameworks.

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1. Summary

A summary of compiler review recommendations are as follows, and will be used as a basis for any follow up visits in the future.

UK

1. A database management system that integrates all stages of the compilation process is desirable and would help to minimise errors associated with storing data in different locations and formats.
2. A central web site would provide a central UK focus for the food composition data with appropriate links to stakeholders and other collaborators.
3. Data is /will be published in different versions including electronic and hard copy. A strategy is needed ensure consistency of published values.
4. Original documents should be stored securely, scanned and saved electronically.
5. An overall SOP should be prepared that describes the links between the overall IFR QMS and specific SOPs for the compilation process.
6. Formal SOPs should be prepared from currently available documents that describe project based procedures.

Slovakia

1. The Slovak online database should continue to be developed, making use of data from industry and scientific literature.
2. The focus on foods that are produced in the Slovak Republic or that are traditional and an important feature of the diet should continue, using analytical data wherever possible
3. SOPs and guidelines for Slovak specific procedures should be produced.
4. Attention should be given to users' needs via website questionnaires to obtain feedback and identify problems
5. Old documents could be scanned and saved electronically.

Netherlands

1. Plans to implement the FoodCASE database management system should continue, in collaboration with EuroFIR AISBL.
2. Collaborative surveys to produce analytical data, with NEVO input into sampling design, should continue to be a significant source of new data.

3. Specific funding for analytical work is essential to maintain a dataset that provides high quality and up to date food composition data for all users at a national and individual level and to underpin research and policy related to diet and health.
4. The NEVO quality management document should be further developed with additional appendices where possible.
5. Procedures for survey design and sampling for specific food groups, e.g. meats, could be shared with other FCDB Compiler organisations members states via EuroFIR AISBL partners to help develop a repository of practice guidelines for sampling specific food types.

France

1. An overall SOP could be made to reference and structure all current documentation including adapted flow chart and could link to the ISO-9001 SOPs.
2. Having a relational database management system developed for maintaining food composition data, e.g. the FoodCASE software available through EuroFIR, is recommended to assure data processing and data quality more easily
3. To assist the FCDB Compiler team, an advisory board would be useful.
4. OQALI and CIQUAL, being two strong databases in one unit, should explore the possibilities to work together with respect to harmonization, data collection etc.
5. E-books could be considered as an alternative for printed food comp table

Turkey

1. The Turkish online database should continue to be developed, making use of analytical data generated under quality assurance and metrological principles.
2. The focus on foods that are produced in Turkey or that are traditional and an important feature of the diet should continue, using analytical data generate by TÜBİTAK or published in scientific literature.
3. Specific food composition study SOPs and guidelines should be completed.
4. Attention should be given to users' needs via website questionnaires to obtain feedback and identify problems.

Finland

1. The Fineli online database should continue to be developed, using new, quality assured analytical data wherever possible. Initiatives taken to secure funding for new nutrient analyses are encouraged and possibilities to collaborate on nutrient analyses within EuroFIR or the Nordic network should also be explored.
2. Continue the work of documenting all procedures and guidelines for the specific procedures on the internal information system.

3. Further develop automatic checks to help the FCDB Compilers checking data and reduce manual checks.
4. Document tasks and responsibilities of the team members. Set up a training program for new food FCDB Compilers and define criteria for when staff can be signed off for the different FCDB Compiler tasks.
5. Store all basic information used for the compiler process electronically. Information that is only available on hard copies should be scanned and stored electronically.

Belgium

1. The current version of the documentation of the NUBEL QMS can be extended with written and more detailed procedures or references to existing documents. Critical steps should be identified and preventive or corrective actions should be included in the documentation.
2. The NUBEL DBMS has been built in such a way that there is no need to replace it by a specific relational DBMS now. However there is some functionality that could be improved or added.
3. New data are added to the NUBEL database by manual data entry. It is recommended to explore the possibilities of an automated data input facility.
4. The NUBEL DBMS does not include any automated consistency checks. To improve and assure data quality it is recommended to add these checks to the NUBEL DBMS.

Iceland

1. Set up a food database group and involve more than one person in the food compilation work.
2. Develop some automatic data checks.
3. Training of staff and training documentation needs to be addressed.
4. Organise an external reference group to guide the work.
5. Continue the conversion of hard copies of documents to electronic copies to ensure safe storage of older data.

Czech Republic

1. The Czech online database should continue to be further developed and refined in compliance with EuroFIR requirements.
2. Foods from the Czech food market should be analysed and published online to improve quantity and quality of the data.
3. Procedures of the CZFCDB are described in internal documents. It is recommended to introduce SOPs with respect to specifications for the Czech compilation process.

4. Implementation of data management software, possibly FoodCASE, should be considered to reduce manual work and to reduce the possibility of errors.

Poland

1. Production of the Polish food composition database should continue and foods from the Polish food market should be analysed and data compiled and published.
2. All mandatory information according to the EuroFIR standard should be documented to sustain links with European Food Composition Database (eSearch facility).
3. Archive scans or copies of original reference sources in both electronic and paper form.
4. A flowchart for the Polish food composition compilation process should be produced with CCPs and SOPs.
5. Investigate the possibility to change from Excel to a more secure database management system. Using FoodCASE as a data management system should be considered.

Italy - IEO

1. Increase the visibility and importance of the IEO/BDA database more visible by forming a network / advisory board or group of stakeholders within the contributing organizations or beyond.
2. Adjust the EuroFIR generic flow chart to the IEO specific work flow wherever needed.
3. Explore possibilities for additional funding to allow additional activities, e.g. training, and further work on the database. Funding could be used for attendance at the Food Comp course.
4. Investigate the possibilities of moving to FoodCASE as a new relational food database management system or invest in the functionality of the current Access database to add functions (e.g. specific queries, recipe calculation, consistency checks).
5. To avoid the risk of sending datasets and original documentation between the three compilers, it is recommended to explore the possibilities of having the database available through the internet or to have an internet area where shared documents can be stored and edited.

Italy - INRAN

1. The INRAN online database should continue to be developed, making use of analytical data generated under quality assurance and metrological principles.
2. The focus on foods that are produced in Italy or that are traditional and an important feature of the diet should continue, using analytical data generated by INRAN or published in scientific literature.
3. Food composition study SOPs and guidelines should be completed and should be specific for INRAN processes.

4. Attention should be given to creating a specific budget to allocated activities related to compilation processes.

Spain

1. The BEDCA online database should continue to be developed, making use of analytical data generated under quality assurance and metrological principles.
2. The use of software engineering methods specifically developed for the Spanish situation should continue.
3. The focus on foods that are produced in Spain or that are traditional and an important feature of the diet should continue, replacing data from unknown or less relevant sources.
4. SOPs and guidelines specific to the Spanish compilation process should be completed.
5. Attention should be given to creating a specific budget allocated directly to activities related to the compilation process.

Norway

1. To improve and guarantee a high quality of the food composition data it is recommended that a food composition database management system is introduced.
2. Until a food composition database management system has been introduced we recommend that efforts are made to secure traceability of value changes and to make the work in the Excel spreadsheets safer by e.g. locking the spreadsheets.
3. The main documentation should be included in the document control system and quality documents and instructions in the quality management system.
4. To make an induction programme for the food compiling work for new employees and to keep track of training by uploading all new training in the HR system Gitek.
5. Errors that the compilers consider significant should be corrected between the database releases. We suggest that the compilers at NFSA report significant errors to the reference group and if the reference group agrees the errors could be corrected directly instead of waiting for a new version of the database to be published.

Serbia

1. CRENM (Centre of Research Excellence in Nutrition and Metabolism) should focus on expanding the SFCDB to include analytical data where possible with a focus on foods that are produced and consumed in Serbia.
2. Development of SFCDB relies on projects that fund work related to production and use of food composition data. Funding specifically for food composition data production and management should be sought to help maintain a concentrated focus on building the content of the SFCDB according to needs identified by the compiler team rather than needs matched to project requirements.

3. Links with the Serbian food industry, including manufacturers and retailers, should be improved to enable access to data that can be used to inform collection of new data and to validate existing data.
4. Consideration should be given to publishing the SFCDB to a wider group of users.
5. A steering group or expert group could be established to advise on development of the SFCDB. Such a group could provide valuable links to user groups including, industry, academics, health practitioners, food industry and consumers and could provide feedback on proposed developments and on data produced.
6. The process of documenting values entered into the FCDBM system could be reviewed with a view to streamlining the process and reducing the time needed to enter and review data.

Germany

1. It is recommended to include all original analytical data in the BLS database, not only calculated mean or median values. When calculation of mean and median values can be done within the DBMS the use of procedures performed outside the DBMS can be limited.
2. It is recommended to include more queries for data checking linked to the production or error reports to limit manual work and ad hoc checking of data.
3. It is recommended to start building a quality approach for the BLS work. The BLS food data compilation process can be described by adapting the EuroFIR generic flow chart. It is recommended to write standard operation procedures including critical control points, hazards, preventive and corrective measures at least for the critical steps. A standardized approach will assure that all BLS staff work in a similar way.
4. It is recommended to further investigate the possibilities to collaborate with other German organizations in food sampling in order to create efficient (time and money saving) procedures for food analyses.
5. It is recommended to consider the installation of an advisory board or steering group to advice on policy and content of the BLS database.
6. It is recommended to work together with other countries that plan to use FoodCASE, in order to share the resources needed to extend and improve the functionality of FoodCASE.

2. Definition/terms

FCDB Compiler organization – Institution where food composition data compilation is performed.

Food Composition Database – Database of composition data. Can contain published and unpublished data.

Food Composition Database Management System – Software system used to manage the compilation and publication of data.

Working Group (Task 1.2.2) – Working group to manage the task and review FCDB Compiler organizations. Consists of IFR ((Paul Finglas (PMF), Mark Roe(M)), NFA - Anna Karin Lindroos (AKL), FRI-SK - Anna Giertlová(AG), RIVM - Susanne Westenbrink(SW), INSA - Isabel Castanheira (IC), EuroFIR AISBL - Hedwig Beernaert (HB).

3. Introduction

This report describes progress on reviewing implementation of the EuroFIR quality management framework by FCDB Compiler organizations (Task 1.2.2). Review of FCDB Compiler processes is important to monitor and further harmonize how FCDB Compiler organizations operate and to ensure that they generate the highest quality and traceable food data for their users. Review of FCDB Compiler organizations and a process of improvement are essential to ensure the full implementation of standards and best quality practices by FCDB Compilers, ensuring the quality and validity of food composition data being generated at both national and European levels.

Task 1.2.2 requires review of national FCDB Compiler organizations during the EuroFIR Nexus project. The areas of review for national FCDB Compiler organizations are based on the outcome of the initial pilot audits carried out under EuroFIR NoE (EuroFIR deliverable D1.3.27) in 2009/10, and the criteria in ISO 9001:2008 (BSI, 2008) and ISO 17025:2005 (BSI, 2005) related to food composition activities. Each FCDB Compiler organization is organized in different ways and implements processes differently but FCDB Compilers are expected to work within the general framework described by the EuroFIR generic compilation flowchart (Westenbrink et al 2009) and will compile data that is compatible with the EuroFIR Technical Annex (Becker et al 2008) and with the draft CEN Food Data Standard (Becker 2010).

The framework for review of FCDB Compiler organizations was developed by members of the Working Group for Task 1.2.2 and is described in Deliverable 1.5 (Report on framework for certification scheme). The aim of the reviews was to identify strengths and weaknesses of each FCDB Compiler organization and to make recommendations on ways to improve quality systems through identification and dissemination of 'best practice' processes, leading to improved quality of food composition data. This report discusses the processes and outcomes of reviews of 16 FCDB Compiler organisations that took place between December 2011 and March 2013.

4. FCDB Compiler Review Process and visits and FCDB Compiler organisations visits

The programme of reviews was overseen and managed by the Working Group for Task 1.2.2, namely INSA, NFA, FRI-SK, EuroFIR AISBL, RIVM, and led by IFR. A draft schedule for audits was prepared by the Working Group in September 2011 and presented to the EuroFIR FCDB Compiler Network at the EuroFIR Nexus 1st Annual meeting on September 13th 2011 (see Table 1.). NFA and INSA were reviewed in December 2009 for the pilot audit assessments and were not included in the draft schedule. The aim was to review 20 FCDB Compiler organisations (including NFA and INSA pilot assessments).

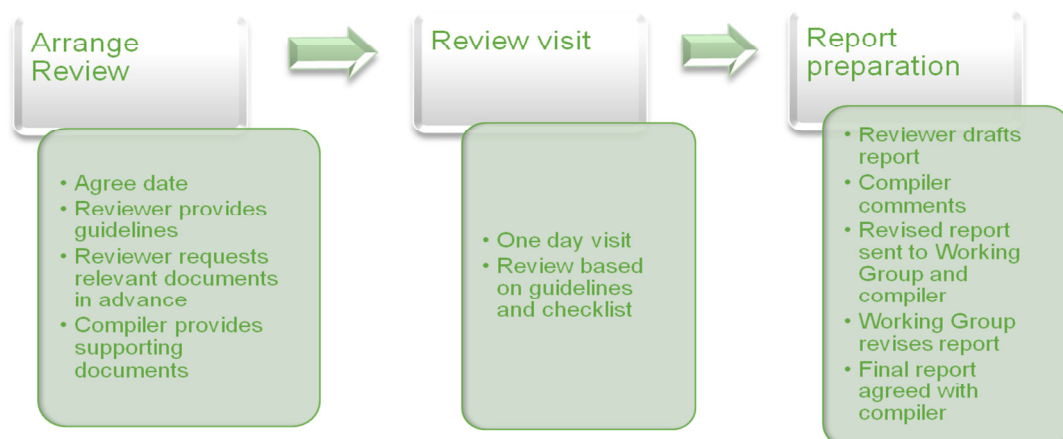
Table 1: Summary of reviews of FCDB Compiler

Date	FCDB Organisation	Compiler	¹Reviewer(s)
November/December 2011	IFR (UK) FRI-SK, (SK)		SW, AKL MR, IC
January – March 2012	RIVM (NL) ANSES (FR) TUBITAK (TR) THL (FI)		MR, AG SW IC AKL
April – May 2012	NFNI (PL) DTU (DK) INRAN (IT) IMR (SE) NUBEL (BE)		AG AKL IC MR SW
June – August 2012	UZEI (CZ) MRI (DE) MATIS (IS) HHF (GR) FCFVS (LV)		AG SW AKL IC MR
September – October 2012	NFSA (NO) UVI (AT) IEO (IT) UGR (ES) UCC (IE)		AKL AG SW IC MR

¹ SW = Susanne Westenbrink, AKL = Anna Karin Lindroos, MR = Mark Roe, IC = Isabel Castanheira, AG = Anna Giertlová

FCDB Compiler organisations were contacted as far in advance as possible to arrange suitable dates for review visits. An outline of the review (based on D1.5 guidelines) were sent to the FCDB Compiler organization by the Working Group at least one month before the review visit. An outline of the review process is given below (Figure 1).

Figure 1: Outline of the compiler review process



Each FCDB Compiler organisation was visited by one reviewer, except during earlier reviews where two reviewers took part to gain experience in the process. The geographical distribution of the reviewers and spoken languages was taken into account where possible during development of the review schedule. Reviewers were members of the working group and had experience in monitoring and/or implementing quality systems, a profound knowledge of FCDBs and were familiar with the EuroFIR technical annex and the CEN Food Data Standard.

The approach to reviewing quality systems and processes and reporting findings was based on the outcome of the initial pilot audits carried out under EuroFIR in 2009/10 (EuroFIR NoE deliverable 1.3.27). Reviews were based on criteria included in ISO 9001:2008 (British Standards Institute, 2008) and ISO 17025:2005 (British Standards Institute, 2005) standards that can be related to food composition activities of the FCDB Compiler organization. Details of the review framework are described in D1.5.

16 FCDB Compiler organisations were reviewed between December 2011 and March 2013 and details are given in Table 2.

Table 2: Reviews of FCDB compiler organisations

Organisation	Country	Review dates	Reviewer	Report
IFR	UK	1-2 Dec 2011	Susanne Westenbrink Anna-Karin Lindroos	Appendix A
VUP	Slovakia	29 Feb -1 Mar 2012	Mark Roe Isabel Castanheira	Appendix B
RIVM	Netherlands	19-20 Mar 2012	Mark Roe Anna Giertlová	Appendix C
ANSES	France	12-13 Apr 2012	Susanne Westenbrink	Appendix D
TUBITAK	Turkey	17-18 Apr 2012	Isabel Castanheira	Appendix E
THL	Finland	23-24 Apr 2012	Anna-Karin Lindroos	Appendix F
NUBEL	Belgium	21-22 May 2012	Susanne Westenbrink	Appendix G
MATIS	Iceland	31 May -1 Jun 2012	Anna-Karin Lindroos	Appendix H
UZEI	Czech Republic	30-31 May 2012	Anna Giertlová	Appendix I
NFNI	Poland	2-3 July 2012	Anna Giertlová	Appendix J
IEO	Italy	24-25 Sep 2012	Susanne Westenbrink	Appendix K
INRAN	Italy	6 Sep 2012	Isabel Castanheira	Appendix L
UGR	Spain	13-14 Nov 2012	Isabel Castanheira	Appendix M
NFSA	Norway	26 Feb 2013	Anna-Karin Lindroos	Appendix N
IMR	Serbia	7 Mar 2013	Mark Roe	Appendix O
MRI	Germany	12 Mar 2013	Susanne Westenbrink	Appendix P

Reports of review outcomes, including clarifications agreed by the FCDB Compiler organisation are presented in Appendices A-P.

5. Discussion

Reviews of FCDB Compiler organisations have been very useful for both the EuroFIR AISBL FCDB Compiler network and the compiler organisations themselves. Co-operation between FCDB Compiler organisations and reviewers has been excellent and FCDB Compiler organisations have been very well prepared for the reviews. The review process has been very open and FCDB Compilers have been able to share their current procedures and comment on where they have developed procedures following guidelines developed in Nexus. All reviews were drafted by the reviewer and the FCDB Compiler organisation then had the opportunity to add any additional clarification or details needed.

The focus on review, rather than audit or certification, was well received by FCDB Compilers and allowed review of organisations that operated in different ways and started from different levels of development. These reviews have helped both reviewers and FCDB Compiler organisations to get a better understanding of the aims of the EuroFIR quality framework and how it can help them in their daily work and SOPs. For many FCDB Compiler organisations, the review proved to be a stimulus to start working on or improving their quality management, with emphasis on developing an amended flow chart for their organisation and on documenting their own steps of the compilation process. It is clear from the reviews that for many FCDB Compiler organisations the major restriction to further progress in implementing quality standards is limited funding, particularly for development of systems and for staff resources.

The reporting format was amended after the first round of reviews to include a summary, including conclusions and recommendations, at the beginning of the report. Many FCDB Compiler organisations have used the summary reviews as an opportunity to demonstrate

future possibilities to their management teams or funding bodies so helping to promote/justify additional resources or new funding.

A summary of the main findings in relation to each of the review topics is given below based on an analysis of where compiler organisations have demonstrated that they meet quality framework criteria. This analysis was based on review of the reports for each organisation and it should be noted that in some cases compilers may have procedures in place but they were not evident from the report. The analysis showed that for 47 of 73 criteria assessed, at least 50% of compilers demonstrated that procedures were in place and for 24 of the 73 criteria assessed, at least 75% of organisations demonstrated procedures. Compiler organisations are at different stages of implementation of quality framework with those that already have formal procedures, e.g. ISO standard, in place likely to meet many of the criteria. Some compiler organisations are continuing to develop while databases are produced by networks involving more than one organisation, meaning that some criteria were difficult to assess.

5.1 Management requirements

All FCDB Compiler organisations had defined management structures and distinct remits from their organisations and funding bodies. In most cases the food composition teams are a small subset of a larger work area and activities are often limited by funding and staff resources. Descriptions of work were clear in some organisations but were more ad hoc in others, with a broad level of detail at the organisation level but much less detail directly relevant to food composition. Some FCDB Compilers are advised by an external steering group or advisory board and that approach serves to bring in a useful additional level of review and can provide a link to user feedback.

Most organisations have well managed contracts in place to provide additional services include analysis, sampling and IT services. Document control is usually maintained by a central sign off system and electronic documents are usually stored on a central server with access and back up secured by central IT systems. Some FCDB Compilers do not yet have access to centralised systems and should consider more sophisticated systems for document control. Even in compilers with document control systems in place there may be areas that could be improved, particularly formal identification, versioning, updating and approving updated documents.

Quality management frameworks vary between organisations. Some organisations have well developed systems and are already accredited to ISO9001 and/or ISO 17025 and have systems for internal and external audit of processes. Other organisations do not have a formal system in place but are working to ISO principles and are in the process of improving quality management procedures. It is clear that the focus of the quality management procedures developed by EuroFIR has been well received and has encouraged FCDB Compiler organisations and their food composition teams to focus on and improve their quality systems wherever possible. In particular there is a need for compiler organisations to continue to produce SOPs that are specifically related to their own compiler processes rather than relying on generic process descriptions. While staff resources are needed to continue to improve quality management, there are significant benefits related to continuity of processes and standardisation of data produced. Training of staff can also be extended based on documentation of processes.

5.2 Technical requirements

5.2.1 Personnel and training

Personnel with the correct skills and knowledge are a very important resource for food composition FCDB Compiler organisations. All organisations have benefitted from the EuroFIR harmonisation process and many FCDB Compilers have attended the International Postgraduate Course on the Production and Use of Food Composition Data in Nutrition that has been supported by EuroFIR AISBL in recent years. Exchange of knowledge within the EuroFIR FCDB Compiler network, including training exchanges and published guidelines, is also an important facility that has been useful for most organisations. While existing staff are generally well trained and experienced, the unique skills and knowledge of food composition data compilers means most organisations are not able to demonstrate that systems are in place to cover key staff in the event of long term absence or resignation.

5.2.2 Database management systems

Many FCDB Compiler organisations are limited by their current food composition database management system or the lack of a system. Even where bespoke systems have been developed and used for many years, they are often inflexible and may not be fully compatible with all EuroFIR guidelines and full documentation may not be integrated. Development of an extensive system is likely to be prohibitively expensive and modifications may also be expensive if external IT input is required. Some organisations use relational database software (Access and/or Oracle) to manage data and while that approach can be very flexible, a high level of user skill is needed and standardisation and control of processes is more difficult.

The FoodCASE food composition database management system (http://www.foodcase.ethz.ch/index_EN) was developed by ETH Zurich/Premotec GmbH during the EuroFIR NoE project (but not funded from the NoE) and is available for FCDB Compiler organisations to use and may provide a solution for updating or implementing a system that is fully compatible with the EuroFIR technical annex. FoodCASE may also provide a solution to problems associated with importing data into a database management system or exporting data subsets for publication or other uses. The FoodCASE support is available for use by FCDB Compiler members, and supported centrally by EuroFIR AISBL with a service and management contract in place between EuroFIR AISBL and Premotec GmbH for 3 years. Currently 5 countries are trialling the system for adoption.

Vertical audits of data were tested during reviews of some organisations. Published values were selected and traced back within FCDB Compiler data management systems to identify original data sources and documentation. All systems tested were found to identify data sources and allow traceability of values, although the depth of data and documentation varied according to the system and age of the data.

5.2.3 Sampling and Analysis

In most cases, analytical services, including sampling, are provided by external analytical laboratories under a contract agreement. In house analytical services are available to TUBITAK (Turkey), NFNI (Poland), MATIS (Iceland), INRAN (Italy) and MRI (Germany).

FCDB Compilers are aware of the need for tender specifications and the need to use analytical laboratories that are accredited wherever possible. Funding for sample analysis is limited for all FCDB Compilers and there is a need for FCDB Compilers to use data calculated from recipes, from literature and data provided by manufacturers making the availability of calculated food data increasingly important. Some FCDB Compilers have good collaborations with industry and their experiences could be beneficial for other FCDB Compilers who are likely to need improved links with industry. e.g.

- UK has an expert user advisory group that includes food industry representatives and has obtained funding for additional analyses from trade associations.
- RIVM, Netherlands collaborated with the Dutch Product Boards for Livestock, Meat and Eggs, who provided funding and advice on survey design during a survey of meat and the Dutch bakery centre who financed a survey of bread.
- CIQUAL collaborates with a number of food companies such as Ferrero, Kellogg's and Unilever, in some cases using signed agreements, to exchange food composition data.
- The Belgian FEVIA (national CIAA organization) is a member of the NUBEL board of directors. Individual manufacturers have signed contracts to arrange for providing nutritional data to NUBEL. Individual manufacturers pay a small amount of money to have their data included in NUBEL.
- MRI has a system in place where industry can provide data directly to the BLS system.

5.2.4 Publication process

Most FCDB Compilers are in full control of when and how data is published although some FCDB Compilers are restricted by processes imposed by funders. Online publication is increasingly the main, and sometimes the only, publication format with hard copy publishing limited. Most of the data produced by FCDB Compilers is published in a format that is freely available to users and also available through the EuroFIR eSearch facility.

5.2.5 FCDB Compiler Processes

The EuroFIR generic flowchart (Westenbrink et al. 2009) for the compilation process has provided a starting point for most FCDB Compilers to produce their own process documentation (Figure 2 and Figure 3). Each organisation works in slightly different ways and some parts of the process are more applicable and critical than for others. Some level of process documentation was evident in all organisations and all FCDB Compilers are intending to extend their documentation as fully as possible. Documentation is not always in the form of formal standard operating procedures but may be available as an informal instruction document. FCDB Compilers should be encouraged to compile process documents and SOPs into food composition quality manuals wherever possible. Process documentation is very important for the continued development and implementation of harmonised data compilation processes. The possibility of sharing key process documents within EuroFIR should be considered. In particular, documents describing sampling and sample preparation protocols for specific food groups would be useful starting points for FCDB Compilers working on similar foods.

Figure 2: EuroFIR generic flowchart; describing the compilation process, including critical control points and standard operating procedures required.

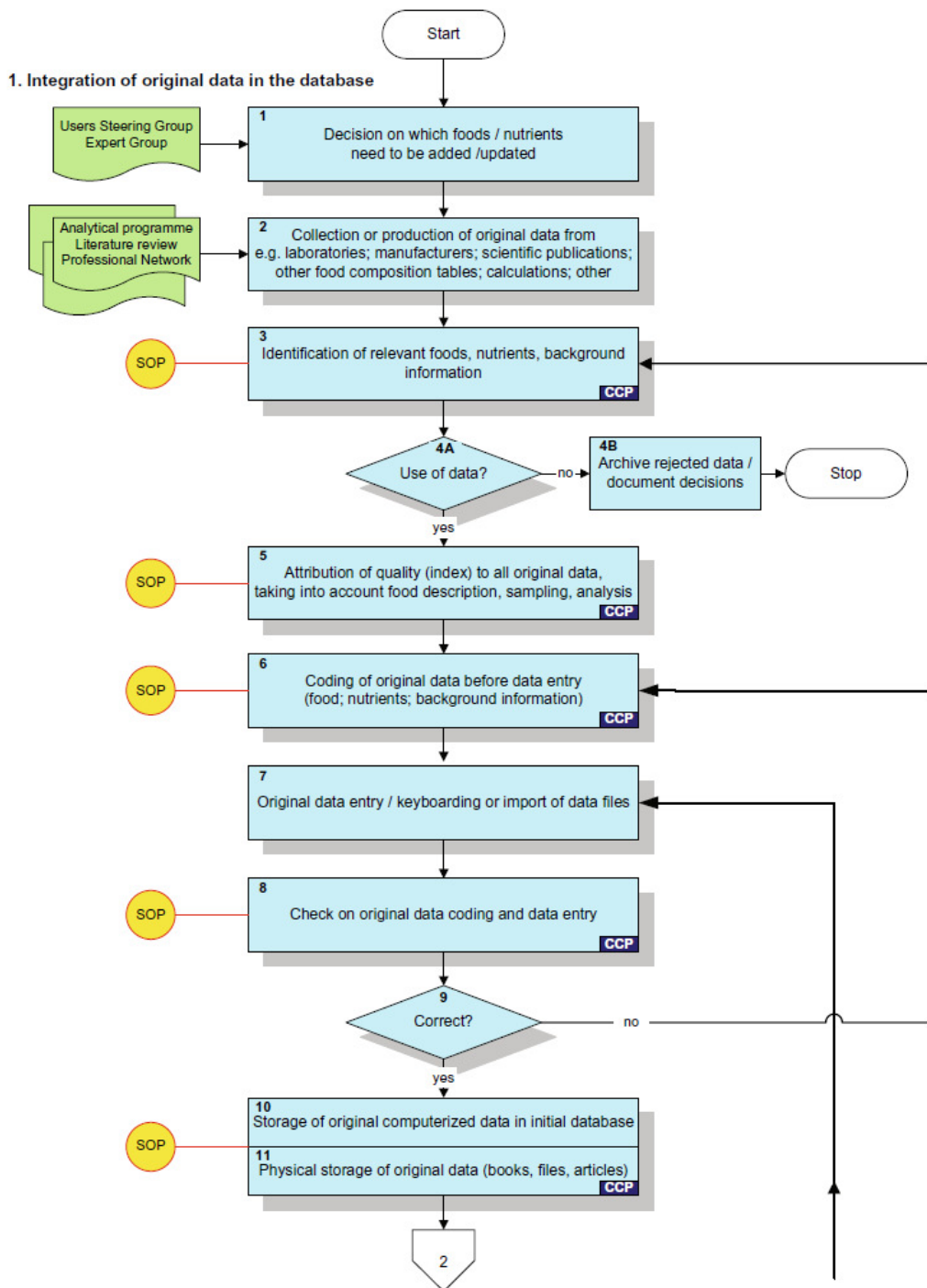
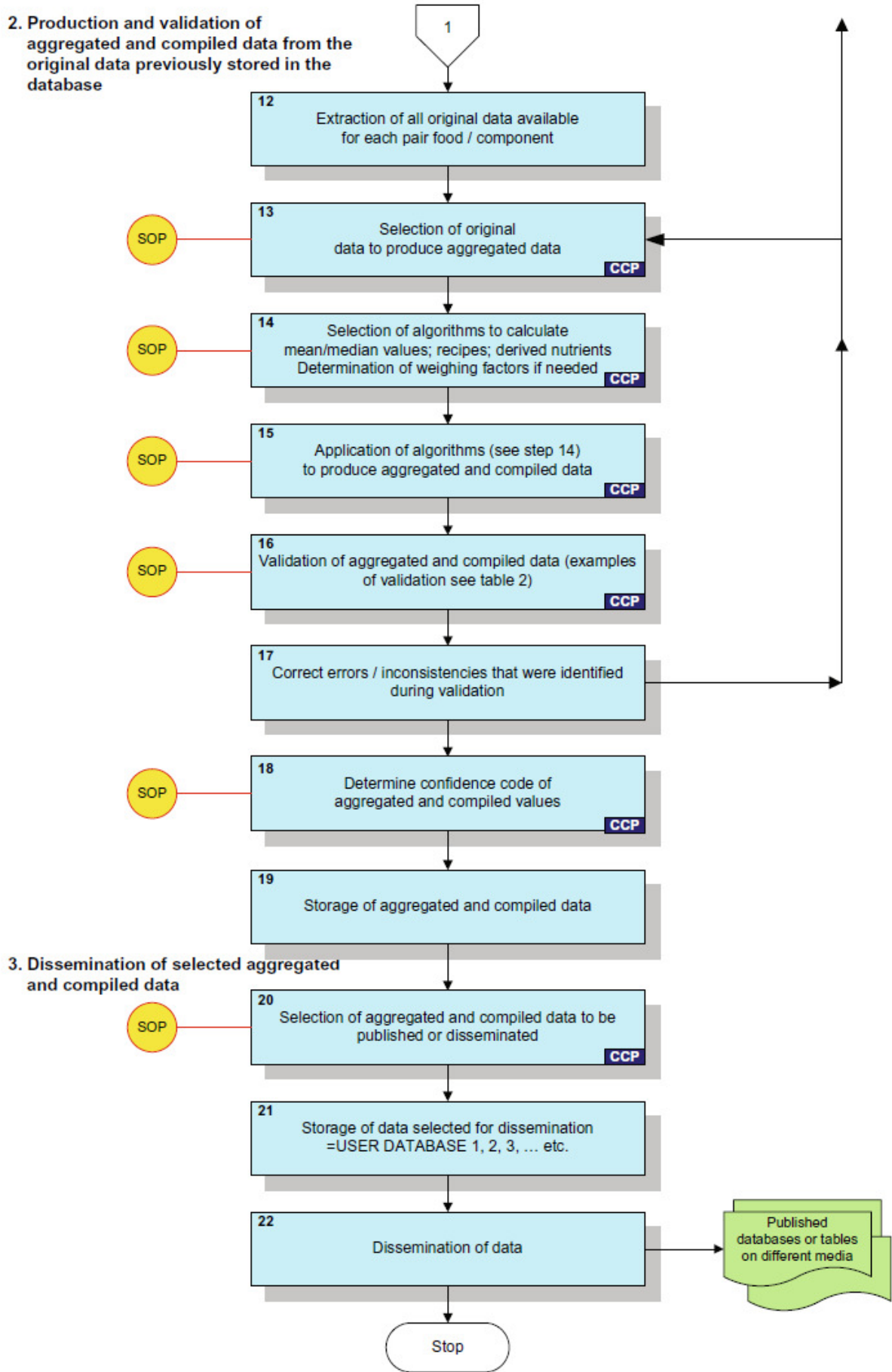


Figure 3. Continuation of generic flowchart; describing the compilation process, including critical control points and standard operating procedures required.



6. Conclusions and future recommendations

The process of reviewing food composition activities at 16 FCDB Compiler organisations has been a very useful for both FCDB Compilers and EuroFIR. Reviews have identified areas for improvement within organisations and have identified 'best practice' procedures which could be adopted by other FCDB Compilers. All reviews have demonstrated that FCDB Compilers have made good use of standards and guidelines produced by EuroFIR and are working towards improved harmonisation of processes wherever possible.

EuroFIR AISBL can provide a suitable umbrella for a continued peer review process and it is envisaged that a working group of compilers, associated with the EuroFIR Compiler Network, continue the work. Peer review visits will depend on availability of funding but the importance of quality processes can also be highlighted through meetings and online forums to enable continual sharing of ideas and best practice.

7. References

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Appendix A – Review of IFR, UK

EuroFIR – Nexus WP1.2.2

Report from review visit at Institute of Food Research (IFR), UK on 1-2 Dec 2011

Participants

Auditors:

Anna Karin Lindroos, NFA, Partner 10

Susanne Westenbrink – RIVM (3rd Party to EuroFIR AISBL, Partner 2)

FCDB Compiler organization IFR

Paul Finglas (Head of Food Databanks; introduction and closing discussion)

Mark Roe

Hannah Pinchen

Pauline Key (IFR Quality Manager)

The audit is based on D1 5_Framework_for_Certification_revised_Sep2011.docx

Background

The review of food composition data compilation processes took place 1-2 December 2011. The review was carried out by two reviewers from EuroFIR Nexus, who are both national food composition database FCDB Compiler managers.

Management requirements

Organization structure and management policy

IFR is an independent research institute that receives strategic funding from the Biotechnology and Biological Sciences Research Council (BBSRC). IFR is a world leader in research into harnessing food for health and preventing food-related diseases. Approximately 150 people are employed by IFR, and in addition, many visiting scientists and post graduate students visit IFR for collaborative research and training.

The Food Databanks National Capability (FDNC) is a national resource platform that manages, develops and publishes food composition data for research purposes in the UK, and is led by Paul Finglas. It is closely linked to two other National Capabilities, and works closely with the Food and Health Institute Research Programme. One of its key objectives is to ensure the UK's food composition databases are compatible to the European (CEN) Food Data Standard and the data are integrated into the EuroFIR Food Data Platform. The mission statement of the Food Databanks is to be a "National provider of credible and validated food composition data to support nutrition and health research and policy".

IFR's support services are supplied by a central operation covering HR, Communications, IT, Maintenance, Finances and contracts, as well as Health and Safety.

IFR has an overall quality system with a quality manager. The Quality Management System is approved by Lloyd's Register Quality Assurance (LRQA) to the Quality Management Standards ISO 9001:2000 for the provision of research and innovation including the three

National Capabilities. IFR has a quality manual that was provided to the reviewers. Due to recent organisational changes the organogram of the institute needs to be updated. There is also an organogram of the key functions in the Food databanks platform, but the people currently working in the group are not all included.

Responsibilities/ performance

Line management is clear. Next to the line manager a countersigning manager is available for every staff member.

Role of funding bodies

The Food Databank's key funding organisations are BBSRC and the Department of Health (DH).

BBSRC has an interest in the food composition tables as the work provides important knowledge transfer skills. The work also benefits the public. The funding covers part of the Food Databanks work, including the underpinning of the National Capability Leader (Paul Finglas), and two research assistants, and provides support for databank maintenance and support, technical development, quality standards, dissemination and stakeholder engagements and training.

The DH provides the major funding for the UK food composition tables, including food analyses, data on industry branded data, publication of 7th edition of the McCance and Widdowson's (M&W) Composition of Foods in 2013. The DH's main interest in the UK food composition database is getting nutrient values for the National Dietary Nutrition Survey (NDNS). Work is currently commissioned through four year projects via tenders. The food composition data has Crown Copyright but the data can be widely used for research purposes and non-commercial purposes. DH has an advisory role in the work, contributes to data evaluation and has the final approval for data releases and publications.

Additional funding for the UK food composition database work is provided by EFSA and EU projects (e.g. EuroFIR NEXUS, PlantLIBRA and Total Diet Study (TDS)), and industry.

Other collaborations

The FDNC collaborates with several strategic partners and organisations:

- MRC Human Nutrition Research on food composition data for the NDNS survey;
- Royal Society of Chemistry - publication of the M&W food composition books and new eBooks;
- British Nutrition Society - supports dissemination and stakeholder engagements;
- Susan Church – an independent nutritional consultant that previously worked for the Food Standards Agency;
- The food industry (egg industry and shellfish organisation) and other national food database FCDB Compiler organisations (e.g. the National Food Agency in Sweden on analyses of fish to share data and avoid duplication) either bilaterally or via EuroFIR AISBL, and INFOODS.

Description of work

Most of the work is organised as separate projects and the work progress is reported as periodic reports to funding bodies including a number of deliverables and milestones. The project information, all reports and other documents are kept in project specific folders with access to all team members.

The largest part of the work, funded by the DH, is described in the four years contract. Every task is described in detail and the DH is closely involved in the work. Milestones and

requested deliverables, including yearly reports, are listed. Dates for reports and deliverables are planned over the year, but sometimes deadlines for reports and/or deliverables are modified for a variety of reasons and any changes are formally approved by DH with an associated contract amendment. All reports and deliverables have to be submitted and approved by the DH with some payments being linked to specific outputs. The DH publishes the final reports and data releases so publications on any of the work have to be approved by DH.

There are no overall time plans for fitting the different projects together, but this is managed by the National Capability Leader (Paul Finglas) to ensure that all team members are aware of their role, tasks and timescales with formal annual staff appraisals.

The work progress is monitored through reporting and ad-hoc project meetings within the team, and with external collaborators/DH. Full team meetings are organised as necessary as the team is small and effective communications and dialogue is frequent. All team members have laboratory notebooks, where notes and plans are recorded. All project details are extensively documented and archived in an organised way in folders on the IFR network server with frequent backing-up.

Steering group

A small steering group of experts with expertise in food composition data has been established to review the food composition project work and this consists of Jayne Ireland (DFI, DK) and Joanne Holden (USDA, USA), together with DH, BNF, LGC and IFR representatives. The steering group meets annually and also provides input into the future direction and planning of the work. Minutes from these steering meetings are recorded and archived.

Stakeholder user group

There is also a stakeholder user group of around 20 users of food composition data from a wide range of different fields (industry, academia, dietetics and health professionals, and software developers). The user group is used as a reference group and is consulted via telephone and email. Some members are also invited to stakeholder meetings. All external enquiries via email, telephone and via the Help Desk are recorded and added to our external dissemination network (currently 500+ contacts for the UK).

Wider dissemination and communications

The FDNC team have a strong and impressive dissemination record and publish research papers and other popular articles, give a number of talks and poster presentations at relevant national and international conferences and workshops, and various media outputs. This is done both individually and in conjunction with BNF (DH Project) and other project partners especially EuroFIR partners. All dissemination and publications are recorded and available on an IFR Publications database at <http://www.ifr.ac.uk/info/search/publications.asp>.

Contracts and sub-contracts

Contracts and sub-contracts are available for all projects carried out. They cover all the aspects of the work to be carried out. The central contracts manager reviews and signs the contracts.

The work is described in a detailed contract that was discussed during the visit. There are sub-contracts for analytical services by two external laboratories. BNF, RSC and Susan Church are also sub-contracted as project members. For collaboration with industrial partners, contracts are also made for specific tasks. An example is the analytical project for the egg industry in 2011.

Document control

Documents and data are ALL held electronically.

The overall IFR quality management system includes an extensive list of SOPs. The FDNC work is not documented in formal SOPs, however, project based procedures are documented in SOP style.

Electronic contract folders, maintained by the Contracts Department, are created for each project where the principle documents (contracts, work plans, financial details, subcontracting, reports, deliverables, and dissemination materials, etc) are kept. All FDNC team members have access to these documents but cannot delete them from the folder.

For each project, a shared folder which contains work in progress is created. These folders contain initial work plans, raw data and other working documents. IFR team members have access to these documents and have rights to add, change and delete documents within the appropriate projects. Once documents are finalised, for example as final datasets or reports, they are copied to the project contract folder.

Analytical data is handled in Word, Excel, pdf and in Access files or in databases. Depending on the laboratory more or less sophisticated tools are available to report and exchange data with IFR. Eurofins Laboratories allows online access to sample logging, ordering and results while LGC Ltd provide results as scanned hard copies (pdf format) of data extracted from their Laboratory Information System.

Food composition data is transferred to Excel files. For several steps in the evaluation and compilation process a number of Excel files are created, which all need to be maintained. If some data changes it has to be updated in all Excel files. The Excel files are backed up hourly, allowing retrieval of previous versions if necessary. Maintaining data in more than one file is not ideal but is necessary to produce data in the formats required by DH using their 'Composition of Foods' Access database.

After data evaluation and compilation procedures are finalised the food composition data is stored in an Access database. This requires manual data entry. EuroFIR value documentation is held in a separate Access database because the bespoke DH 'Composition of Foods' database is not compatible with the EuroFIR/CEN technical standard. The Access databases are backed up hourly.

Hard copies

Analytical reports are the most important data sources for the food composition databank. Although recent reports are electronic documents, older reports are only available in hard copies. The original reports containing analytical data are stored on a shelf in one of the offices.

Review of the Food Databanks Quality Management System

Internal audits are arranged at IFR on a regular basis, using a rolling system for auditing the respective groups / departments of IFR. The Food Databank is therefore audited on a regular basis.

Official ISO 9001 audits: Official audits for ISO 9001 are arranged at IFR on a regular basis. Using a rolling system the respective groups/departments of IFR are audited with certain time intervals. External reviews for each project including the DH project are undertaken regularly by external experts for that project.

The last external review was in February 2011 with no non-conformities noted.

Technical requirements

Personnel

The process for ensuring that staffs have the skills and qualifications appropriate for their work is embedded in the overall quality management system.

Every employee has a detailed job description outlining the tasks involved in the job and the proportion for each task of the total job time. Annual performance development reviews (PDR) are held with every staff member. Tasks included in the job descriptions are also reviewed and new objectives for the following work year are agreed on. PDRs are signed by line manager, employee and counter signed by a senior staff. The reviews are then checked by HR and stored with them. Information related to the employment (CV, detailed job descriptions, objectives, sick leave, projects that the employee is involved in, visits, and publications/training records) is available on the intranet.

The Food Databanks team is small and if someone is away for a longer time due to for example sickness this could potentially be problematic. This was discussed and it is possible to relocate tasks within the Food Databanks group. However it would cause problems in the longer term as the amount of work would be too much for the small team. -This would be managed by the NCG-L and the HR department who can provide additional funding to cover unforeseen circumstances.

Equipment

Although the Food Databank team is largely involved in sample collection and sample preparation, the analytical work is done at external laboratories. Therefore analytical equipment is out of the scope of this review.

Sample collection is mainly done in the Norwich area without specific equipment. The FDNC team members can use IFR cars for food purchases and collections. A new, large and fully equipped kitchen is available for sample handling. The team is the main user of the kitchen.

Records of maintenance, modifications, repair, calibration and validation of the kitchen equipment were not discussed but it is assumed that these are covered as part of the overall IFR QMS.

Other equipment is mainly computer hardware and software. Maintenance, modifications, repair, calibration and validation is organised through the central IT department within the central support services (TOC). The Food Databank team does not use currently specific software, like a database management system (DBMS). Plans are in place to implement the FoodCASE system in early 2012.

Sampling

Sample planning and actual sampling for analyses is an important part of the food composition work within FDNC and is performed in conjunction with external collaborators. Procedures for the collection of samples for analysis are documented in detail. Procedures include identification of relevant samples, design of sampling plans, sample handling and processing and sample storage. Documents are stored electronically in folders. When the samples are ready, they are transferred to the analytical laboratory for further homogenisation and analyses.

Analysis

Analytical work is done under contract by two external laboratories. Analytical work is subject to the QMS of each laboratory. Laboratory accreditation, use of standard analytical

procedures (e.g. CEN, AOAC), performance and cost are all taken into account when selecting the laboratory, and these are reviewed annually. A procedure for the identification and correction of incorrect data is available. The procedures vary slightly depending on the more or less sophisticated procedures of the laboratory to transfer the analytical results to the FDNC team.

Publication process

Policy and procedures for publication of data, technical reports and other publications are documented. The FDNC team provides food composition data for use in the national dietary nutrition surveys (NDNS) and also for publication via the book, electronic dataset and new eBooks (subset of overall dataset). The release of the data and any publications or talks relating to its production has to be approved by DH prior to release. The next M&W book is due to be published in 2013. This means that the period between the officially printed editions of the food composition tables in the UK is very long (6th edition printed in 2002 versus the 7th edition in 2013), in particular since new analytical data are produced on a yearly basis.

UK food composition data from the UK Composition of Foods Integrated Dataset is also available online in Excel format at <http://tna.europarchive.org/20110116113217/http://www.food.gov.uk/science/dietarysurveys/dietsurveys/>. The web site is currently not being updated. Processes for selection of data were explained. An extensive procedure for verification of the data prior to the final selection is in place. Data is checked by FDNC and double checked by the Department of Health before approval and release.

Compilation process (critical control points – see EuroFIR generic compilation flowchart)

The EuroFIR generic flowchart for the food data compilation process gives an overall description of the compilation process and identifies critical control points and SOPs needed. The Food Databank team does not use the EuroFIR generic SOPs, although the team intends to adapt to these SOPs in the near future. A number of specific SOPs is available, e.g. on gap filling, brand data, food name consistency and sampling procedures and more will be developed as required. These SOPs are essential to have especially as they can serve as a training document for new staff.

Standard operating procedures (SOPs; possibly modified versions of EuroFIR generic SOPs) for these processes should be available at all times. It is likely that in some cases there may be overlap with more generic topics that have already been written. The EuroFIR generic SOPs that include critical control points are considered to be the essential SOPs. However this can vary per organisation. The EuroFIR generic SOPs include:

- Identification of relevant foods, nutrients, background information
This step is part of the project for DH. Relevant foods and nutrients and sampling plans are defined before the actual sampling collection. Additional measurements (both additional foods and nutrients) can be done for other commissioners, like in the case of the egg project. Because food composition data is mainly analytical data produced directly for IFR, non-relevant data does not occur.
- Attribution of quality (index) to all original data taking into account food description, sampling and analysis
- Coding of original data before entry (food, nutrients, background information)
Coding of data is done in the course of the work. For each version of the M&W tables new food id's are assigned.

- Check on original data coding and data entry
Checking original data is done in a number of steps, for which separate excel sheets are produced. Finally the analytical data are entered into the database manually after the final approval of the values. This implies the risk of typing errors but data are double checked by FDNC staff to minimize errors.
- Physical storage of original data
Most of the original data are received in electronic format and are stored properly in folders in the computer. However hard copies of reports are kept on a shelf including original versions of older reports that have not yet been scanned for electronic storage. This implies the risk of loss through whatever reason (damage, fire etc).
- Selection of original data to produce aggregated data
Most values are single values (based on composite samples). Sometimes more than one analytical value is available. Examples are vegetables sampled in more than one season.
- Selection and application of algorithms to produce aggregated and compiled data
Algorithms to calculate mean values or recipes are pre-defined, but need to be applied manually for all calculations in the Excel spreadsheets. If one of the components of a recipe ingredient is changed, the recipe is not re-calculated automatically. The same applies for derived nutrients like energy. These procedures imply some risks for errors (like forgetting to recalculate if a basic value was corrected etc).
It was discussed that the algorithm for recipe calculations in the DH Composition of Foods database is hard coded, but gives incorrect values for nested recipes. This means manual corrections need to be done as well as additional data entry, with the risk of new errors.
- Validation of (aggregated and compiled) data
Validation is done very thoroughly in a number of steps, using several evaluation sheets in Excel. If an error is detected corrections need to be made in all prior datasheets. This implies the risk of new errors (typing errors, forgetting steps like recalculation etc).
- Selection of aggregated and compiled data to be published or disseminate
For each food separate versions are kept in the database for each analytical (composite) sample. For dissemination the appropriate food needs to be selected.

Miscellaneous

Inquiry handling

An email address is available for inquiries. As this is not common knowledge, due to DH restrictions, among users of the food composition data, it is not being used. Questions should be sent directly to the databank team to be answered.

Gap filling

The dataset produced for the DH contains the data as analysed. Values not analysed for nutrients of lower priority, or nutrients that are supposed to be absent, or very low, are missing in the dataset, and not filled in. The NDNS team fills in these missing values, but these values are not included in the published M&W tables. This implies that several user groups will have to do this again for their own purposes. This seems inefficient as the same work is done several times now. And it is likely to result in different nutrient values for the same food.

Conclusions

The FDNC team is small and well-balanced team with complementary backgrounds, expertise and skills including laboratory analyses, quality systems and nutrition. It is impressive what this small team can achieve and deliver. The systems are managed very well within the constraints of not having a proper database management system. Many detailed checking procedures are used to ensure high quality data. The sampling and production of analytical values are particularly impressive. The role of the DH complicates the release of data, and can slow down the publication procedures but its funding is essential for the overall management and development of the UK food composition database.

Recommendations

1. The FDNC team has no database management system. The data is compiled using several Excel worksheets which makes the process vulnerable and increases the risk of mistakes. A database management system is desirable, and would facilitate the work and reduce the risk of errors.
2. There is no central web site (especially as the old FSA website is no longer maintained) and it can be difficult for users to locate and retrieve the electronic data. It is suggested that FDNC improve its National Capability web pages on the IFR website to provide a central UK focus for the food composition data with appropriate links to DH and other collaborators.
3. The focus is very much on undertaking project work for DH and other funding bodies, but less on the needs of end users. More attention should be given to these users via the website, newsletters, training workshops and other events.
4. Data is / will be published in different versions: The M&W 7th edition, online IDS and e-book. A strategy is needed to avoid different versions of the values and an overview explaining the different food table versions would also be useful for end users.
5. Original documents of old analytical reports are stored on a shelf in one of the offices. Original documents should be stored in a safe cabinet. Additionally the documents could be scanned and saved electronically.
6. It is advised to prepare an overall SOP that describes the links between the overall IFR QMS and specific SOPs available for the FDNC team to the generic EuroFIR compilation process and the EuroFIR SOPs.
7. Formal SOPs should be prepared from currently available documents that describe project based procedures

Appendix B – Review of VUP, Slovakia

Report on FCDB Compiler review of VUP Food Research Institute, Bratislava, Slovak Republic

Report from review visit at Výskumný Ústav Potravinársky (VUP), SK on 29th February – 1st March 2012

Participants

Auditors:

Mark Roe, IFR, Beneficiary 1
Isabel Castanheira – INSA, Beneficiary 15)

FCDB Compiler organization: VUP (FRI-SK)

Anna Giertlová
Lenka Bartošová
Danka Šalgovičová (Head of Department of Risk Assessment, Food Composition Data Bank and Consumer Survey)
Kateřina Věntusová (Director)
Peter Šimko (Deputy Director for Science and Research)
Marcela Matulová (Secretary for Science)

The audit was based on D1.5_Framework_for_Certification_revised_Sep2011.docx

Background

The review of food composition data compilation processes at VUP took place on 29th February and 1st March 2012. The review was carried out by two reviewers from EuroFIR Nexus – a national database FCDB Compiler from IFR, UK and an analytical services/quality assurance expert from INSA, Portugal.

The reviewers were provided with web based documentation prior to the review visit and were able to familiarize themselves with the current status of food composition work and the organizational framework at VUP.

During the review visit a meeting was held (1st March 2012) with the senior management team at VUP to gain further information on management processes in relation to food data compilation and quality assurance.

Management requirements

Organization structure and management policy

VUP is an 'allowance' organisation which is funded 50% by the Ministry of Agriculture and Rural Development with 50% of funding coming from EU, industry and national project sources. The VUP Director is nominated and approved by the Ministry of Agriculture and Rural Development but all staff are employed by the Institute. The purpose and mission of VUP are available on the public website. A clear organisational structure was provided giving details of the senior management structure and departmental structure. VUP consists of three science departments (Department of Chemistry and Food Analysis, Department of Risk Evaluation, Food Composition Data Bank and Consumer Survey and Department of

Microbiology and Molecular Biology and Biotechnology) based in Bratislava and employing approximately 50 scientific staff.

The food composition data bank working group has three staff (Anna Giertlová, Lenka Bartošová and Eva Kováčiková) and is part of the Department of Risk Evaluation, Food Composition Data Bank and Consumer Surveys, led by Danka Šalgovičová. The Slovak Food Composition Data Bank (SFCD) project is fully funded by the Ministry of Agriculture and the work can be audited by the Ministry. The food composition working group has a 'flat' structure and does not formally have a group leader but Eva Kováčiková is the most experienced staff member and would take that role where necessary. The Deputy Director for Science coordinates activities in research areas and has responsibility for the future scientific programme. VUP Director has final responsibility to the Ministry for the food composition data bank work. There is no formal quality assurance management framework operated at VUP although there are policies that control specific areas of work, mainly related to control of finances and contracts.

Collaborations

There are no direct links between the food composition working group and the risk assessment and consumer survey teams.

The Czech Republic food composition dataset is based on Slovak data and there are areas of overlap but no direct links.

The food composition working group is a beneficiary of the EuroFIR Nexus project and are part of the EuroFIR FCDB Compiler network and full member of EuroFIR AISBL.

Description of work

A contract for work on the SFCD is agreed with the Ministry of Agriculture on an annual basis. Work plans are produced by the food composition working group and are approved by VUP management before final agreement by the Ministry. Proposed work plans are developed based on the funding (calculated as staff time) available. Tasks are related to the ongoing process of developing and updating the SFCD e.g. tasks for 2012 include, publication of traditional dishes, which were calculated from recipes, publication of approximately 30 traditional Slovak foods and 10 traditional food products (e.g. sheep cheese) in a format similar to the EuroFIR traditional foods recipe cards, and calculating total sugar contents for all foods included in the dataset to support food labelling requirements. VUP has an advisory group which consists of management members and Ministry appointed representatives and that group may also input into production and modification of work plans. Tasks included in work plans may also be identified from user and stakeholder feedback obtained by direct contact with the food composition working group. VUP produces a 5 year plan that includes reference to food composition data bank work.

An annual report is delivered at the end of each funding year (January 31st) and is reviewed by the Ministry. An interim review is held each June at which point the annual work plan may be amended depending on progress and priorities.

Project progress is monitored within the Department and food composition working group but there is no formal performance review although there may be performance bonuses based on outputs such as publications. Work plans generally contain quite broad targets and do not have specific milestones and targets although externally funded project work (e.g. EuroFIR Nexus) may have very specific deliverables and milestones. Job descriptions for individual staff members are prepared but are generic e.g. 'fulfil orders of management' and relate more to broader team and Institute outcomes than to individual targets.

Other related projects include development of an information system for food composition data management and a development programme for Central and Eastern European Countries that is supported by the Ministry of Agriculture and Rural Development and Ministry of Foreign Affairs to support capacity building.

Contracts and sub-contracts

VUP does not currently undertake nutrient analysis of foods so there are no contracts with external or internal laboratories.

There is a contract with an external supplier to produce a new food composition database management system (DARIS) to allow management and full documentation of new data. The system has been developed to be fully compatible with the EuroFIR technical annex. The work was contracted via a publically available tender and awarded to the supplier who could best fulfil all requirements. A version of DARIS is under test in Ukraine with VUP support.

VUP also has contracts with external IT companies who manage:

- a) The Institute's networks and VUP website. The IT maintenance contract is managed by an administrator at VUP.
- b) The web interface that is used to manage, via the intranet, the online version of the SFCD and the server housing the online SFCD is also managed by the external IT supplier. This contract is managed by the food composition working group.

All contracts are reviewed by the VUP management team including the Finance Director and legal representatives and are formally signed off by the Director. Signed copies of contracts are held within VUP and as scanned Pdf files.

There are no contracts or service level agreements for services provided by other staff, teams or departments within VUP.

Document control

Electronic documents used for food composition work are stored and accessed via the VUP computer network and intranet and are managed according to standard networking protocols. Access to files is restricted to members of the food composition databank working group and the Head of Department by individual username and password combinations. Each team member has a personal workspace to store and work with files in addition to the shared workspace.

All electronic files are automatically backed up and the working group also manually backs up files to CD/DVD disks or backup facility at least four times per year. Disks containing backed up files are stored locally in a fireproof cupboard. There are SOPs describing procedures for storing and backing up data.

Hard copies

Hard copies of data, publications and contracts are stored in the food composition data bank working group offices at VUP.

Review of the Quality Management System

There is no formal quality management system in place at VUP although many management processes are controlled by written procedures or guidelines e.g. finance, tender processes. VUP is subject to financial audits by project funding bodies including EU and the Supreme Audit Office of the Slovak Republic.

VUP laboratories are accredited for analysis of food components but accreditation is mainly limited to contaminants including heavy metals and mono and disaccharides in beverages.

Technical requirements

Personnel

Each member of staff has a work plan but the level of detail appears to be quite broad and may not be related to specific tasks or deliverables. Employment contracts are often fixed duration related to project funding. Staff may have access to job specific training provided by external organisations but opportunities may be limited by funding. Anna Giertlová attended the 'Food Comp' course in 2008 and Lenka Bartošová will attend a future course if funding can be found. Anna Giertlová has 4 years of experience and a background in chemistry. Furthermore both have skills in English Language

Equipment

Equipment used for food composition work is limited to office equipment, including PCs and bespoke software for data management. IT provision and software is maintained and developed by external suppliers contracted to VUP.

Sampling

There are no samples collected for analysis but samples are identified for data updates based on priorities identified by the food composition data bank working group and also gaps identified by users.

Major updates in the last three years included breakfast cereals and confectionery. Foods were identified by reviewing products available in Slovakia with reference to product descriptions, nutrient and ingredient information available and levels of consumption. All brands were included where possible and descriptions such as 'with added vitamins' were used to discriminate between different brands and types of products. All product information and documentation was stored in project folders (either hard copy or electronic copy). Some data is also obtained from scientific literature, particularly from Slovak sources, including the national food science journal edited by VUP. Data from literature sources tends to focus on locally produced foods e.g. cheese, honey, juices.

Analysis/Data production

No products have been independently analysed but the quality of data for each product is evaluated for completeness and possibility of errors in label data. There is no formal evaluation process and rules for accepting data are not defined, judgements are made based on FCDB Compiler interpretation and knowledge. Legislation for food labelling should apply to all products but information is not specifically checked for legal compliance. For data from scientific literature, assessments based on the EuroFIR system for evaluation of data quality may be used to inform decision making.

Updated food information and values are referenced to the data source and the date of data compilation is recorded within the Food Composition Database Management System (FCDMS).

The 'Alimenta 4.3e' software that is used to manage existing data (most of the data published online) contains a recipe calculation module that includes retention factors (Bognar) that can be applied at food level. Recipes are based on an industry standard publication that provides recipes for foods prepared by canteens and on information from school catering. Foods calculated by recipe are mainly traditional Slovak foods and some commonly consumed

foods that are considered important either because of high consumption or ingredient content.

Publication process

The Slovak user database is published online and managed through a web based intranet interface. The last hard copy publication was in 2002 and was reviewed by trade associations associated with particular food groups prior to publication.

The online dataset consists of >1400 aggregated and composite foods and new data for 15 traditional foods and has been documented for EuroFIR. Data from the 2002 publication is included online and forms the basis of the dataset and consists of aggregated data and data from literature sources. A list of references is compiled online. An e-book is being prepared for publication by EuroFIR AISBL.

Primary food composition data are drawn from inland (Czechoslovak and Slovak since 1993) as well as foreign sources. Databases (Slovak and foreign) are stored separately and published data are derived from the mixed database, thus achieving a higher qualitative level of the submitted data. Analytical data originates from the published bibliography, laboratory reports, algorithmically calculated data from the original analytical data and from foreign food tables and food databases. Most of the data from the primary database were published but obsolete food products or foods with a limited range of nutrient values were not published.

Data is checked by FCDB Compilers prior to publication. The new FCDMS – DARIS, allows data to be flagged as 'new' until it has been verified. User feedback is also used to identify errors and correct published values where necessary.

Compilation process (critical control points – see EuroFIR generic compilation flowchart)

The EuroFIR generic flowchart for the food data compilation process gives an overall description of the compilation process and identifies critical control points and SOPs needed. The Food Composition Data Bank Working Group team does make use of the EuroFIR generic SOPs.

Specific SOP or guidelines, which are used by the FCDB working group include:

SOP 5 Priradenie indexu kvality k pôvodným dátam (Attribution of quality index to the different types of data sources) –adopted from general SOP 5 and related specifically to the Slovak FCDB.

SOP 6 Postup ručného typovania pôvodných dát: kódovanie potraviny, kódovanie nutrientu, dokumentácia meta dát (Coding of data before data entry).

SOP 11 Fyzické uskladnenie/archivovanie pôvodných zdrojov dát (Physical storage (hard copies) of original data).

SOP 14 + 15 Postup pre výber a aplikáciu algoritmov na produkciu agregovaných a kompilovaných dát (Selection and application of algorithms in order to produce aggregated and compiled data). This SOP will be specified and finished, when DARIS is completed.

Tvorba názvu potraviny (Guidelines for creating food name).

Spracovanie zákazky (Guidelines for executing an order related to selling food composition tables and related services.)

- Attribution of quality (index) to all original data taking into account food description, sampling and analysis. Quality index is not assigned to original data although the principles of the EuroFIR system for quality assessment of data from scientific publications may be applied when evaluating data. SFCDB adopted the general SOP for attribution of quality index for scientific literature and created Excel spreadsheets, where it was possible to document.
- Coding of original data before entry (food, nutrients, background information) The FCDMS (Alimenta 3.4) uses a 20 character code that includes information related to food group and edible portion. This code will be kept for use in the new FCDMS (DARIS) that is currently being tested. There is a document describing coding in SFCDB.
- Physical storage of original data Data from physical sources is scanned and converted to pdf format and stored in fireproof cupboards.
Selection of original data to produce aggregated data Principles of the EuroFIR system for quality assessment of data from scientific publications may be applied when evaluating data.
- Selection and application of algorithms to produce aggregated and compiled data. Algorithms are used to check aggregated values and published data e.g. summation of proximates, total carbohydrates, fatty acids and total fat. Recipe calculations are made within the Alimenta software system but where recalculations are necessary (e.g. where ingredients are changed) changes would need to be made manually.
Primary data are managed by the DMS (Data Management Software) which is used for compilation of raw data. Data input to the DMS becomes first-level data, which is statistically processed, using algorithms, to produce second-level data with mean, minimum, maximum, standard deviation. Additional information can be added to second level data including calculations of sum of essential amino acids, sum of saturated, monounsaturated or polyunsaturated fatty acids etc. These algorithmically derived data are used for various purposes, including provision of more comprehensive information for users, but can also be used for data quality control checking. DMS was developed for statistical processing of data and for creating food composition tables (7 food commodities). Second-level data from DMS were transferred to Alimenta software.

Recipe calculations are made within the Alimenta software system but where recalculations are necessary (e.g. where ingredients are changed), changes are recalculated automatically.

Currently Alimenta software is not maintained by the programmer who developed it and some recalculations, e.g. to recalculate energy values according to new legislation, have to be done manually.

- Validation of (aggregated and compiled) data. The validation process is currently based on comparison of values with data from other food composition datasets. A specific SOP for this important step would be very beneficial.
- Selection of aggregated and compiled data to be published or disseminate Data is maintained in the Alimenta software and published online using a web based interface. All food from Alimenta and some new foods were published online and on EuroFIR eSearch. It would be useful to produce SOPs describing this process.

Vertical audit of data

The review concluded with a vertical audit of selected data to look at how published data can be traced back to data compilation processes.

New values for 'Museli bar, raspberry' were traced back to full documentation stored in the DARIS software system. Data was produced by aggregating data from industry and there was a clear process that could be traced back to data for individual products.

'Old' values (Protein) from the 2002 version of the SFCD were reviewed using 'Wheat bread, Graham' as an example. Documentation was stored in the Alimenta software and values could be traced back to the original reference source.

Conclusions

The VUP food composition data group has developed their work processes to be compatible with the EuroFIR technical annex and has made good use of progress made during the EuroFIR project. The DARIS food composition database management system that has been developed and is currently being tested appears to be very impressive and should ensure that VUP are able to continue to produce and manage their data efficiently. The process of online publication of data is also impressive. The group's work seems to be largely controlled 'in house' which allows the group to set their own workplans although, as with most FCDB Compiler organisations, the major restriction to progress is funding. There is no funding available for analysis of samples at the moment but the group's standing in EuroFIR may open up possibilities for future collaborative work. The group also plays a major role in the CEEC network and contributes significantly to training and improving standards in the CEEC region. The review didn't highlight any particular limitations but it would be beneficial for the group to further develop SOPs and guidelines for continuation of their work.

Recommendations

1. The Slovak online database should continue to be developed, making use of data from industry and scientific literature.
2. The focus on foods that are produced in the Slovak Republic or that are traditional and an important feature of the diet should continue, using analytical data wherever possible
3. SOPs and guidelines for Slovak specific procedures should be produced.
4. Attention should be given to users' needs via website questionnaires to obtain feedback and identify problems
5. Old documents could be scanned and saved electronically.

Appendix C – Review of RIVM, Netherlands

EuroFIR– Nexus WP1.2.2

Report from review visit at RIVM, Bilthoven NL, on 19-20 March 2012

Participants

Reviewers:

Mark Roe, IFR, Beneficiary 1

Anna Giertlová, FRI-SK, Beneficiary 13

FCDB Compiler organization: RIVM

Susanne Westenbrink (Project leader/NEVO FCDB Compiler)

Martine Jansen-van der Vliet (NEVO FCDB Compiler)

Hans Verhagen (Head of Centre for Nutrition and Health)

Zohreh Etemad (Quality Manager of Centre for Nutrition and Health)

The audit is based D1.5_Framework_for_Certification_revised_Sep2011.docx

Background

The review of food composition data compilation processes at RIVM took place on 19th and 20th March 2012. The review was carried out by two reviewers from EuroFIR Nexus – a national database FCDB Compiler from IFR, UK and national database FCDB Compiler from FRI, Slovak Republic. The reviewers were provided with web based documentation prior to the review visit and were able to familiarize themselves with the current status of food composition work and the organizational framework at RIVM.

The review began with a welcome and an overview of RIVM Centre for Health and Nutrition (CHN) activities presented by Prof. Hans Verhagen. An overview of quality assurance in CHN was presented by the Quality Manager, Zohreh Etemad.

Management requirements

Organization structure and management policy

RIVM (The National Institute for Public Health and the Environment) is an independent Institute (established by an Act of Parliament) that works to prevent and control outbreaks of infectious diseases promote public health and consumer safety and protect the environment. Its primary role is to provide practical, reliable and impartial information for the benefit of government policy, health professionals and the general public. RIVM employs approximately 1500 staff and is mainly funded by

- The Ministry of Health, Welfare and Sport
- The Ministry of Infrastructure and the Environment
- The Ministry of Economic Affairs, Agriculture and Innovation
- The European Union
- The United Nations
- Government Inspectorates

RIVM is entitled to report its research findings without reference to commissioning clients who have an influence over the findings of research. Scientific quality of work and output is monitored by a Scientific Supervisory Committee, consisting of eminent scientists, that produces an annual report which is published in the RIVM annual report.

RIVM has 4 sectors of interest, one of which is the Nutrition, Medicines and Consumer Safety Division. The Centre for Health and Nutrition (CHN) is one of the units in this sector. However, the organisation of RIVM is subject to significant changes effective from around mid-2012.

The NEVO (Dutch Food Composition Database) project is a project within CHN which is managed by a project leader (Susanne Westenbrink) under the direction of the head of CHN (Hans Verhagen) and also consists of Martine Jansen-van der Vliet, an IT manager and two dietitians. The NEVO project was moved from TNO to RIVM in 2006 and has benefited from centralisation and concentration of associated work. NEVO is funded and owned by the Dutch Ministry of Health, Welfare and Sport. An advisory committee consisting of expert NEVO users and suppliers of nutrient data, including nutritionists, dietitians, analysts and industry representatives, assists RIVM and provides additional input to the management and maintenance of the database. The NEVO team works to the requirements of the RIVM and CHN quality management systems.

Collaborations

The NEVO team does not have direct links with other RIVM units but does overlap with other projects within CHN, e.g. the national food consumption survey, of which one of the project leaders, Caroline van Rossum, is an advisor for the NEVO project.

The NEVO database together with the branded database, which is maintained at the Netherlands Nutrition Centre, form one virtual database, referred to as NethFIR. Both organisations work together to collect, maintain and exchange data on food composition of foods consumed in the Netherlands.

Projects associated with NEVO may involve other organisations, dependent on funding and project requirements. For example, the survey of meat composition in the Netherlands involved collaboration with TNO, Zeist (sample analysis) and the Dutch Product Boards for Livestock, Meat and Eggs (funding and advice on sampling).

Description of work

NEVO is funded by the Ministry of Health, Welfare and Sport through an annual bid which has to justify what will be done and what the cost will be. The work plan is prepared by the NEVO project team and discussed with RIVM CHN staff members as well as higher RIVM management. When approved by the Ministry, budget for the next year is made available. The work plan is a broad level plan based on continual maintenance and update of NEVO. Standard interim progress reports are produced. An annual progress report (and additional reports if planned) is prepared and is evaluated by the Ministry project manager. Project plans are signed off according to the CHN processes for project management that include budgeting, allocating resources, setting outputs (e.g. milestones and deliverables, publications), reporting, auditing and evaluating.

A more detailed annual working plan is prepared for discussion and review by the NEVO advisory committee that includes the Ministry project manager. Results are discussed with the advisory committee on a yearly basis as well.

The annual workplan is based on a budget that supports the NEVO team although more staff can become involved in NEVO if a bigger budget is available or if deadlines necessitate increased staff resources. Students, including work experience students, may also be used to help. The NEVO project leader deals with all issues including staff and finances.

The workplan, contracts and associated documents are available electronically on a shared folder with access restricted to members of the NEVO project team. The project folder includes sub-folders related to specific aspects of the workplan, including minutes of project meetings, the NEVO quality manual and an organogram. The project plan for 2012 was presented as an example.

Contracts and sub-contracts

External contracts with RIVM are managed through frameworks, which are operated in accordance with the RIVM quality management system (residing under ISO-9001) and approve companies to bid for specific services. Bidding procedures depend on the budget involved; small projects can be approved by CHN management and project leaders, larger projects need to be approved on a higher management level. Some activities, e.g. building the NEVO website, are controlled by in house agreements.

The NEVO database management system is maintained by an external IT company through an continuous contract, including licenses for software and a service level agreement to provide a helpdesk.

RIVM has written procedures documenting the authority to sign for contracts. This is related to the budgets involved.

Document control

Electronic documents used for food composition work are stored and accessed via the RIVM computer network and are managed according to standard networking protocols controlled by the RIVM IT Department. Access to files is restricted to members of the NEVO project team. Access is provided by the CHN IT team by instruction of the project leader. Each team member has a personal workspace to store and work with files in addition to the shared workspace. Permission to access folders can be given to other staff by request of the project leader.

All electronic files are automatically backed up on a daily basis through network control systems.

Hard copies

Hard copies of data, publications, reports and contracts etc. are stored in a secure, fireproof storage location. Reports are filed using a code which is used within the NEVO database to enable easy retrieval of reports. An example was demonstrated during the vertical audit.

Review of the Quality Management System

RIVM has a quality management system (QMS) and the organisation is ISO-9001 certificated. CHN is certified for ISO-9001 and operates under the overall RIVM QMS but also implements other processes and SOPs according to its own requirements. Some RIVM centres are also accredited to ISO-17025. RIVM CHN has a quality manager (Zohreh Etemad).

The CHN QMS includes control of

- project planning
- staffing (competencies, performance and training)

- contracts and sub-contracts (including framework agreements)
- documents (electronic storage and back up and hard copy storage)
- internal audits
- external audits

Auditing

Internal audits are carried out at RIVM level and also within CHN. Auditors are from a pool of trained staff at RIVM and CHN and audit themes are chosen by RIVM. Each theme within ISO-9001 should be audited once every three years.

External audits for ISO-9001 certification are carried out by an external company (DEKRA) that is responsible for certification of RIVM (including CHN). Extensive audits take place every three years with more limited audits taking place every second and third year.

Corrective action procedures will be identified and will be implemented according to requirements of the QMS.

Shortly before the publication of a new version of NEVO online or the printed NEVO table an audit by the NEVO advisory committee is organised. 3-4 members of the committee volunteer to perform the audit. The findings are reported and the report, including a list of corrective measures, is forwarded to the CHN quality manager who files it according to the RIVM quality approach.

Technical requirements

Personnel

Staff are employed directly by RIVM and are managed according to procedures described in the QMS. CVs, job descriptions, performance reviews and training records are managed using the 'P-Direkt' application for human resource management. For all Dutch civil servants a limited number of functions are described at a generic level. Appropriate qualifications and competencies are defined for each specific role within the organisation. Staff are allocated to projects depending on budget and work plans produced by 'micro-planning' (Excel spreadsheet based), as well as on competencies by the CHN management team with advice from project leaders.

Staff performance is reviewed annually by the CHN management assisted by project leaders and includes evaluation of progress in the previous period and an evaluation of capabilities. A personal work plan will be produced for the following year and a personal improvement plan, including training requirements will also be produced. Each staff member has a personal training budget that allows three days of relevant training each year.

Staff and students are selected based on applications and interviews and their competencies in relation to requirements of the work plan and individual role.

Equipment

Equipment used for NEVO food composition work is limited to office equipment, including PCs and bespoke software for data management. CHN and NEVO have an IT employee who is responsible for maintenance and update of some IT systems and there is also access to IT staff that support the wider RIVM network. The CHN IT staff member is involved in investigating the possibility for implementation of FoodCASE to manage the NEVO dataset. The current bespoke NEVO database management system is maintained, under continuous contract, by an external company. The RIVM IT employee is involved in some aspects of the

database management. The NEVO database runs on a separate server because of network incompatibility issues.

NEVO database management system

The NEVO database management system enables foods to be extensively documented at value level. Data entry can be done manually or values can be imported into the database from an Excel spreadsheet (in a standard format) that is the starting point for each food.

Individual foods can be selected as active or non-active codes and the software includes an 'approved/validated' status filter for values. A source code documentation facility is included and enables documentation of reference type, value type, reference citation etc. Values may be aggregated within the system using weighted averages with weighting factors for each component value. Values used for aggregation are documented to include details of sampling, analysis etc.

Values within the system may also be 'borrowed' for use in another food.

Recipe details can be stored within the database and there is an option to allow recipes to be published (some recipes may be confidential).

Derived values (e.g. energy; fatty acid groups based on individual fatty acids, RAE) are calculated automatically using pre-defined algorithms. The system tracks when an individual value was used elsewhere in the system (e.g. a borrowed value, a value used to calculate a recipe or a value used for aggregation) and allows auto-updating of dependent values if the original value is changed.

An option is available for consistency checks based on pre-defined algorithms. All checks and corrections need to be done manually after the inconsistency has been detected.

Reports, generally by food group, can be produced to check data entry, to change or update weighting factors and to show where values need to be recalculated. The report is also used for consistency checks.

Data added to the database is initially flagged as 'raw' and can only be flagged as 'validated' after carrying out the control procedure. This control procedure is required by the NEVO database management system and must be carried out manually by FCDB Compilers. Output to be checked is produced automatically and includes each food and each value added or changed. If data are not approved, values remain 'raw' and will not be selected for publication. The procedures assure that all values go through the control procedures and are scrutinised. This is an important procedure to assure the quality of original values. Depended values that are auto-updated do not need to be checked in this way, as the procedure has been checked very carefully and was approved when building the DBMS.

There is a function for exporting data in the formats needed for publication both for NEVO online and the printed NEVO table.

Data sources

For the NEVO database no regular budget is made available for food analyses. In general the FCDB Compilers collect analytical data from research laboratories that performed their analytical work for another research goal. However NEVO staff has been involved in a number of recent collaborative surveys where specific foods have been sampled and analysed. A standardised (as far as possible) procedure for sampling and analysis was produced which is described below.

Sampling

Recent collaborative surveys where specific foods have been sampled and analysed, are 2007 survey of breads financed by the Dutch bakery centre, 2008 survey of 150 foods important to the Dutch diet (commissioned by the Ministry of Health) and the 2010 survey of fresh meats (financed by the Product Board of Livestock and Meat). NEVO staff were

involved in design of the sampling plans but were not directly involved in sample collection. Purchasing and sample collection plans are produced with the aim of collecting samples that are as representative as possible within the limitations of the project. NEVO was very closely involved (bread and meat) or fully (150 foods) responsible for the selection of foods to analyse. The meat survey involved purchasing samples from 16 locations (4 regions x 2 cities x 2 shops (supermarket and butcher)) and combination of the sub-samples to produce a composite sample for analysis. The purchasing plan included specific instructions for amounts and types of meat. The other projects followed a more or less similar approach.

Plans for sample preparation are prepared and include information on how to take sub-samples, how to prepare and cook samples, how to store samples (before and after preparation) and how to homogenise samples. Cooking procedures are based on a 'standard' cook book published in the Netherlands (Henderson HHF. Het Nieuwe Kookboek, 38e druk, Uitg. Kosmos-Z&K, Utrecht/ Antwerpen. 2008.)

Sampling and preparation plans are stored in a NEVO project network fileshare folder.

Sample handling was done at project partner institutes/laboratories, as was the storage of the final composite samples. After finalising the project some of the remaining composite samples (the 150 foods) have been transferred to deep freeze facilities at RIVM, as these samples might be used for additional analyses in the future.

Analysis/Data production

Samples are not analysed at RIVM but by project partners e.g. TNO Zeist, Wageningen University or commercial laboratories. The range of nutrients to be analysed is agreed upon as part of the project plan, dependent on NEVO requirements and budget. The laboratory is selected based on the analytical services/accreditation in relation to the components that need to be analysed. For analytical work commissioned by RIVM, the RIVM bidding procedure is followed and a contract between RIVM and the laboratory is signed. Analytical methods are defined by the analytical laboratory and are usually based on SOPs normally used by the analytical laboratory

Data is initially checked and evaluated by the laboratory and is provided to RIVM in a format produced by the laboratories. Data is then evaluated and checked by the NEVO project team by comparison with existing NEVO values, data for similar food types, label values for branded foods and data from other food composition datasets (using EuroFIR eSearch). Data that is accepted after evaluation is used to add data for new foods or to update existing foods in NEVO.

Other data sources

As mentioned earlier NEVO has no annual budget for analyses. Therefore analytical data is also sourced from other Dutch 'grey literature' sources e.g. analytical reports from Wageningen University, The Consumer Product Safety Authority, Dutch Consumer Association, Dutch Federation of Food Industry. Based on the longstanding relation between NEVO and these organisations and the confidence that was built, most results are provided to NEVO without costs. An agreement was reached with the Consumer Product Safety Authority and with the Dutch Consumer Organisation that all of their results will be made available to NEVO. NEVO has no influence of which foods are analysed but can evaluate available data for use in NEVO. Data can also be obtained from the online resource for manufacturers' data operated by the Netherlands Nutrition Centre. Information on approximately 850 branded foods from this resource was used to add or update values for the 2011 edition of NEVO.

Values may also be calculated from recipes which are collated by the NEVO team. Recipe values and values for generic composite codes based on recipes are calculated within the NEVO database management system. Furthermore values are calculated as derived components, borrowed from similar foods, collected from the food industry (websites, shops, direct contact) imputed by logical deduction and by expert estimation.

Publication process

In 2012 the NEVO database contains 2784 foods, of which 2080 are included in the most recent (2011) published version of NEVO. 47 nutrients are published in the hard copy version and 178 nutrients (including fatty acid isomers) are published in the online version. All data is referenced to an internal source code used for value type or reference type and all codes are documented. NEVO initiated (in 1985) from a merge between a computerized food composition table for research purposes and the Dutch food composition table. Some very old data is referenced to these early food composition tables because the original source code information is no longer available.

All publications have to be signed off by the head of CHN and the next higher RIVM management levels.

EuroFIR

NEVO follows EuroFIR requirements from the EuroFIR technical annex whenever possible. LanguaL classification, component identification and value documentation is done for each food item and for each component and value. The NEVO value documentation structure is not identical to the EuroFIR value documentation. As the NEVO DBMS does not allow documentation of mandatory EuroFIR variables within the database, documentation is done elsewhere using Excel and Access formats. LanguaL classification is done using the Food Product Indexer.

Recipe calculations deviate from the EuroFIR recommended approach with respect to the application of yield and retention factors, because it is not possible to change this functionality of the NEVO DBMS. Therefore the use of yield and retention factors in NEVO calculations is very limited.

The NEVO dataset was provided to EuroFIR eSearch in 2009 as a test version. A new dataset (equal to NEVO online 2011) will be provided for eSearch in 2012.

Compilation process (critical control points – see EuroFIR generic compilation flowchart)

The NEVO project has its own collection of quality management documents that include an introduction to the project and an organogram. This is a working document that is updated and extended at regular times.

A compilation process flowchart for NEVO has been prepared based on the EuroFIR generic compilation flowchart and notes where EuroFIR SOPs exist and where specific NEVO SOPs or documentation is or should be available. Each step in the flowchart notes where NEVO quality management system appendices (procedure descriptions) exist and how they relate to each step. In some cases the process steps described by NEVO are not in the same order as the EuroFIR flowchart because of the way different processes relate to each other within NEVO.

Procedures described in NEVO quality management system appendices include:

- Criteria for adding a food item
- Nutrient list with EuroFIR component identifiers
- List of analytical methods known to be used in the NEVO database
- Source codes

- List of documents for each source type
- Sampling procedure descriptions
- Descriptions of specific surveys
- Procedure for naming foods – this could be the basis for harmonizing food descriptions in EuroFIR datasets
- Rules for using ‘Trace’ in relation to analytical values reported as below the limit of detection
- Procedure for weighting sub-samples when aggregating data
- List of food groups mapped to consumption survey food groups
- Process for adding text to comment fields
- Procedure for recipe preparation [including priority list of cooking books, use of default ingredients (e.g. semi skimmed milk instead of full fat milk), use of cooked or raw ingredients, algorithms applied)
- Procedure for importing spreadsheets that hold ‘original’ data
- Procedure for quality evaluation
- Procedure for checking new or updated values to change the database status from ‘raw’ to ‘validated’ and for checking weighting factors, recipe calculations etc.
- Audit procedure for published tables (online and hard copy)
- Procedure for calculation of derived components
- Use of fatty acid conversion factors
- Procedures for consistency checking using algorithms e.g. total proximates, sum of fats, sum of carbohydrates etc. 20 checks are included in the database management system.
- Procedure for aggregation of data
- Procedure for selection of data for publication
- Rules for naming dataset files
- Rules for rounding and use of significant figures
- Procedures for storage of datasets outside of the NEVO database management system

Vertical audit of data

The review concluded with a vertical audit of selected data to look at how published data can be traced back to data compilation processes.

As an example of an ‘old’ value, the copper content of yard long beans was investigated. The NEVO value was found to be referenced to the USDA dataset value although it is no longer included in the current USDA release.

Values for total and individual sugars in cooked courgettes were also investigated and were found to be an average of two values analysed by RIKILT. The values were traced back to the hard copy of the original analytical report which was stored in the NEVO hard copy filestore room.

Conclusions

The NEVO project is very well established with robust procedures that have been developed over many years. Many procedures are integral to the bespoke database management system and data compilation is generally compatible with the EuroFIR technical annex and CEN standard for food composition data, although not fully incorporated in the NEVO DBMS. The overall quality management framework is certificated by ISO-9001 and works at three levels, RIVM, CHN and NEVO, and the NEVO project has procedures that are specific to food composition data compilation. Processes are described and documented based on the generic EuroFIR flowchart for the compilation process. Both the flow chart and many

processes have been adapted specifically for NEVO. The way that the quality framework has been put together could serve as a model for other FCDB Compiler organisations that don't yet have a specific framework in place. There is a plan to further develop process documentation to fill some gaps which have been identified. The database management system has a limited shelf-life without significant and expensive adaptation to be compatible with networked current operating systems and the NEVO project is investigating possibilities for adoption of FoodCASE as an alternative. There are a number of significant functions that are not yet handled by FoodCASE but there is a plan to address these in collaboration with EuroFIR AISBL and other FCDB Compiler organisations that plan to use FoodCASE.

Although NEVO is funded by the Ministry, NEVO seems to have a high degree of independence enabling the project to adopt practices and standards that have been developed by the EuroFIR project. There is a good collaborative network within the Netherlands which has been involved in recent surveys that have produced analytical data for NEVO. RIVM and NEVO's links with European projects should help to enable efficient use of available funds and maximise possibilities for data sharing. There were no significant limitations highlighted by the review and the NEVO team are already aware of areas that could be strengthened e.g. database management system, additional documentation of procedures.

Recommendations

1. Plans to implement the FoodCASE database management system should continue, in collaboration with EuroFIR AISBL.
2. Collaborative surveys to produce analytical data, with NEVO input into sampling design, should continue to be a significant source of new data.
3. An annual analytical budget would be needed to continuously update and extend the NEVO database with representative analytical data. Having specific funding for analytical work is essential to maintain a dataset that provides high quality and up to date food composition data for all users at a national and individual level and to underpin research and policy related to diet and health.
4. The NEVO quality management document should be further developed with additional appendices where possible. Some existing procedures could be refined in collaboration with EuroFIR AISBL partners who are interested in harmonising the same procedures e.g. rules for naming foods, algorithms for data checking.
5. Procedures for survey design and sampling for specific food groups, e.g. meats, could be shared with other FCDB Compiler organisations members states via EuroFIR AISBL partners to help develop a repository of practice guidelines for sampling specific food types.

Appendix D – Review of ANSES, France

EuroFIR – Nexus WP1.2.2

Report on the review visit at ANSES, Paris, FR on 12-13th April 2012

Participants

Reviewers:

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Laure Du Chaffaut, CIQUAL FCDB Compiler

Martial Ledoux, CIQUAL

Céline Ménard, head of UOQNA (CIQUAL-OQALI)

Jean-Luc Volatier, head of DMO

The audit is based on D1.5_Framework_for_Certification_revised_Sep2011.docx

Background

The review of the CIQUAL food composition data compilation processes at ANSES took place on 12th and 13th April 2012. The review was carried out by one reviewer from EuroFIR Nexus – Susanne Westenbrink who is a national database FCDB Compiler from RIVM, the Netherlands. Some information on the ANSES organization, including the online CIQUAL dataset, from the internet was available beforehand.

The review began with a welcome and an overview of ANSES (French Agency for Food, Environmental and Occupational Health & Safety) activities, in particular the Risk Assessment department in which CIQUAL is included. The overview was presented by Jean Luc Volatier and Celine Menard. An overview of quality assurance in ANSES was presented by Marine Oseredczuk, who was recently appointed as one of the quality correspondents of the Risk Assessment department.

Management requirements

Organization structure and management policy

ANSES is a public authority reporting to the Ministries of Health, Agriculture, the Environment, Labour and Consumer Affairs (established in 2010 from a merger of AFSSA and AFSSET).

Its principal mission is to contribute to the protection of human health with respect to the environment, the workplace and food. It also contributes to the protection of:

- the health and welfare of animals;
- the protection of plant health;
- the evaluation of the nutritional and functional characteristics of food.

Finally it undertakes missions regarding veterinary medicinal products. In its sphere of competence, the Agency's mission is to conduct risk assessments, to provide the competent authorities with any information about these risks as well as the expertise and scientific and technical support necessary to draft legislative and statutory provisions and implement risk management and mitigation strategies. It conducts monitoring, alert, vigilance and reference

missions. It defines implements and funds scientific and technical research programs. It proposes to the competent authorities any measure likely to protect public health. When public health is threatened by a serious hazard, it recommends the necessary health measures to these authorities. It participates in work undertaken by European and international bodies (EFSA, ECHA, EEA, EU-OSHA, ECDC and EMA), and represents France at the request of the Government.

At <http://www.anses.fr/> under 'missions' complete documentation is available.

The core values of ANSES are described as independence & impartiality, transparency, access to stakeholders and excellence/scientific expertise. The Government (the 5 Ministry's of Health, Agriculture, the Environment, Labour and Consumer Affairs) mainly funds ANSES. The ANSES Risk Assessment department 2012 program of work includes the CIQUAL work plan for 2012.

Some details on the ANSES organisation (<http://www.anses.fr/>) are:

- 1350 staff
- 800 external experts solicited (20 Expert Committees, working groups)
- Annual budget: 130 million Euros
- More than 8000 Opinions issued since 1999
- (AFSSA + AFSSET) 51 National Reference Laboratory mandates, 9 EU-Reference Laboratory mandates
- 250 scientific publications per year
- More than 100 doctorate and post-doctorate students

Decision-making processes take place at several levels in the ANSES organization and are clarified using the ISO 9001 (although ANSES have not yet applied for ISO 9001 certification), ISO 17025 and NF X 50-110 documentation. These processes are described in quality documents available at ANSES intranet.

The organisational chart of ANSES is included as Figure 1.

Food composition work is positioned within the Risk Assessment department and includes:

- UOQNA, unit Observatory of food nutritional quality, with 2 main databases
 - CIQUAL (French national food nutrient composition database)
 - OQALI (French resource mainly for labelling information)
- OCA, Dietary survey unit (in charge of national dietary surveys INCA)
- MER-PC unit, unit for methodology and studies for physical and chemical risk assessment for research on exposure
 - Contaminant data base (contaminants, pesticide residues)
 - Total Diet Studies (to study exposure to substances such as inorganic contaminants, minerals, dioxins and furans, PCBs, mycotoxins...)

The CIQUAL food nutritional composition database is the topic of the EuroFIR FCDB Compiler peer review. FCDB Compilers working on the CIQUAL database are Marine Oseredczuk, Laure Du Chaffaut and Martial Ledoux. The CIQUAL team is responsible for the compilation process for the CIQUAL database. This is explicitly mentioned in the program of work and in the signed job description of the staff concerned. General missions of the Risk Assessment department (including CIQUAL) are described in internal documents.

Collaborations

ANSES collaborates with many national and international organisations like national and EU Reference Laboratories for monitoring food safety and animal health, FAO (UN Food and

Agriculture Organisation), OECD (Organisation for Economic Cooperation and Development), WHO (World Health Organisation), OIE (World Organisation for Animal Health), Codex Alimentarius, Assessment bodies in other countries, research and reference bodies in other countries, ISO (International Standards Organisation) and European agencies (*topics between brackets*) like ECHA (chemicals), AEE (environment), ECDC (infectious human diseases), EFSA (food, animals, plants), EMA (medicines), EU-OSHA (working conditions), 4 scientific committees advising the European Commission, Agencies of other Member States, CEN (European Committee for Standardization). ANSES coordinates a network of research institutes.

The CIQUAL team has a close contact and overlap with other food related units within the Risk Assessment department, e.g. the OQALI unit and the OCA, dietary survey unit. Some analytical data for branded foods are obtained from OQALI.

CIQUAL collaborates with a number of food companies such as Ferrero, Kellogg's and Unilever, using in some cases signed agreements, to exchange food composition data.

ANSES is full member of EuroFIR AISBL. The CIQUAL team is involved in EU and EFSA projects (e.g. EuroFIR-NEXUS, EFSA food composition, CEN Food data standard development) on food composition issues.

Through EuroFIR and the EuroFIR FCDB Compiler network links are made with national FCDB Compiler organizations similar to CIQUAL.

OQALI has a steering committee in place, but CIQUAL does not. The CIQUAL FCDB Compilers have recently focused on the production of a new version of the French composition table, with intensive internal work within the CIQUAL database. More collaboration outside ANSES in new projects is planned in the near future. Colleagues are found in other countries. A steering committee/advisory board could be a helpful tool to discuss relevant technical issues and share experiences regarding the CIQUAL database.

Customer requirements

At a very general level, customer requirements are gathered thanks to participation of various parties in the Administrative Board of ANSES. The ANSES Board relies on thematic steering committees, such as the Food technical orientation committee, where customer requirements can be more precisely formulated and collected.

At the level of a project to be led by CIQUAL, 'customers' can be directly contacted to define customer requirements. For the production of a fatty acid composition table by CIQUAL, the ANSES unit in charge of nutritional risk assessment was questioned and decisions on fatty acids of interest were based on an ANSES opinion.

At the level of a CIQUAL project, feasibility studies can be performed. This will be done for a new project aiming at producing an ingredient composition table.

Description of work

At the ANSES level general procedures common to all projects are implemented and followed. Details are documented in guideline documents. There is for example a guide to identify, describe, monitor and analyse macro-processes at ANSES (macro-processes are here considered as major general activities, such as bringing a scientific expertise in the field of health).

The working plan for CIQUAL is part of the ANSES working plan and is established in cooperation with the ANSES board of directors on a yearly basis. As required from the board of directors for 2012 starting an ingredient database is part of the working plan. Collaboration with the dietary survey unit leads to lists of foods that need to be added to the CIQUAL database in order to be able to calculate food intake data.

According to priority objectives, the working plan depends on a yearly budget. For example in 2012, an analyses campaign is implemented to collect nutritional values on baby food

products, and a survey will be conducted to identify the needs of food data producers to guide the development of a nutritional composition table on ingredients.

The detailed version of the programme of work, contracts and associated documents are available electronically on a shared folder with access restricted to members of the CIQUAL team. The project folder includes sub-folders related to technical aspects of the work plan implementation.

The CIQUAL work plan, as part of the ANSES work plan, is publicly available in a summarised version on the internet (draft policy orientations).

A formal personal yearly definition of objectives is also made leading to a document signed both by the employee and their superior.

Contracts and sub-contracts

Internal

Request for technical scientific support, made from one ANSES unit to another can be regarded as internal contracts. Description of expected work (expected result, details, date) and admissibility assessment were mentioned in the Qual'net software.

External

- CIQUAL is responsible to prepare contracts for sample collection and analysis. Sample collection and analysis are performed by an external company selected after a public call for tender made in cooperation with the department of Financial and Technical Affairs following the Code for procurement contracts, which is the collection of procedures that the French Civil Service has to follow when ordering goods or services. Procedures including administrative conditions, technical description of the service needed, analysis of the offers, notification of acceptance, procedure for ordering a service and signing off procedures are described in detail and depend on the budget involved.

- CIQUAL has signed contracts with some food companies to exchange food composition data and/or to assist in checking the food composition data shortly before publishing the next food composition dataset. Review request by mail is used nowadays instead of formal contracts.

Document control

Electronic documents used for food composition work are stored and accessed via the ANSES computer network and are managed according to standard networking protocols controlled by the ANSES IT Department. Access to files is restricted to members of the CIQUAL team through username/password controls. An additional password is needed to perform modifications on some core structure elements of the CIQUAL food composition database. Each team member has a personal workspace to store and work with files in addition to the shared workspace. Permission to access folders can be given to other staff by request of the team leader.

CIQUAL documents are stored on a directory that is backed up every hour. Daily, weekly and monthly copies are stored.

ANSES, as any public administrative institution, follows official governmental document control procedures. These procedures include rules as to what to archive, for how long and where to store the documents. Procedures are documented in detail and will become part of the ISO 9001 system.

An archivist is available at ANSES to store important documents and to allow easy retrieval of these documents.

Official analytical results and the documents obtained in the framework of tenders are stored in the ANSES archives. Specific locations are attributed to the CIQUAL team for electronic data storage. Storage of data on personal computers is not recommended.

Documents remaining from earlier versions of the French Food composition tables are archived in such a way that they can be easily retrieved by the CIQUAL FCDB Compilers. This means that hard copies are not kept in a central archive facility at the unit level; they are kept in a filing cabinet close to the FCDB Compilers office which is protected against fire in the same way the whole building is. Electronic files may be kept on a separate server, but remain available for the FCDB Compilers.

Relevant documents emitted outside CIQUAL are stored on a dedicated part of the UOQNA directory, using a coding system to reference and retrieve documents.

Review of the Quality Management System

ANSES has an internal QMS and is working towards ISO-9001 certification. Part of the ANSES QMS has been implemented and conforms to ISO-9001 already e.g. personal and training issues, but not yet the daily working processes. At the time of this peer review the formal ISO-9001 certification was not yet in place.

ANSES / CIQUAL implement working processes and SOPs according to its own requirements. An important standard is NX 50-110, which is a standard for expert panels that ANSES works with. Furthermore, a system called Qual'net was in place to register internal questions and follow up between units, including official signing off by the head of the department. CIQUAL is not very often involved in these types of questions. Qual'net will be replaced by a new system fitting needs of staff coming from both former entities (AFSSA and AFSSET) now merged to form ANSES.

CIQUAL has documented its working processes in a detailed way using specified documents and formats for many aspects (e.g. coding, production of compiled data).

Work has started to merge the quality approach of different units and departments. CIQUAL is contributing to it, thanks to knowledge and experience gained from the EuroFIR project. A CIQUAL FCDB Compiler, identified as quality correspondent, has to maintain the link between staff in the units and the quality management. She has to take care of exchanging information in both directions.

In the framework of this FCDB Compiler review, elements presented and contributing to the building of the ANSES QMS includes control of

- project planning
- staffing (competencies, performance and training)
- contracts and agreements
- documents (electronic storage and back up and hard copy storage)
- Internal audits; auditors (ANSES employees from various background) were trained in 2011 to perform internal audits. CIQUAL was not internally audited till now.
- External audits are not carried out yet. ANSES aims at having an organization fully fulfilling the ISO 9001 standard by the end of 2012.

Technical requirements

Personnel

Staff are employed directly by ANSES. CVs, job descriptions, performance reviews and training records are managed through the human resource management. Appropriate qualifications and competencies are defined for each specific role within the organisation. Staff are allocated to projects depending on budget and work plans.

For each vacancy, a job offer including descriptions of missions and activities is available through the ANSES website. The requested profile is precisely defined in terms of diploma, experience and competences. Another type of document are the job descriptions that are written for each employee describing the work done in the current position. Job descriptions can be related to specific projects as well.

All CIQUAL staff have a permanent contract, all have a MsC degree and all have participated in the Food Composition Courses in Wageningen or will participate in 2012. For OQALI both employees with MsC degree and dieticians are employed. Due to annual financing, the OQALI team in general has short-term non-permanent contracts (but all contracts are renewable) and not all have taken part in the Food Composition Courses.

Performance reviews are held annually with the head of UOQNA, whose performance review is also made with their immediate superior. The review includes work done and goals reached in the past year as well as plans for the next year. A limited performance bonus can be discussed during these reviews. In the performance reviews the need for training is discussed as well as the efficiency of training followed. Standard documents are used to record details of the performance review and need to be signed off by the employee involved and his/her immediate superior.

At CIQUAL's level, progress review is made through informal meetings and exchanges.

Training

On a yearly basis individual training is planned. A list of training offered by ANSES is available for the staff, but specific training outside this list can also be requested. Institute level priorities for training are set and permission for training is given to individuals taking into account available budgets. Also evaluation of training is done yearly, monitoring what is achieved, costs and number of days spend on training. This is documented in the yearly signed training report for each employee. Individual staff members have the right to apply for training, and have the right to save training days over the years so that longer training periods become possible.

Equipment

Equipment used for CIQUAL food composition work is limited to office equipment, including PCs and software for data management.

Computer hardware is rented by ANSES. A cycle for renewal of computers is established. A hotline can be reached by e-mail or by phone.

List of equipment:

- Computers; large screen are required.
- Internet access
- Access to scientific paper database <http://www.scopus.com/home.url>, innovation monitoring database <http://www.gnpd.com/sinatra/gnpd/frontpage/>, regulation databases <http://www.wk-hsge.fr/index.php>
- Qual'net licenses (to be replaced)
- Office Pack, including Access 2007 and Oracle 8i. Servicing is managed by the ANSES IT team.

CIQUAL database management system

CIQUAL does not have a database management system (DBMS). To manage the CIQUAL dataset both Oracle and Access software are used. Oracle software is used as a basic tool and is maintained for security reasons. The Access software is used for daily work by the CIQUAL FCDB Compilers who are very experienced in making standard and ad hoc queries to manage and retrieve the data needed. All Oracle and Access files are automatically backed up every hour. Due to the lack of a DBMS data are maintained in a large number of files, some of which are related to each other and some are not. Files that are not related need extra attention with respect to data consistency and completeness of the compilation procedures. The way CIQUAL FCDB Compilers manage the dataset in Access including all the relations made between files is impressive. However, in fact the FCDB Compilers now do the work of a proper DBMS. This requires high levels of precision, structured approach and a high level of experience with Access. It could be emphasised that with a good DBMS FCDB Compilers could spend more time on other aspects of food composition database management.

To expand, update verify and make use of the CIQUAL dataset a series of queries is developed to calculate mean values, recipes, derived components, to fill in borrowed and missing values and to perform consistency checks. At the moment the number of queries is about 200, which need to be activated one by one. For CIQUAL FCDB Compilers this amount of queries is more or less the maximum that can be handled by Access. In the process of updating the dataset all queries need to be executed. Therefore, changes (e.g. corrections after data checking) are collected in large batches before the queries are run again. For the 2012 food composition dataset fatty acids are added and therefore specific queries for checking fatty acids are now included.

The risk of this approach is that steps can be missed; the advantage is that it is easy to go back to a certain point in the procedure if needed. Another advantage is that all the process can be modified and refined directly by FCDB Compilers, without waiting for action and financing of a third party.

The queries and steps to be taken are very well documented in a technical specification report with all variables corresponding with the EuroFIR approach. The queries are followed precisely by the CIQUAL FCDB Compilers.

FoodCASE

The CIQUAL team is interested in the development of FoodCASE, since this might be the appropriate database management system for food composition data. Costs to maintain might be a problem, since at the moment no costs are charged on the budget of the unit for using Access and Oracle. These licenses are considered as ANSES basic common tools and therefore financed on a different budget line. The current limitation of FoodCASE is that data entry can only be done manually and is therefore unacceptable for CIQUAL that inserts large batches of data (e.g.; USDA data...). The CIQUAL team acknowledges that further investigation and testing of FoodCASE is needed to be able to take decisions.

Analytical work

CIQUAL usually has an approximate annual budget of €150.000 for analytical work. To select laboratories a public tender is put out following governmental rules (Code for procurement contracts). Procedures are described in detail and depend on the budget available. ANSES has a department taking care of the tendering and putting up the contract. CIQUAL requires one organization both for sampling and for analyzing the samples to which all the work is outsourced. CIQUAL documents the requirements in much detail prior to the tender. The document includes details on sample collection, sample handling, method specification, proficiency testing, accreditation, results delivery, data checking, which food to sample how-where-when, how to prepare foods, how to prepare a composite sample, analytical methods to apply and how to report the results.

Sample identification is the responsibility of the laboratory since ANSES do not see the results of sampling. Nevertheless ANSES is collecting the packaging of the products to be able to control sample identification.

Examples of previous analytical work are stored in the CIQUAL folders and were shown during the review. As analytical work for CIQUAL is outsourced and CIQUAL FCDB Compilers are not analysts, the team strongly feels that obtaining factual elements of competence of the laboratory is very important.

The laboratory is asked to document proceedings of the actual work done, including a report of the foods actually sampled and information if, how and to what extent the requirements from CIQUAL are met.

Consistency checks are performed on analytical results. The checks depend on the type of data and sometimes on the laboratory, as previous experiences with laboratories are taken into account. An official document with questions and remarks will be sent to the laboratory for feedback. This document is officially archived. A recent example concerns dairy products data that were found inconsistent with data from other sources or from similar products

Data production

Analytical data are initially checked and evaluated by the laboratory and are provided to CIQUAL in a format produced by the laboratories. Data are then evaluated and checked by the CIQUAL team including consistency checks. Data that are accepted after evaluation are used to expand or update the CIQUAL dataset.

Analytical data are also sourced from other sources e.g. scientific literature and foreign food composition databases. Analytical data can also be obtained from the OQALI brand database. Values may also be calculated from recipes or for generic composite foods. These values can be calculated within the Access database.

Publication process

CIQUAL has developed a procedure to select foods for publication. Foods with >20% missing components are not published. Sometimes other approaches are decided in collaboration with other parties. For example the analytical values on meat produced by the Centre d'Information des Viandes were transmitted to Ciqua and are all published, not only to mark cooperation from a political point of view, but also because in this group of foods the availability of national recent data is very useful. Also all compiled data needed for the national food consumption survey (INCA) are published. Single values can be used to determine average values and/or to indicate the range of values present in the database. The procedure stating how and when to publish values is described in detail in a CIQUAL protocol. The CIQUAL database contains 4556 foods, of which 1440 will be included in the 2012 version, to be published. 54 nutrients will be published online (including fatty acids). All data are referenced to the original source and all data are documented compatible with the EuroFIR technical annex.

CIQUAL is working directly with the IT team of ANSES which is responsible for managing the ANSES website where the CIQUAL table is available. CIQUAL is consulted to test a provisional version of the internet pages before the table is put online.

Current publications:

- online CIQUAL 2008 table
- a few scientific papers and posters to which the CIQUAL has contributed e.g.:
 - du Chaffaut-Koulian L, Nadaud P, Daniel-Lamazière M-D, Labarbe B, Margaritis I, Kalonji E. Nutritional analysis and characterisation of popular weight-loss diets in France. 9th International Food Data Conference, Norwich, 14-17 septembre 2011

- Vingerling N, Oseredczuk M, Du Chaffaut L, Ireland J, Ledoux M. Fatty acid composition of commercial vegetable oils from the French market analysed using a long highly polar column. OCL - Oleagineux Corps Gras Lipides, Volume 17, Issue 3, May 2010, pp 185-192)

Compilation process (critical control points – see EuroFIR generic compilation flowchart)

An organization specific compilation process flowchart for CIQUAL was prepared based on the EuroFIR generic compilation flowchart and notes the steps that are considered critical control points (CCP) (Appendix 1, which is a separate document). No indications to existing or required SOPs or documents are made in the flow chart. The process steps described by CIQUAL are not fully identical to the EuroFIR flowchart because of the way different processes relate to each other within CIQUAL.

Strictly speaking, there are no official ANSES SOPs describing the CIQUAL food compilation process but there is a detailed list of instructions, protocols and manuals that aims at allowing traceability and repeatability of the process.

Procedures described in CIQUAL quality documents related to EuroFIR SOPs include:

- Identification of relevant foods, nutrients, background information.
- Attribution of quality (index) to all original data taking into account food description, sampling and analysis.
- Coding of original data before entry (food, nutrients, background information). Data are collected from several analytical and other sources in varying formats. CIQUAL has proposed to work with a standard format, but this is not consequently used by data providers. Checking and harmonizing formats takes a lot of time. After this is done data can be uploaded automatically.
- Check on original data coding and data entry. Practically, a check is performed randomly on 3 to 10 original data having different specificities.
- Physical storage of original data. Storage of CIQUAL food composition data sources
- Selection of original data to produce aggregated data. CIQUAL has developed a procedure to select original data to produce aggregated values using the CIQUAL Quality index score (which is different from the EuroFIR QI index). Each food/component combination with a QI score > 50 is selected for aggregation. If no such values are available the first 3 data points are selected.

Selection and application of algorithms to produce aggregated and compiled data

- Validation of aggregated data and compiled data including checks on proximates, fatty acids and carbohydrates. Original values that are produced on a contract basis, like analytical protocols carried out for ANSES, are checked for consistency. For other data standard consistency checks are only done after the aggregation step is finalized, e.g USDA values are not checked for consistency
- Selection of aggregated and compiled data to be published or disseminated.

Feedback from users

Request from users or other contacts are replied by the CIQUAL FCDB Compiler team. Examples are feedback given on the published vitamin K values and food manufacturers asking for new foods in the dataset. Depending on the type of question a more or less official answer can be given using the ANSES/CIQUAL system to register letters. Anyone can comment and make suggestions to CIQUAL thanks to a dedicated e-mail address: <http://www.anses.fr/TableCIQUAL/>, (see FAQ, contact us).

Contact with the food industry

CIQUAL is aware of the importance of being in touch with the food industry in particular to collect analytical compositional data for the food composition database. Since OQALI requires a lot of data (mainly from labels) from the food industry, communication from UOQNA is challenging in so far as two types of needs have to be expressed to the same contacts in the food industry. Communication from UOQNA has to enhance the different specificities, objectives and timeframes of the different needs of CIQUAL and OQALI. On the other hand OQALI does provide CIQUAL with information on changes in the sectors of the food market monitored (5-8 per year) as well as changes in food composition of specific brands. CIQUAL does not systematically monitor these changes because the CIQUAL database concerns the whole diet and the number of foods and nutrients to be checked is too huge. CIQUAL needs input directly from food companies as well.

As part of the procedure to check for consistency of data the association of Food Producers is involved. Experts per food group selected from manufacturers who provided original data are asked to check the data on a voluntary basis. Cooperation varies per branch. Some companies require a signed contract in which the responsibilities of both parties are documented.

Dissemination of data

CIQUAL is maintained using governmental funding and therefore makes the dataset freely available through the searchable CIQUAL website. The next version of the CIQUAL table will be launched in 2012. Since 2002, no printed food composition tables are made anymore. CIQUAL does not provide nutritional calculation tools. This can be done by software programmers, who are free to use and publish the CIQUAL data if the correct references are given.

EuroFIR

ANSES is full member of EuroFIR AISBL. CIQUAL has documented the food composition values in accordance with the EuroFIR technical annex. The CIQUAL dataset is included in the EuroFIR eSearch facility.

Conclusions

ANSES has a QMS in place with respect to many issues (organizational structure, human resources, responsibilities and tasks, project organization, IT, training, performance review ect) and is working towards ISO 9001 certification.

The CIQUAL unit is very well established with very detailed procedures specific to food composition data compilation that have been developed over many years. The procedures are integrated to the CIQUAL working processes, although not presented as one single QMS. Data compilation is generally compatible with the EuroFIR technical annex and CEN standard for food composition data.

Although the government funds CIQUAL, CIQUAL seems to have a high degree of independence enabling the project to adopt practices and standards developed by the EuroFIR project. ANSES and CIQUAL links with European projects should help to enable efficient use of available funds and maximise possibilities for data sharing.

CIQUAL uses Access for their database management system. The FCDB Compiler team manages to maintain their data very well within the limitations related to this approach. However using Access instead of a proper relational DBMS gives risk for the quality assurance of the data.

The CIQUAL dataset is a very large database with every value documented precisely. The FCDB Compiler team has developed original approaches from a practical point of view that could be made more visible to other FCDB Compilers, to be used as examples or input for further standardization, such as

- Selection of values for aggregation using QI scores as criterion
- Use of values for mean values and/or to indicate ranges.

The EuroFIR flow chart was adopted and amended according to CIQUAL needs
No formal SOPs, but many detailed documentation are available.

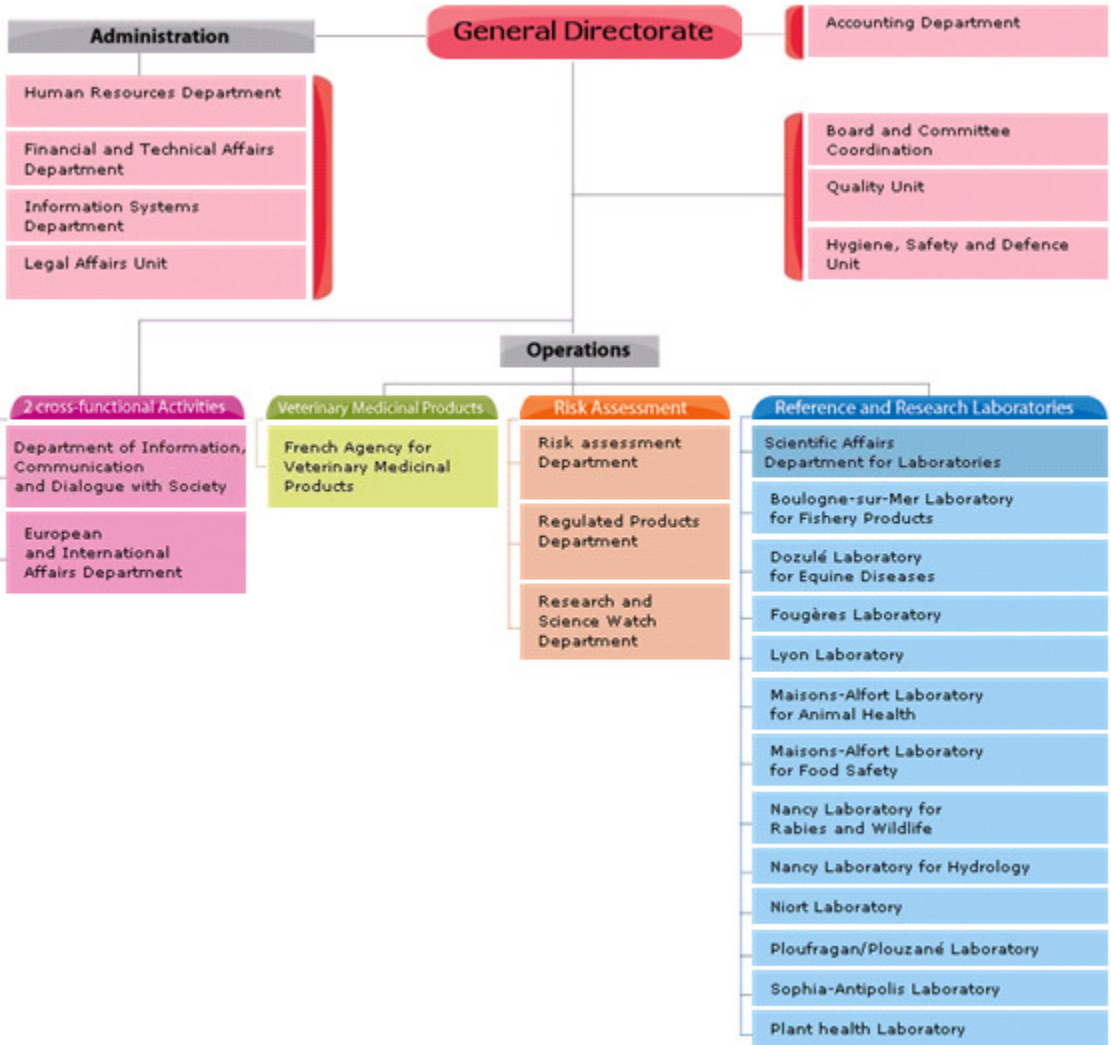
Procedures to select labs are very well defined. The process of producing data is outsourced, and seems to be very well in control. Data checking of the results is done very precise and detailed. The yearly budget allocated to CIQUAL for analyses is a strong point for the development of the database.

The review was very well prepared by the CIQUAL FCDB Compilers. The compilation procedures were discussed in a structured way. The CIQUAL team was very open and willing to show the working process and all requested documents.

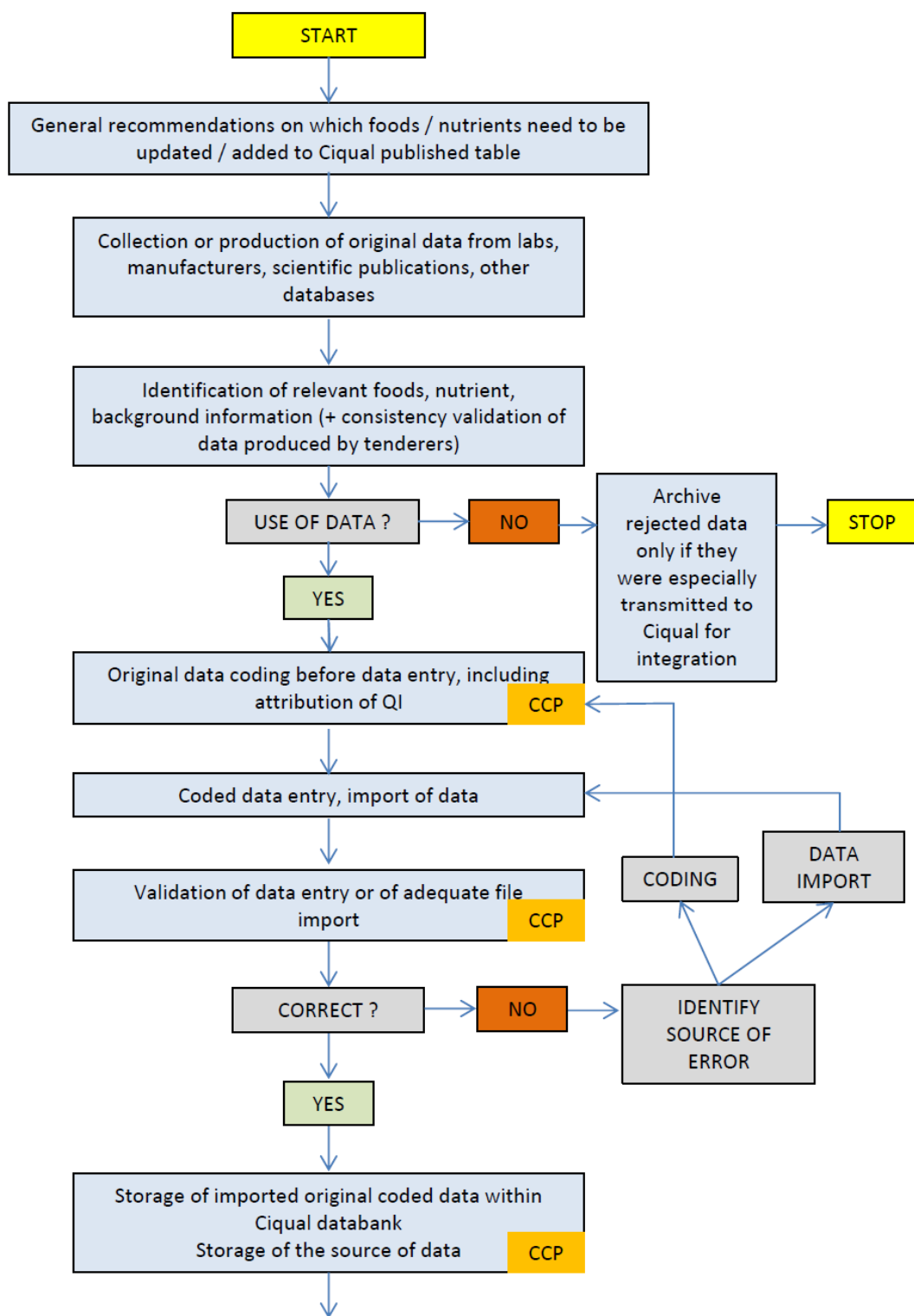
Recommendations

1. An overall SOP could be made to reference and structure all current documentation including adapted flow chart. This overall SOP could be the link to the ISO-9001 SOPs and could avoid the rewriting of all documents in another format.
2. Having a relational database management system developed for maintaining food composition data is recommended to assure data processing and data quality more easily. The FoodCASE software is available through EuroFIR. It is recommended to explore the use of FoodCASE (among other options) for CIQUAL.
3. To assist the FCDB Compiler team at technical and detailed level (relevant foods and food groups identification, naming, components, algorithms, choices for DBMS, publications etc) an advisory board could be useful.
4. OQALI and CIQUAL, being two strong databases in one unit, could maybe explore the possibilities to work together and to benefit from each other a bit more, with respect to harmonization, data collection etc.
5. Some suggestions with respect to dissemination issues could be to investigate if improvements are needed for the website (search ability, comparing foods, user friendliness)
6. E-books as an alternative for printed food comp table (e.g. EuroFIR offering) to enlarge the visibility in the professional field through publications in scientific literature. CIQUAL has a lot of experience to show to the food composition area that could be shared with others

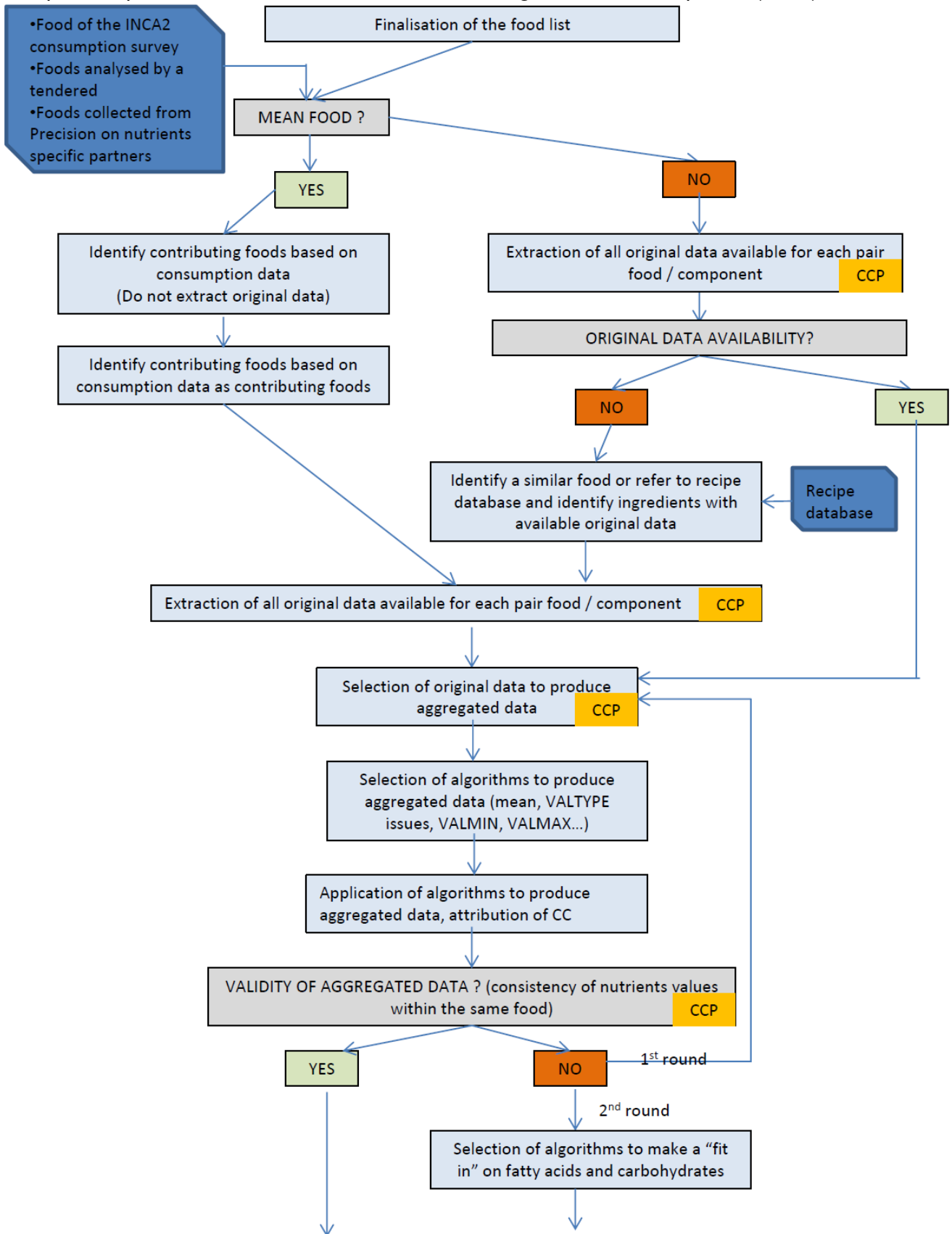
Figure 1: ANSES Agency organization



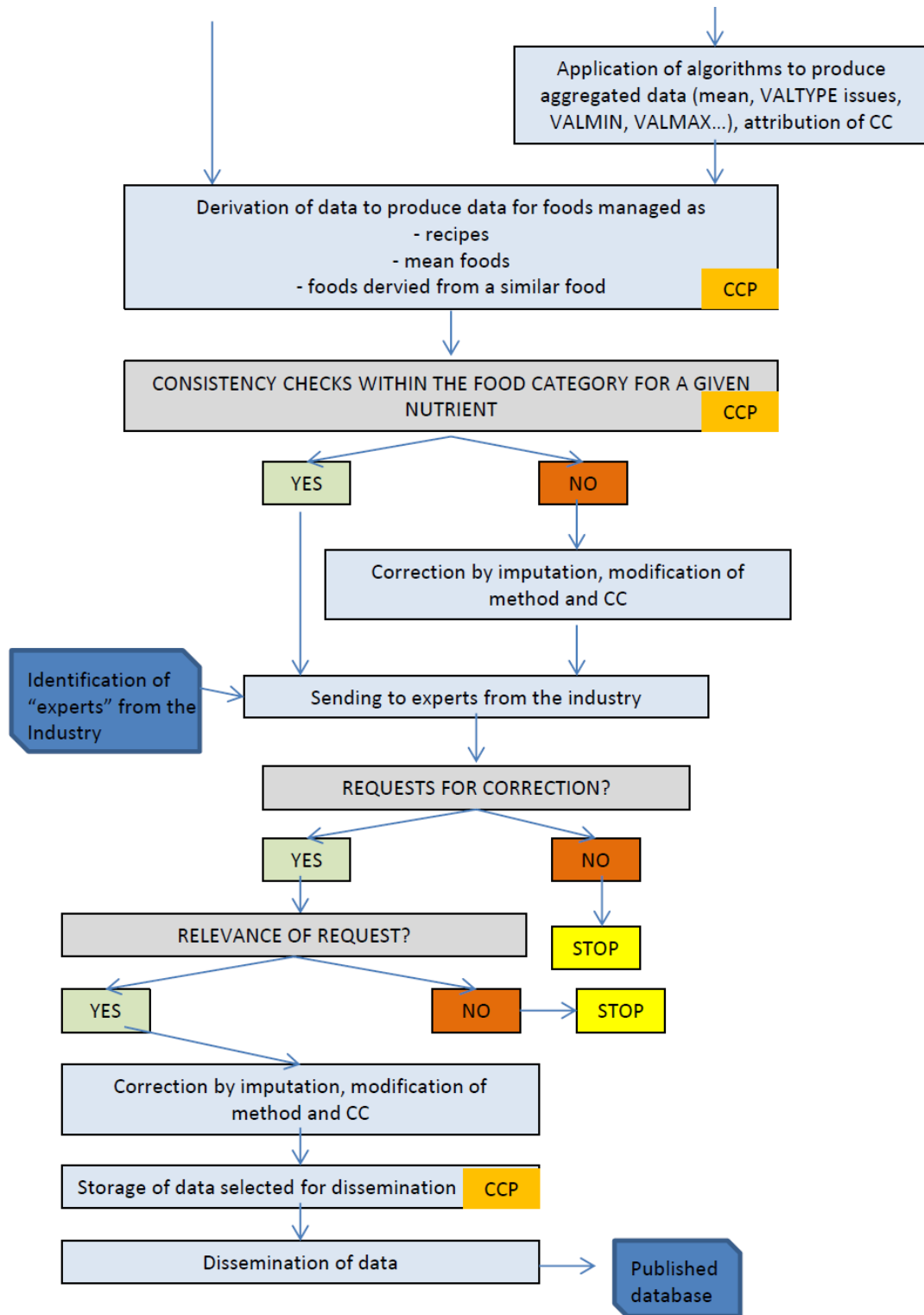
Ciqal compilation process for table 2012 flow chart 11 April 2012, project version



Compilation process flowchart for CIQUAL including critical control points (CCP). Part 2



Compilation process flowchart for CIQUAL including critical control points (CCP). Part 3



Appendix E – Review of TUBITAK, Turkey

EuroFIR – Nexus WP1.2.2

Report from the review of The Scientific and Technological Research Council of Turkey, Marmara Research Center- Food Institute (TÜBİTAK MRC FI), TK on 17th – 18th April 2012

Participants

Auditors:

Isabel Castanheira – INSA, Beneficiary 15)

FCDB Compiler organization: TÜBİTAK MRC FI (TK)

Gül Biringen Löker

Birdem Amoutzopoulos

Mustafa Yaman

Senem Akkus

Aysun Ünlü (Quality Management Representative Assistant)

Sena Saklar Ayyıldız (Deputy Manager)

The audit is based on D1.5_Framework_for_Certification_revised_Sep2011.docx

Background

The review of food composition data compilation processes at TÜBİTAK MRC FI (MRCFI) took place on 17th and 18th April 2012. The review was carried out by one reviewer from EuroFIR Nexus – an analytical services/quality assurance expert from INSA, Portugal.

The reviewer was provided with web and scientific based documentation prior to the review visit and was able to familiarize herself with the current status of food composition studies and the organizational framework at TÜBİTAK MRC FI.

During the review visit two meetings were held with executive board. On 17th April, the Quality Management Representative Assistant presented the Integrated Quality Management System in place:

The Food Institute's quality policy is based on meeting the expectations and needs of the stakeholders by providing them with high quality, true and reliable services in order to ensure continuous improvement in R&D, test/analysis, training and consultancy activities in the field of food science and technology.

MRCFI services meet the requirements of:

- EN ISO 9001:2000 Quality Management System,
- EN ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories,
- EN ISO/IEC 17020:2005 Operation criteria for the operation of various types of bodies performing inspection,
- OHSAS 18001 Occupational Health and Safety Management System Specification,
- ISO 14001 Environmental Management Systems,

- Institute laboratories were previously accredited by DAR/DAP (2002-2010). Accreditation has been certified by TURKAK since the beginning of 2011.

The next day a meeting with the Deputy Director took place to gain further information on management processes in relation to food data compilation.

Management requirements

Organization structure and management policy

The mission of the MRCFI is; conducting scientific and technological studies in accordance with the national priorities; technological development and strengthening the competitiveness of Turkish food industry; assisting safe and quality food production and solving nutrition related problems in the society. The institute has been conducting R&D, testing/analysis, education and consultation studies in the fields of food science and technology to contribute to technical development in the food industry. The institute carries out interdisciplinary studies in the field of food science, nutrition and technology.

The purpose and mission of MRCFI are available on the public website <http://www.mam.gov.tr> and <http://www.tubitak.gov.tr>. A clear organisational structure was provided giving details of the senior management structure and departmental structure. TÜBİTAK MRC FI consists of three Strategic Business Unit (SBU); Food Science and Technologies SBU, Nutrition and Functional Foods SBU and Food Microbiology and Biotechnology SBU. A Quality Management team is based in Gebze-Kocaeli. MRCFI employs approximately 77 scientific staff (46 researchers; (18 PhD; 17 Masters; 11 BSc); 11 Technicians and 2 Administrative assistants. The Deputy Director coordinates activities in research areas and has responsibility for the future scientific programme. The food composition data production process involves various laboratories of MRCFI.

The food composition data set (EuroFIR Nexus) working group has four staff (Gül Biringen Löker, Birdem Amoutzopoulos, Mustafa Yaman, Senem Akkus Çevikkalp) and is part of the Nutrition and Functional Foods SUB

The Turkish Food Composition Data Base (<http://www.turkomp.gov.tr>) project is fully funded by TÜBİTAK the Public Research Grant Committee (KAMAG) of Support Programme for Research Projects of Public Institutions (1007), 107G208 and periodically audited by KAMAG audits.

TÜBİTAK MRCFI Director has final responsibility to the Ministry for all R&D activities. There is a formal quality assurance management framework operated at TÜBİTAK covering all areas of work including food composition activities.

Collaborations

MRCFI has collaborations with national and international stakeholders. These are; ministries, chambers of industry and commerce, association, universities, SMEs and various platforms.

The food composition working group is a beneficiary of the EuroFIR Nexus project and are part of the EuroFIR FCDB Compiler network and full member of EuroFIR AISBL.

Description of work

The MRCFI food composition working group included food composition studies under various projects such as; industry, public and international.

The management of food composition studies have been developed “to match as closely as possible the research typology and fulfil the Turkish and international expectations in terms of data quality to give confidence (reliability and credibility) in the results of Food composition carried out by analytical and compilation activities led by the food composition working

group". The work in terms of quality management is a hybrid dedicated to both compilation and analytical activities incorporating the requirements of EuroFIR and of the integrated quality management system in place at MRCFI.

Contracts and sub-contracts

All contracts are reviewed by the MRCFI management team including the Finance Director and legal representatives and are formally signed off by the Director. Signed copies of contracts are held within TÜBİTAK MRC and as scanned Pdf files.

Document control

The document control of food composition studies are one part of the MRCFI Quality Management System (QMS). The pyramidal structure of the documentation associated with the QMS includes a quality manual, describing clearly the quality requirements to be met. The second documentation level is the quality plan, also designated as the research plan which is the written format of the research project. Food composition based projects are associated with a quality plan defining the objectives to be met, the tasks involved, the constitution of the research team (including the appointment of the project leader), the associated resources, the milestones, the time limit planned. Research activities performed as thematic actions such as laboratory analysis and compilation are included in the main project and are accompanied by a quality plan. The third documentary level, is common to all activities and consists of general and specific procedures. All the documents are written, revised and approved according to a competency matrix. Coding and revising of documents is in compliance with a specific Working Instruction (Y.01.4.2.01). A dedicated coding system for external documents is in place.

Review of the Quality Management System

There is an integrated QMS in place at MRCFI covering all items from EN ISO 9001:2000 Quality Management Systems; EN ISO 14001:2004. Environmental Management System; EN ISO 17025: 2005 General requirements for the competence of testing and calibration laboratories to EN ISO/IEC 17020:2005 Operation criteria for the operation of various types of bodies. MRCFI laboratories are accredited for analysis of approximately 135 food components and most of the assays are to generate new accurate and reliable analytical data in line with international standards.

Management reviews are the responsibility of the Director and conducted quarterly via written reports from project leaders to unit and then to the senior manager. The Quality Management Representative Assistant is responsible for providing the Director with a consolidated report on institute issues addressed in these reports. MRCFI is subject to financial audits by project funding bodies including EU. Formal internal and external audits, fitting the audit plan in appropriate time intervals, are carried out by auditors' qualified by a national accreditation body. Project plans are audited by experts on regular basis.

Technical requirements

Personnel

Personnel involved in food composition studies have adequate combinations of academic and professional qualifications. Each member of staff has a work plan ensuring their competence for operation of specific equipment, performing tests, evaluating results, signing test reports. Each member of staff has a work plan in accordance with QMS, the training manual with updated records of curriculum and training activities. Personnel responsible for opinions and interpretation of reports have relevant knowledge of technology including legislation, understanding significance of deviations and tasks related with the compilation process. Training needs are identified and training programmes are evaluated according to

the QMS. Three categories of training are defined and complete by staff, initial, on-going and professional development. Some of the food composition working group members have attended the International Graduate Course on Production and Use of Food Composition Data organized by FAO and EuroFIR in Wageningen. Records on training were checked and are up to-date on the relevance of qualifications in terms of experience and professional qualifications.

Equipment

Equipment covering all areas of work is calibrated on a regular basis in compliance with quality requirements. A detailed program of calibrations and checks with specialized standard procedures for each class of equipment is in place. An acceptance criterion was established for the equipment. Detailed instrument records are kept and were presented. IT provision and software is maintained and developed by suppliers contracted to TÜBİTAK MRC IT Department.

Sampling

Food composition studies sampling procedure is conducted according to the MRCFI quality system. According to the projects, project based specific protocols could be prepared or the laboratory samples may be provided by the customers of projects.

Analysis/Data production

In MRCFI an impressive plan of analysis has been implemented. Nutrients are analysed applying the adequate metrological tools and quality assurance practices. Most of the assays are carried out under accreditation to the ISO 17025 umbrella, using analytical methods that fit the purpose which are fully validated with performance matching the international acceptance criteria on adequate matrix. Internal and External Quality Control are in place for all analysis. For each nutrient, Internal Quality Control is carried out with blanks or chemical calibrants, spiked samples or blind samples. The values obtained with QC tools are plotted in dedicated Control Charts with 'warning limits' setting t at $\pm 2s$ ($\pm 2s$) about the mean value, and 'action limits' setting at $\pm 3s$ ($\pm 3s$) about the mean value. The laboratory participates in PT schemes, operated by accredited PT providers, three times in a year to demonstrate traceability at national and international levels. The monitoring of results and actions are in compliance with ILAC guidelines and Control Charts are plotting using the limits defined by International Organizations. An uncertainty budget is described for each analysis using the bottom up approach supported in modelling. Recipe calculation, nutrients losses and gains and retention factors follow EuroFIR and USDA guidelines using dedicated software and excel spread sheets.

Publication process

All the researchers are registered to the TÜBİTAK ARBIS (TÜBİTAK Researcher Information System of Turkey) user data base.

The Turkish food composition data set (TÜBİTAK Food Composition Data Set-Value Documentation 2010) consist of more than 1200 aggregate and composite foods. This contains information for most components, obtained from scientific literature and published project reports. This data is stored separately and checked by the group of FCDB Compilers who generate new data in the laboratory and define quality plans and quality criteria.

Compilation process (critical control points – see EuroFIR generic compilation flowchart)

The Compilation process is underway following the EuroFIR generic flowchart. The process of document (writing and revising and approval) is in compliance with TÜBİTAK MRC QMS. The Food Composition working group is going to prepare a specific SOP for their data compilation process.

Identification of relevant foods and nutrients.

In the context of the food composition projects, foods and nutrients are analyzed and methodologies adopted to select their prioritization according to the project aim and needs. In some projects, the Languag food classification system is used.

Attribution of Quality Index and Confidence Code

The SOP in draft format follows six criteria as defined by EuroFIR and USDA, Food Description and component, sampling plan, sampling handling, number of samples, method of analysis and quality control. The document in draft format is designed to score data and to attribute confidence code to data generated.

Physical Storage of original data

MRCFI has a special SOP containing information on how original data is stored in hard copy or electronic format, responsibilities, and physical integrity of folders which contains original/raw data.

Selection of original data to produce aggregate data

MRC FI has a draft SOP for Selection of original data to produce aggregate data for use in some projects. Selection and application of algorithms to produce aggregated and compiled data. The methodology is under discussion to adopt the procedure describing in CEN standard.

Validation of aggregate and compiled data

Validation is done through a rigorous plan implemented in several steps by a group of compilers with appropriate skills.

Vertical audit of data

A vertical audit was applied to trace back documentation of nutrient values in key foods. This was done using a casual key food summary report and traced back to raw data and ancillary information (certificate of analysis, or literature data source).

Values for “Hacıhaliloğlu apricot, sun-dried” were traced back to full documentation using compiled data from certificates of analysis as a data source which was aggregated and published in “Löker, G.B., Açkurt, F., Amoutzopoulos, B, Alaşalvar, C., Bahar, M.G.B., Özay, G. Fonksiyonel gıda olarak taze ve gün kurusu kayısının bazı fizyolojik özelliklerinin belirlenmesi ve sağlıklı beslenme açısından değerlendirilmesi klinik araştırma. In, Otlu, A., Öztürk, F., Asma, BM. Kayısının İnsan sağlığına Etkileri Konusunda Yapılmış Bilimsel Araştırmalar, Malatya Valiliği, Malatya, 2007, 9-47, ISBN 978-975-01192-1-7”. and “Löker, G.B., Açkurt, F., Amoutzopoulos, B, Erdoğan, Ş., İşik, T., Tekel, M. Kayısının sağlık ve beslenme açısından değerlendirilmesi klinik uygulamalar. In; Otlu, A., Öztürk, F., Asma, BM., Kayısının İnsan sağlığına Etkileri Konusunda Yapılmış Bilimsel Araştırmalar, Malatya Valiliği, Malatya, 2007, 49-65, ISBN 978-975-01192-1-7” Malatya, 2008. The approach was in casuistic form. The audit results confirmed that results were complete, and it was possible to identify all steps and associated documentation.

Conclusions

The TÜBİTAK MRC FI, food composition working group have developed impressive work to create new analytical data following the quality criteria designed during the EuroFIR project. The analytical data and software programs have been developed and are currently being tested for food composition data production. The food composition data production work is done under appropriate Quality requirements. The team seems to control all the activities from selection of foods and nutrients up to published of data.

The information about “Determination of National Food Composition and Formation of a Widely Spread-Sustainable System” was not given in the review report while the project is continued, and data on the project work is still confidential. However, general information on data production in the project can be found in a paper published by project group in “*Löker, G.B., Ozkoc, S.O., Amoutzopoulos, B., Yaman, M., Akkus, S., Şanlı, F., Küçük, F., Establishing a food composition database for Turkey based on European standards, Nutrition Bulletin, 36 (2), 253-257, 2011*”.

Recommendations

1. The Turkish online database should continue to be developed, making use of analytical data generated under quality assurance and metrological principles.
2. The focus on foods that are produced in Turkey or that are traditional and an important feature of the diet should continue, using analytical data generate by TÜBİTAK or published in scientific literature.
3. Specific food composition study SOPs and guidelines should be completed.
4. Attention should be given to users’ needs via website questionnaires to obtain feedback and identify problems.

Appendix F – Review of THL, Finland

EuroFIR – Nexus WP1.2.2

Report from the review of the Finnish Food Composition Database at the National Institute for Health and Welfare (THL), Helsinki, FI on 23rd – 24th April 2012

Participants

Auditors:

Anna Karin Lindroos, NFA, Sweden

FCDB Compiler organization: THL, Helsinki, Finland

Salla Luhtala
Heikki Pakkala,
Tommi Korhonen,
Suvi Virtanen, Head of the Nutrition Unit

Heli Reinivuo (not present at the visit but provided additional information after the review)

The audit is based on D1.5_Framework_for_Certification_revised_Sep2011.docx

Background

The review of the food composition data compilation processes at THL took place on 23 April and 24 April 2012. The review was carried out by one reviewer from EuroFIR Nexus – Anna Karin Lindroos (AKL), head of the Food Data Division at NFA, Sweden and responsible for the Swedish Food composition database. She is also a director of the EuroFIR- AISBL. Before the visit the reviewer had access to web based information on the Finnish food composition database (www.fineli.fi) and The National Institute for Health and Welfare (THL) (www.thl.fi) and was provided with two leaflets describing THL.

The head of the Nutrition Unit, Professor Suvi Virtanen participated in the opening meeting. A separate meeting was also held with Professor Virtanen on day 2 as she could not participate in the closing meeting. Heli Reinivuo responsible for the Finnish food composition database was not able to participate in the review. After the review she provided additional information.

Fineli is the Finnish Food Composition Database (FCDB); **Finarkki** is the Fineli FCDB management software

Management requirements

Organization structure and management policy

The National Institute for Health and Welfare (THL) is a research and development institute under the Finnish Ministry of Social Affairs and Health. THL was formed on 1 January 2009 when the National Public Health Institute (KTL) and the National Research and Development Centre for Welfare and Health (STAKES) were merged into one large institute. The main office is located in Helsinki and there are also satellite offices in six different places outside Helsinki. In total around 1200 people (person-years) are employed by the institute.



Figure 1. Organizational structure of THL. Nutrition Unit is situated in the Department of Lifestyle and Participation under the Division of Welfare and Health Promotion.

The purpose and mission of THL are available on the public website. THL's operations are guided by an annual performance agreement made with the Ministry of Social Affairs and Health. A clear organisational structure is available on the web page. THL is divided into four main divisions that are further divided into 14 departments and 66 units. Food composition work is carried out within the Nutrition Unit under the Division of Welfare and Health Promotion. The Nutrition Unit, headed by Suvi Virtanen, consists of around 30 researchers and experts with university degrees in nutrition, medicine, statistics and computer science and the unit is involved in many different studies on diet and chronic diseases. Nutrition policy and nutrition communication are also tasks of the unit. Staff are mainly externally funded by project money. The work carried out at the Nutrition Unit is not described on the web page, however there is a separate website for Fineli (<http://www.fineli.fi>) where foods and nutrients can be searched and accessed with accompanying information.

The food composition work is regarded as an important basic nutrition tool at THL and for external users, but there is no specific mission statement for the food composition work and database.

The Fineli team consists of Heli Reinivuo, Salla Luhtala, Heikki Pakkala and Tommi Korhonen. In addition, staff on short term contracts with the dietary surveys are compiling food composition data.

Heli Reinivuo has an M Sc in Nutrition and is responsible for the development, maintenance, quality assurance and dissemination of Fineli and also manages the Fineli team.

Salla Luhtala has an M Sc in Nutrition and is responsible for the day to day food composition database work including quality control and documentation. She oversees and trains the FCDB Compilers and tests the food database management software Finarkki.

Heikki Pakkala has an M Sc in ecology and has 30 years' experience in IT. He is responsible for the design, implementation and maintenance of Fineli and Finarkki. He also

works with the development and maintenance of the information systems used in the harmonized data interchange.

Tommi Korhonen has an M Sc in computer science. He is involved in the design, implementation and maintenance of several in-house software packages for nutrition research. He is involved in the design, implementation and maintenance of Fineli and the Fineli public web site.

The Fineli team does not work full time on compiling foods and maintaining the FCDB maintenance systems. Time spent on Fineli and Finarkki varies depending on the on-going studies, other projects and available resources and is decided by the head of the Nutrition Unit.

Administration services (e.g. Human resources, IT, Finances, Communications, Legal issues) are managed centrally at THL.

There is no formal quality assurance management framework at THL, however units and departments with laboratory work have quality assurance schemes (e.g. ISO 17025). The Nutrition Unit does not carry out any laboratory work and is therefore not involved in these quality assurance schemes.

The work carried out at the Nutrition Unit is reviewed yearly by the department head. The Finish academy may also carry out audits for the nutrition research carried out in the unit and the FCDB could be part of this audit.

Collaborations

The food composition work is closely linked with the dietary assessment work within the Nutrition Unit at THL.

THL is a beneficiary of the EuroFIR Nexus project and Heikki Pakkala is EuroFIR NEXUS Work Package leader for "Systems integration and operation services". THL is a full member of EuroFIR AISBL and Heikki Pakkala is vice President of EuroFIR - AISBL. Heli Reinivuo coordinates the European FCDB Compiler network.

The Nutrition Unit has initiated a Nordic analytical network with the purpose to collaborate on analytical projects for the Nordic food composition databases and to jointly apply for money to carry out nutrient analyses. The network is funded by the Nordic Working Group for Diet, Food & Toxicology (NKMT).

The Fineli team also has a close dialogue with users of Fineli e.g. researchers working in THL outside Nutrition Unit or in other institutes or universities, the Finnish Food Safety Authority (EVIRA) and people working within the catering services companies.

Description of work

The Fineli Team is responsible for the overall planning and monitoring of the food composition work. Heli Reinivuo is the chair of the team. Internal stakeholders, researchers and food FCDB Compilers are represented in extended Fineli team meetings which are organized four times per year to plan and monitor progress of the food composition activities. The head of the Nutrition Unit – Suvi Virtanen - also participates in these meetings. The food composition activities are directed by the needs of the dietary surveys, requests from the food safety authority (EVIRA), catering services companies and other stakeholders. In addition, the Fineli team is also looking into new products on the market. The team plans the overall work over the year.

The Fineli FCDB Compiler working group, chaired by Salla Luhtala, meets regularly (about every two weeks) to discuss the work and distribute work tasks between the team members. Ad hoc working groups are also formed if needed for specific purposes related to the food composition work.

The yearly work plan is quite general and may be revised at the Fineli Team meetings. The job details are planned each month in the FCDB Compiler working group.

The work of the Nutrition Unit, including Fineli, is reported annually to the department head by Suvi Virtanen. This is done in the form of a yearly meeting where achievements and activities of the Nutrition Unit are discussed and future activities are planned. The institute also has a joint table of activities where work progress is monitored.

Externally funded projects (e.g. EuroFIR Nexus, dietary assessment studies) have specific deliverables and milestones according to funding bodies.

The job descriptions of staff are quite general. The specific tasks and responsibilities of team members are not documented.

Training of staff is encouraged but there are no formal training records. Yearly performance reviews with staff are held with the head of the Nutrition Unit. In addition, the general performance of the Nutrition Unit is reviewed once a year by head of the Department of Lifestyle and participation, and by head of the Division of Welfare and Promotion.

Contracts and sub-contracts

THL does not currently undertake nutrient analysis of foods, therefore there are no contracts with external or internal laboratories.

All contracts with external projects are reviewed by the THL management team including the Finance Director and legal representatives and are formally signed off by the Director. Signed copies of contracts are held centrally at THL and as scanned pdf-files with the Fineli team.

There are no contracts or service level agreements for services provided by other staff, teams or departments within THL.

Document control

Electronic documents related to the food composition work are stored in a project folder on the intranet. Access to the files is restricted to those involved with the food composition work. Moreover, the FCDB management system and FCDBs are documented in the intranet. Part of the documentation is included with the source code of the management system.

THL also has an internal information system on the intranet (based on a wiki system). The FCDB team has a section in the system where they can add information, work lists (to-do lists), instructions and minutes from meetings. The system has an automatic version control and it is possible to track who added what and when to the system. All THL employees have reading access to the system.

The internal network and all electronic files are automatically backed up every day. In addition, the source code of the FCDB maintenance system is stored in a software version and revision control system on the intranet. The FCDBs are backed up with the full backup when the database is created. After that, every database is backed up twice a week with an

incremental backup. Copies of the back-up files are stored not only in THL but also they are stored outside the institute. The IT department is responsible for this work.

Hard copies of data and publications are stored in the Fineli team's offices.

Technical requirements

Personnel

Job descriptions for individual staff members are prepared but they are quite broad and generic and they are not related to specific tasks or deliverables. Employment contracts are often fixed duration related to project funding. Staff may have access to job specific training provided by external organisations but opportunities may be limited due to lack of funding. Salla Luhtala will attend the Food Composition course in Turkey in the autumn 2012. Training is not documented in any formal training records. Yearly performance reviews are carried out with staff.

The staff on short term contracts and involved with food compiling work have a basic degree in nutrition and are trained before they are allowed to access Finarkki and work on their own. They also work closely with Salla Luhtala who monitors the work and does regular checks.

All involved in the food compiling work have good skills in the English Language.

Equipment

Equipment used for food composition work is limited to office equipment, including PCs and bespoke software for the FCDB management system. The FCDB system is a relational database developed in house. All food compiling (including meta data) is managed within the system. Algorithms and factors are included in system for automatic data calculations. It is version controlled and foods not used are archived in the system. The FCDB management system Finarkki – is linked to the dietary assessment data management system Finessi.

IT maintenance and development is carried out by staff within the Nutrition Unit. General IT support (network and PCs) are carried out by the THL IT services.

Sampling

Samples are currently not collected for nutrient analysis.

Data production

New foods that are added to the database are mainly based on recipe calculations. Core foods (1093 foods) used in the recipes have analysed nutrient values, but since no nutrient analyses are currently carried out the analyses values are often old and need to be updated.

Foods may also be borrowed, primarily from the Swedish, Danish, and USDA food composition databases.

Publication process

The Fineli data consists of more than 7000 foods. When excluding archived foods the database consists of around 5500 foods. The publically available data (approximately 3500 foods of which 1685 are single, raw foods) are published online and managed through the web based intranet interface <http://www.fineli.fi>.

Around 50 new foods are released each year, but the number may vary. For example the next release will include 200 new food codes. Not all compiled foods will be published online and publically available. Foods with information from the food industry may for example not be published, but they are used in the dietary survey nutrient calculations.

Data is released approximately once a year and prior to publication all data is checked manually by the FCDB Compilers and through computerised checks (see below) and ultimately signed off by Heli Reinivuo.

Compilation process (critical control points – see EuroFIR generic compilation flowchart)

The EuroFIR generic flowchart for the food data compilation process gives an overall description of the compilation process and identifies critical control points and SOPs needed.

There is no formal SOP system for the compilation process. Although the Fineli team does not directly make use of the EuroFIR generic SOPs the food composition work is guided by the EuroFIR guidelines and there are written instructions for some of the key steps.

The instructions are currently being added to the intranet information system. These include how to create a new food code based on an existing food, how to create a food from a recipe and how to code nutrient data. Protocols exist for how to code type of food (raw ingredient, dish or supplement), publication status, how to create a new citation, preparation method, classification by raw ingredient, naming of foods, keywords, units (household measures and average portion sizes) and foods for special dietary purposes.

No protocols exist for how to code edible portions, publication, classification by food and composition, Eurocode or Languag coding (codes are currently not updated and checked).

The compilation process

1. Identifying a new food

New foods are identified based on requests from the dietary surveys, the food safety authority (EVIRA), catering services companies and other external users. Foods are also identified by checking the market for new products. Prioritising of the foods is discussed and decided at the Food Composition Developing team meeting and the FCDB Compiler group meetings.

Identified foods are entered on the work list on the internal information system. A traffic light system is used to the food list where green means ready, yellow on-going and red that it is not possible to add this food to the database due to lack of information or other reasons. There is also a comments field in the work list table for queries or comments related to the compiling of the food.

2. Assigning nutrient data to the food

Foods are identified through reviews of the scientific literature or from other databases – primarily the Swedish, Danish and USDA databases. For composite foods recipes are calculated according to the ingredient lists. Information is also taken from food labels and missing values are then estimated and calculated from other foods. Final values are compared with similar foods.

3. QI - Quality indices are not used in the compilation work.

4. Food codes

A new unique food code is generated in FCDB system for every new food entered into the system. A new food can either be created from scratch or be based on a similar existing food code. By using an existing food the accompanying information can be copied and then checked and changed accordingly.

5. Calculations and algorithms
Recipe calculations are made within the Fineli software system. Selection and application of algorithms to produce aggregated and compiled data are based on EuroFIR guidelines. Retention and yield factors are based on Bergström, Bognár and some national data.
6. Data checking
The person creating and entering data for the new food makes a final check that all information is complete and correct. After that the status on the food work list is changed to green or red (if it is not possible to complete the food).
7. Validation of the food information
When a number of foods have been added the data is exported to an excel spread sheet and checked by food group. Maximum and minimum values for important nutrients, approximates and macronutrients, missing nutrient values and logical zeros are checked. Other examples are that PUFA should be less than total fat, that total carbohydrates and sugars are consistent etc.
8. Correction of errors
Errors are corrected where appropriate.
9. Database checking before release.
Before releasing the data (about once a year) a number of electronic checks are run to identify errors related to missing information. Missing information is added and errors are corrected. If this is not possible a comment is written and the food will not be published.

User feedback is also used to identify errors and published values are corrected where necessary.

Vertical audit of data

The review concluded with a vertical audit where the procedure of creating a new food was followed all the way from identifying the need for the food a new food with all associated metadata in the test database. The example food “vegetarian (meat) balls” was used and we went through the different steps. This procedure identified a few minor steps that could be handled in different ways due to subjective decisions. The steps could be made clearer to help the FCDB Compilers in deciding which direction to choose. The comments section in the internal information system is a useful tool in identifying these steps during the FCDB Compiler process.

Conclusions

The Fineli FCDB is well established in Finland and a recognised nutrition research tool at THL. The FCDB is also important for external users and the Fineli website has over one million searches per year. The website is clear and the food data information easy to access.

The core team has long experience of food compiling. The team is involved in the EuroFIR collaborations and the procedures follow more or less the EuroFIR guidelines. All procedures are however not documented. THL has an excellent internal information system where work lists and minutes are stored. Within this system it is also possible to highlight aspects that need to be discussed and give comments on how to improve work procedures. Guidelines and protocols for the food composition work are currently being uploaded to the system.

The work is supported by the in-house built database management system Finarkki which ensures consistency of the food data handling and quality. The close collaboration between the computer scientists and FCDB Compilers facilitates the FCDB work, further improvements of the system and exchange of food data.

The food composition work is to a large degree dependent on external funding for different projects utilizing food composition data. This makes it difficult to ensure that enough and stable resources are spent on the food composition database. Employees on short term contracts (working on the dietary surveys) contribute to the food compiling work. This increases the flexibility of the work. On the other hand it is a challenge to ensure that staff on short term contracts are appropriately trained.

The compiling of foods is mainly focused on creating foods from recipes. The analytical data for foods are old and new analytical data are much needed.

Recommendations

1. The Fineli online database should continue to be developed, making use of data from industry, scientific literature and analysed data from other food composition databases.
2. To use new, quality assured analytical data wherever possible. The initiatives taken to secure funding for new nutrient analyses are encouraged. Money secured for Nordic analyses network is an important start. Possibilities to collaborate on nutrient analyses within EuroFIR should also be explored.
3. Continue the work of documenting all procedures and guidelines for the specific procedures on the internal information system.
4. Identify and clarify steps in the procedures that the FCDB Compilers may find unclear and make instructions for these. The comments section in the internal information system is a useful tool in identifying these steps during the work.
5. Further develop automatic checks to help the FCDB Compilers checking the correctness of data and reduce the manual checks.
6. Document tasks and responsibilities of the team members. Set up a training program for new food FCDB Compilers and define criteria for when staff can be signed off for the different FCDB Compiler tasks.
7. Set up a system for staff training records.
8. Document the organisational structure of the Nutrition Unit. In the work of securing funding for nutrient analyses a mission statement of Fineli would also be very useful.
9. Store all basic information used for the food compiling electronically. The product information used for the recipe calculation of new foods is currently printed out and stored in a paper folder. These could be stored electronically. Other information that is only available on hard copies should be scanned and stored electronically, or alternatively kept in a fire proof cabinet.

Appendix G – Review of NUBEL, Belgium

EuroFIR – Nexus WP1.2.2

Report from review visit at NUBEL, Brussels, BE on 21st – 22nd May 2012

Participants

Reviewers:

Susanne Westenbrink, RIVM, The Netherlands

FCDB Compiler organisation: NUBEL, Belgium

Carine Seeuws, FCDB Compiler

Aurore Van Der Wilt, FCDB Compiler

Marc De Win (Chair Board of Directors)

John Van Camp (Chair Scientific Committee)

David Marquenie (Nutrition Consultant Food Industry)

The audit is based on D1.5_Framework_for_Certification_revised_Sep2011.docx

Introduction

The review of the NUBEL food composition data compilation processes at NUBEL took place on 21st and 22nd May 2012. The review was carried out by one reviewer from EuroFIR Nexus – Susanne Westenbrink who is a national database FCDB Compiler from RIVM, the Netherlands. Some information on the NUBEL organization from the internet was available beforehand.

The review began with a welcome and an introduction of the review procedure. The management of NUBEL was presented on the first day by Marc De Win and Carine Seeuws; technical processes were presented on the second day by Carine Seeuws.

Management requirements

Organization structure and management policy

NUBEL is a non-profit organization which was founded in March 1990.

NUBEL is hosted as an external entity within the Federal Public Service (FPS) – Health, Food Chain Safety and Environment (Federale Overheidsdienst - Volksgezondheid, Veiligheid van de Voedselketen en Leefmilieu), which is located in Brussels. FPS is responsible for nutrition policy in Belgium among other topics. NUBEL is closely related to the work of FPS as the data produced by NUBEL is needed by the FPS.

The organisational structure of FPS including NUBEL is added in Appendix 1.

NUBEL has 3 staff members, who are employed by the board of directors of NUBEL ASBL. NUBEL is located in the FPS building, using the FPS infrastructure including offices, meeting rooms, and electricity, internet and computer facilities. Equipment, including computers, is owned by NUBEL.

The NUBEL ASBL has a board of directors composed of representatives from the three effective members, plus the chair of the scientific council and the person responsible for communication. Effective members pay a membership fee and are represented in the board

of directors. Effective members are:

- Federal Public Service Health, Food Chain Safety and Environment (FPS)
- Scientific Institute of Public Health
- Federation of the Food Industry (Fevia)
- Federation of the Retailers (Comeos) (membership will finish as of 2013)

The board of directors meets 4 times per year.

NUBEL has a scientific council, which is an independent group composed of representatives of Belgian universities that have a faculty related to health and nutrition. The scientific council meets once per year to discuss the working program for the next year. NUBEL policy-making processes take place in the board of directors, who get advice from the scientific council.

In addition, NUBEL has additional members and sponsors.

Additional members (Vlaams Instituut voor Gezondheidspromotie en Ziektepreventie vzw (VIGeZ), Union Professionnelle des diplômés en Diététique de Langue Française (UPDLF), Nutrition Information Center (NICE), Observatoire de la Santé du Hainaut (OSH) do not pay for membership and are not in the board of directors. They do contribute in exchanging information and discussing relevant topics.

A number of food companies financially sponsors NUBEL. Sponsors are listed in the NUBEL products such as the printed food composition table and the website.

The organogram of NUBEL is added as Appendix 2.

Income generation

Being an ASBL organization, NUBEL needs to earn its own money for salaries, food analyses, software development and printing of NUBEL products. Apart from the membership fees, the budget provided by the FPS and the contribution from the sponsors NUBEL earns money by selling products (Belgian Food Composition Table, Food Planner, licenses) and providing licenses to datasets. In addition, food companies pay a small amount of money for each brand food that is added to the database.

Food composition work of NUBEL includes:

The NUBEL food composition activities are the topic of the EuroFIR FCDB Compiler peer review. FCDB Compilers working on the NUBEL database are Carine Seeuws, FCDB Compiler

Aurore Van Der Wilt, FCDB Compiler. A (part-time) administrative person takes care of invoices etc. and she assists in some compilation work.

The NUBEL team is responsible for the compilation process for the NIMS database. The objectives of NUBEL are:

- Development, update and management of Belgian food composition database
- Distribution of the data to potential users
- Exchange of data on a national and international level

Products produced by NUBEL are

- Printed Belgian Food Composition Data table (Dutch and French)
- Food composition database on Brand products on internet available through annual subscription (www.internubel.be) (Dutch-French-English-German)
- Software-program « Food Planner» and « Food Planner Pro» on internet available through annual subscription (www.nubel.be) (Dutch-French)

Collaborations

NUBEL is collaborating with the FPS on practical issues related to the hosting in the FPS building and sharing facilities. NUBEL also collaborates with FPS in the **Federal Food and Health Plan** with nutritional projects like the Food Planner Pro including screening tools to detect malnutrition for geriatric and oncology patients.

NUBEL is collaborating with the Belgian National Food Consumption Survey by providing food composition data.

NUBEL collaborates with several organisations (Food in Action, VIGeZ) in nutrition and health related projects such as the food pyramid.

The **project “Happy Body”** is organized in collaboration with the Food Industry (FEVIA) and the Belgisch Olympisch en Interfederaal Comité (BOIC) to motivate the population to change behaviour (balanced diet and increased physical activity).

NUBEL collaborates with the Belgian Food industry to collect data for the brand database.

Currently collaboration with GS1 is under development to use the GS1 food and drink extension for data collection from all manufacturers.

NUBEL has formed a working group on the analyses of dietary fibre in which representatives of the scientific council participate with representatives from Belgian laboratories.

NUBEL is full member of **EuroFIR AISBL**. Through EuroFIR and the EuroFIR FCDB Compiler network links are made with national FCDB Compiler organizations similar to NUBEL. NUBEL participates in the EuroFIR-NEXUS project.

Customer requirements

Taking into account customer requirements is assured through the organization structure of NUBEL, with the board of directors and scientific council representing the stakeholders from the government, academia and food industry. On a daily basis NUBEL FCDB Compilers are in contact with users of the NUBEL data. See also the chapter on feedback from users.

Description of work

Working plans, including financial budget plans, are written on a yearly basis. FPS, a governmental body, needs to follow strict rules to finance NUBEL. The management plan including the financial budget plans need to be checked and approved by the Inspector of Finance. After approval, the Royal Decree must be signed by the Belgian King and published in the Belgian Official Gazette before money can be made payable.

The balance sheet is audited by an external independent auditor who will report to the General Assembly where the balance is approved.

An annual report is written to report on work done and achievements reached. This report needs to be approved by the board of directors.

Individual working plans for each employee are also prepared each year indicating the work to be done by that person and timetables to follow.

All documents are available and collated both in the computer and as hard copy.

Contracts and sub-contracts

NUBEL does not follow the official governmental procedures for procurement contracts.

Internal

NUBEL is hosted within the FPS building without an official contract.

External

- NUBEL has contracts with Real Dolmen, which is the software company taking care of building the NUBEL DBMS and the websites with the brand database. The Food

Planner is developed by another software company “New Media Events” who is also charged with the hosting of the websites on the internet. This contract also includes a helpdesk for customers of NUBEL.

- NUBEL has a contract with the publisher of the printed food comp table.
- For the food analyses programs contracts with several laboratories are signed.
- With individual manufacturers, contracts are signed to arrange for the data delivery of the companies and the services provided by NUBEL.

Document control

For document control and archiving FPS procedures are followed whenever applicable. Electronic documents used for food composition work are stored and accessed via the FPS computer network and are managed according to standard networking protocols controlled by the FPS IT Department. Access to files is restricted to members of the NUBEL team through username/password controls. Each team member has a personal workspace to store and work with files in addition to the shared workspace. Data is backed up by FPS according to FPS regulations.

The financial administration is archived according to governmental rules.

The complete NIMS database is backed up daily through the FPS IT department. The latest version of datasets selected for dissemination are backed up and stored when ready for dissemination. Back-ups are stored in the building of the FPS, which is considered to be a risk in case of fire. Copies of dataset are also at an irregular basis kept on USB-sticks and/or CD-ROMs.

Data used for the Food Planner and brand database websites is maintained, backed up and stored with a company called New Link in Prague.

Official analytical results and the documents obtained in the framework of tenders are stored in the NUBEL archives.

After producing the first version of the NUBEL QMS, NUBEL will take into account version numbering for future versions of the documents.

Review of the Quality Management System

NUBEL is a very small organisation hosted within the FPS organisation. NUBEL uses the FPS infrastructure and follows governmental requirements whenever possible and applicable. The private law for non-profit organization must be applied. With respect to personnel, private rules are followed. NUBEL is not certified according to ISO-9001 or similar quality structures. NUBEL is in the process of building a quality management structure to assure data quality. The EuroFIR FCDB Compiler review is used as a starting point for this QMS. The food data compilation process is documented in a NUBEL flow chart and detailed in appendices.

In the framework of this FCDB Compiler review, elements presented and contributing to the building of the NUBEL QMS includes control of

- project planning
- staffing (competencies, performance and training)
- contracts and agreements
- documents (electronic storage and back up and hard copy storage)

For NUBEL a SWOT analyses was done recently to identify strong and weak points that will be taken into account when developing the QMS and future plans.

Technical requirements

Personnel

The board of directors directly employs the NUBEL staff. Job descriptions are available and have been formulated according to private requirements. Job descriptions and CVs are available.

FCDB Compilers are in very frequent contact with the chair of the board of directors, who is working in the same building. Working plans and any other issues are discussed when applicable. No formal performance reviews are held.

Training

NUBEL employees are entitled to follow 10 days of training per year, following the FPS rules. All training is documented in personal files. This includes presentations given by NUBEL staff as well.

Technical competencies have been a selection criterion for NUBEL staff members. The senior NUBEL FCDB Compiler has followed the International Food Composition Course in Wageningen.

Additional competencies such as managing and coaching, writing annual reports or brochures are trained on the job and through training courses.

Equipment

Equipment used for NUBEL food composition work is limited to office equipment, including PCs and software for data management.

Office software such as Word, Excel and Access is used and serviced through the FPS IT team. A software company Real Dolmen provides NIMS software.

List of equipment:

- Computers
- Internet access
- Office Pack, including Access, Word, Excel etc

NUBEL database management system

The NUBEL database management system is the NIMS system, which is the abbreviation of NUBEL Information Management System.

The NIMS system is built in Access in such a way that it functions as a relational DBMS. This includes the modules for the brand database as well as the management of historical data points. NIMS has a user interface that enables efficient data management to a large extent.

The NUBEL DBMS allows for selecting data points by date. This functionality is used to identify which values need to be updated or should be included in analytical protocols.

A number of procedures are performed automatically such as storing all historical data points, calculation of median values for the generic dataset and showing the latest data point on brand data on the NUBEL website. NIMS currently only allows for manual data entry. Recipes are maintained and calculated outside the NIMS. EuroFIR value documentation is now included in the NIMS system as well.

Consistency checks are not performed automatically.

FoodCASE

NUBEL has invested in extending the functionality of NIMS in previous years. There is no direct need for NUBEL to change to another database management system. It would take a lot of time to transfer all data from NIMS to FoodCASE, NUBEL has no experts for this task and hiring them would be a large financial burden. Furthermore changing to FoodCASE

would be a step backwards because of all the manual work (mouse clicking) and the lack of tailor-made automated procedures. In addition, the NUBEL database links to the brand database and the food planner, for which functionality in FoodCASE is missing.

Analytical work

NUBEL has an approximate annual budget of €45.000 for analytical work. To select laboratories information from BELAC is used. BELAC (Belgian Laboratory Accreditation Body) provides data on accredited laboratories, analytical methods etc. NUBEL contacts a number of laboratories for an offer. Based on criteria related to the analytical program an accredited laboratory is selected. The director of NUBEL ASBL signs off contracts. Procedures are described in detail and depend on the criteria and the available budget. NUBEL documents the requirements on sample collection, sample handling, method specification, analytical methods and how to report the results.

Foods are selected based on data from market shares provided by GfK. Samples are made for individual brands, not as composite samples with more brands.

Analytical programs do not include the complete nutrient profile by default. In many cases only specific components are measured. Currently dietary fibre and sodium analyses are prioritized.

The FCDB Compiler team does sample collection mostly.

Currently a working group on dietary fibre is working on a policy concerning the choice for a state of the art analytical method for dietary fibre.

Data production

NUBEL data comprises analytical data, data from the food industry, from other food composition databases and literature as well as calculated and estimated data. The NUBEL food composition table and brand database included data on a generic and brand specific level respectively. At the generic level data are published without brand names and analytical data are aggregated before publication. The NUBEL DBMS has a feature that automatically calculates the median value for publication if sufficient data points are available.

The brand database gives single entries using the nutrient data as provided by the manufacturer. The manufacturer is responsible to provide correct data and to inform the NUBEL team of any changes. NUBEL performs analyses on individual brand foods to complete the nutrient composition, in particular for micronutrients.

Publication process

After all steps including data entry and aggregation as well as data checks by the FCDB Compilers and validation by the scientific council have been done data is ready for publication. The NUBEL DBMS allows for multiple selections of data to produce datasets for the food composition table and the brand database that are forwarded to the publisher and the NUBEL website using xml respectively.

The printed table contains data on approximately 1200 foods and 32 components. The brand database provides information on approximately 6000 food items and 32 components. See also the chapter on dissemination of data.

Compilation process (critical control points – see EuroFIR generic compilation flowchart)

An organization specific compilation process flowchart for NUBEL was prepared based on the EuroFIR generic compilation flowchart (Appendix 2). For each step a schematic SOP is written in the form of a detailed flow chart. No specific references are made to critical control points and preventive or corrective actions. The process steps described by NUBEL are not identical to the EuroFIR flowchart because of the way different processes relate to each other within NUBEL. The NUBEL SOPs refer to appendices with examples of documents with more detailed information if applicable. This shows that the compilation procedures are very well

structured and under control. However, no written procedures with detailed working instructions/manuals are available to show traceability and repeatability of the process.

Procedures described in NUBEL quality documents related to EuroFIR SOPs include:

- Relational database structure of NIMS database
- Flow chart of the NUBEL compilation process
- Identification of foods and components for inclusion or update
- Analytical data productions
- Check if food description and component data are accurate and up to date
- Data entry including background information
- Check on data entry
- Production of aggregated data
- Check of aggregated data
- Selection of data for dissemination
- Dissemination of the data
- Encoding of NUBEL data according to EuroFIR standard
- Archiving of NUBEL data

The validation of NUBEL data by the scientific council are described in appendices to the flow chart, but is not mentioned as a step in the flow chart.

Feedback from users

Feedback from users is collected through the board of directors and scientific council, the contact with the stakeholders, the projects that NUBEL is involved in, the organizations using the Food Planner and Food Planner Pro and via direct contact through email and telephone. NUBEL FCDB Compilers are frequently in contact with both food industry and scientific world, which enables them to fulfill needs from both groups. NUBEL FCDB Compilers are actively training users of the Food Planner and Food Planner Pro which allows for direct contact with users.

NUBEL differentiates 7 user groups. In 2011, panel discussions have been organized to discuss the needs of NUBEL users. Results from all groups have been integrated in a report. One of the results is implementation of more advanced search facilities in the online brand database, e.g. the possibility to rank foods according to the content of specific components.

Contact with the food industry

NUBEL has established a good and very intensive contact with the food industry. The Belgian FEVIA (national CIAA organization) is a member of the board of directors. Individual manufacturers have signed contracts to arrange for providing nutritional data to NUBEL. Apart from the financial contribution through FEVIA individual manufacturers are paying a small amount of money to have their data included in NUBEL. NUBEL has developed a system to analyze brand food to complete the nutrient data on micronutrients, which benefits the manufacturers and other users.

Dissemination of data

NUBEL is an independent organization, only partly funded by the Belgian government. NUBEL data is sold to generate income to sustain the organization.

NUBEL produces

- a printed food composition table every 4 to 5 years with data on generic foods.
- an online database with brand data, in which the generic dataset is also included. Access to the website is arranged through an annual subscription. Data from all manufacturers are visible and can be compared with the generic median value.
- a Food Planner which provides a tool for nutritional and weight management both for professional uses and consumers. The Food Planner Pro for professional users is developed in collaboration with the FPS and one version focuses on the detection of

malnutrition by geriatric patients, another on oncological patients. The Food Planners include the food composition table and the brand database. Access is arranged through an annual subscription.

- NUBEL provides also license agreements for commercial use. This agreement includes a copy of the dataset in Excel.

The online brand database and the Food Planners show the actual data from the database and thus data can be different from the printed food composition table. NUBEL publications are in Dutch and French; online data is also available in English and German.

EuroFIR

NUBEL is full member of EuroFIR AISBL. NUBEL has documented the food composition values in accordance with the EuroFIR technical annex. The NUBEL dataset is included in the EuroFIR eSearch facility. Updating the EuroFIR eSearch data is not possible due to technical (and financial) restrictions, as NUBEL has no functionality to produce xml datasets.

Conclusions

NUBEL has no QMS in place but uses many organizational procedures from Federal Public Service (FPS) – Health, Food chain safety and environment - with respect to personnel, IT structure and budget. NUBEL has started to build a QMS that focuses on the compilation process to assure quality to the data. The EuroFIR flow chart was adopted and amended according to NUBEL needs with simple SOPs and with appendices showing documents or examples of documents that are collated into the first version of the NUBEL QMS.

NUBEL is a very small team that is embedded in the organisation of board of directors and scientific council. To build and maintain the brand database NUBEL has developed very good and very well structured contacts with the food industry. NUBEL has achieved that being mentioned in the NUBEL database is a quality label for food companies.

NUBEL uses Access for their database management system. The FCDB Compiler team manages to maintain their data very well within the limitations related to this approach. In fact it was shown that NUBEL DBMS is built as a relational DBMS including secured steps and overcoming many of the usual limitations of working without a proper DBMS.

NUBEL has developed a procedure to combine analytical and industrial data into a generic and brand specific database following specific procedures. Maintaining both the generic and the brand specific database in one organisation is an efficient way of working.

Procedures to produce analytical protocols and select laboratories are well defined. Data checking of the results is done precisely and is validated by the scientific council. It is positive that a yearly budget for analyses is available.

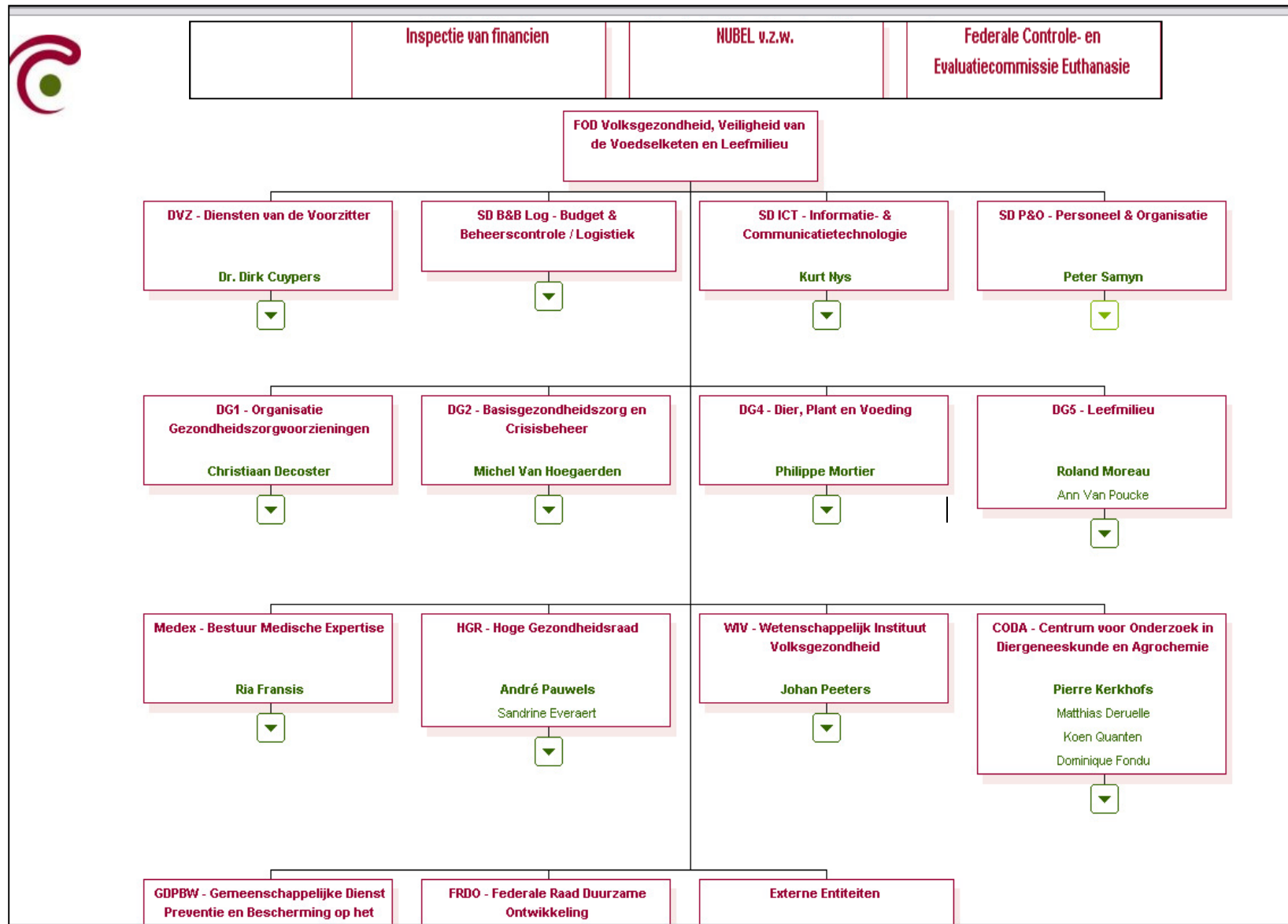
The NUBEL team very well prepared the review. The compilation procedures were discussed in a structured way. The NUBEL team was very open and willing to show the working process and all requested documents.

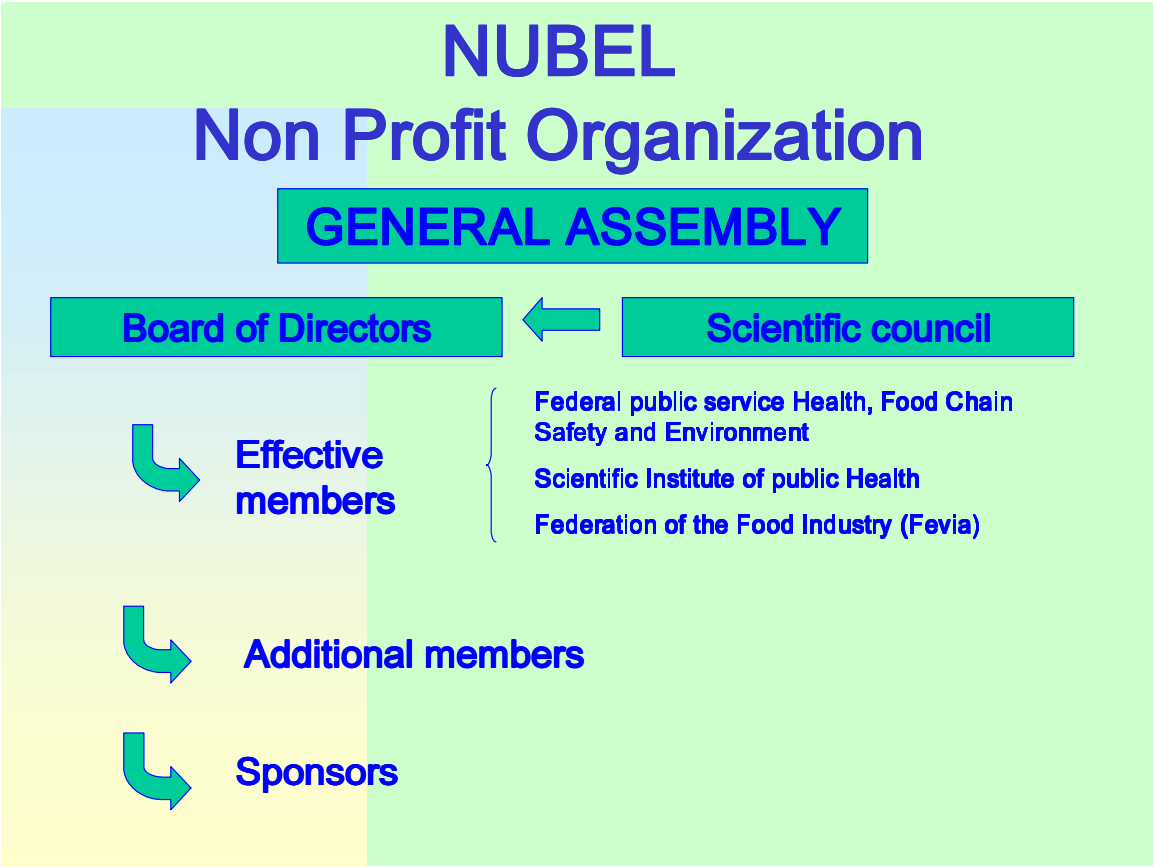
Recommendations

1. The current (1st) version of the documentation of the NUBEL QMS can be extended with written and more detailed procedures or references to existing documents. It is recommended to indicate which steps are critical steps and to include preventive or corrective actions in the documentation. It is recommended to include the step concerning validation of data by the scientific council in the flow chart.

2. The NUBEL DBMS has been built in such a way that there is no need to replace it by a specific relational DBMS now. However there is some functionality that could be improved or added as is mentioned in the recommendations below.
3. All new data are added to the NUBEL database by manual data entry. Although this can be seen as way for the FCDB Compiler to see all detailed data it can be argued that this approach takes a lot of time and might introduce new errors. It is recommended to explore the possibilities of an automated data input facility.
4. Both recipe calculations and the calculation of energy from energy containing components are done outside the NUBEL DBMS. As this is likely to be time consuming and easily introduces errors, it is recommended to explore the possibilities to incorporate this functionality in the current DBMS.
5. The NUBEL DBMS does not include any automated consistency checks. To improve and assure data quality it is recommended to add these checks to the NUBEL DBMS.

Appendix 1: FPS organisation structure including NUBEL





Appendix 3. NUBEL flow chart

See separate document: Nubel flowchart_15052012.pdf

Appendix H – Review of MATIS, Iceland

EUROFIR – NEXUS WP1.2.2

REPORT ON COMPILER REVIEW OF MATIS, REYKJAVIK, ICELAND

REVIEW DATES 31 MAY – 1 JUNE 2012

Participants

Auditors:

Anna Karin Lindroos, NFA, Sweden

Compiler organization: MATIS, Iceland

Ólafur Reykdal, Food database compiler, manages the food database
Sigmar Karl Stefánsson, computer scientist
Arnljótur Bjarki Bergsson, head of section

The review was based on guidelines described in deliverable
D1.5_Framework_for_Certification_revised_Sep2011.docx

Background

The review of the food composition data compilation processes at MATIS took place on 31 May and 1 June 2012. The review was carried out by one reviewer from EuroFIR Nexus – Anna Karin Lindroos responsible for the Swedish Food composition database and head of the Food Data Division at NFA, Sweden. Before the visit the reviewer was provided with web based documentation on Matis (www.matis.is) and the Icelandic food composition database ÍSGEM (www.matis.is/ISGEM/en) and a document outlining the organization structure of ÍSGEM and ÍSGEM contact persons at Matis.

The ÍSGEM review (organization structure, management policy, quality management systems, description of work, contracts, document control and technical requirements) was done together with the ÍSGEM compiler Ólafur Reykdal. When the technical requirements were discussed Sigmar Karl Stefánsson joined the meeting. In addition the quality manager Margét Geirsdóttir gave a short description of the MATIS quality management system and group leaders Helga Gunnlaugsdóttir and Heiða Pálmadóttir explained the analytical laboratory work done at MATIS. The head of section Arnljótur Bjarki Bergsson, participated in the opening meeting and at the concluding meeting.

ÍSGEM – the Icelandic food composition database.
Matis Ltd.- Icelandic Food and Biotech R&D institute

Management requirements

Organization structure and management policy

Matis Ltd. is an Icelandic Food and Biotech R&D institute founded in 2007 following the merger of three former public food research institutes: The Icelandic Fisheries Laboratories (IFL), an independent food research institute; MATRA, a joint venture of IceTec and the Agricultural Research Institute and the research division of the Environment and Food Agency.

Matis is an independent research institute with 100 percent governmental ownership. Around two thirds of the work is externally funded whereas around one third of the work is funded by the Icelandic Government through service agreements. Matis is located in 9 cities or towns around Iceland. Matis has about 100 employees and a lot of the work is done in close collaboration with the universities in Iceland and outside Iceland. Matis is working in research and development for the food industry, fisheries and aquaculture. Matis focuses on innovation in food and biotechnology, various services in the food industry in Iceland and abroad and to increase safety and quality of food products. Matis reports progress to the government in an annual report.

Matis' vision is to increase the value of food processing and food production, through research, development, dissemination of knowledge and consultancy, as well as to ensure the safety and quality of food and feed products.

Work on the ÍSGEM database started in 1987 to provide data for nutrition surveys. The goal was also to collect data for Icelandic foods and provide consumers and industry with these data. Several food analysis projects were carried out in the period 1980-1990 and many traditional foods were analyzed for the first time. Iceland participated in Nordic projects on food composition and an expert from Denmark stayed in Iceland for 4 months in 1988 to help with the development of an Icelandic FCDB. The work on the ÍSGEM database was from the beginning according to advice from Denmark. Some Danish data was incorporated into ÍSGEM and gradually replaced by Icelandic data.

ÍSGEM is located in the section **Value Chain, Processing and Aquaculture** headed by Arnljótur Bjarki Bergsson. There are around 15 employees in the group with open ended contracts and a number of temporary staff. Ólafur Reykdal manages the ÍSGEM database and is compiling the food composition data. He also writes applications to secure funding for food analyses. He works closely with computer scientists and the laboratories at Matis but is the only food compiler.

ÍSGEM objective: To provide consumers, food industry and specialists with the needed food composition data to improve health.

The organization structure of Matis is outlined in Appendix 1. The organization structure of the ÍSGEM and contact persons for ÍSGEM (MATIS and external) is documented in the QMS system (Appendix 2).

Matis has a central management division that handles staff and information on staff (HR). There are job descriptions but they are quite general.

Matis has central IT-support but ÍSGEM also has access to computer scientists within the section.

Annual review meetings are held with the head of section. Topics discussed at the meeting include the progress of work, if goals have been achieved, deadlines met, and the finance of external projects. There is no formal feedback on performance. Salaries are centrally negotiated between employer and trade unions and are not linked to performance.

Collaborations

Matis staff work as one team independent of sections, this is important for Icelandic and international projects. The ÍSGEM work benefits from this team work since expertise on analyses, food processing, sampling etc. can be found in different sections. Contacts with people in food industry have been established and have helped to obtain data when available and also during sampling for projects. Collaborations with the Public Health Institute (now the Directorate of Health) and the Unit for Nutrition Research of the University have been valuable for many years. ÍSGEM has been used for all national nutrition surveys and is also important for other nutrition surveys and several research projects at these institutes.

ÍSGEM participated in the EuroFIR project and are among 3rd parties in the Nexus project. Matis is an associate member of EuroFIR-AISBL. ÍSGEM has participated in several Nordic food composition projects. Currently Matis participates in the TDS-Exposure project and several other European projects in the fields of food and biotechnology.

Description of work

A plan for every year is made including work hours and resources. Work is governed by the needs of external funders (Directorate of Health and external funders). Most of the work is run as projects with deliverables and milestones. In addition the projects are reviewed at the end of the year by the HR section. Ad hoc meetings are also held with the head of section to discuss matters arising over the year.

Contracts and sub-contracts

The Directorate of Health supports the food data work and have an interest in doing so for the Nutrition surveys. The work is regulated in a contract. There are also contracts for all projects supported by grants. Contracts are drafted or checked with help from the finance

department. Head of section then checks the contracts. The contracts are signed by either section head or the director of Matis. Internal collaborations are not regulated by contracts. Contracts are stored in the Matis filing system. The laboratories are responsible for the contracts of foods analysed externally.

Document control

Matis has GoPro filing system where all documents, reports and contracts are stored. Project folders are set up for each project where those involved in the projects, section head and IT have access to. The FDBM system also has its own filing system for references. The references could be either reports, web-links, notes or food labels. The aim is to store everything electronically.

Files are backed up every 24 hours for all files that have changed. Once every month a copy of all data is transported to another building where it is stored in a safe. In addition all the files of ÍSGEM is backed up every month and stored on an external hard drive in the ÍSGEM office.

STAR LIMS is a computer system that stores all analytical data. The analytical department is responsible for storing original data. The information is on hard copies before 2007, part of this information has been scanned.

Review of the Quality Management System

The laboratories at Matis work according to ISO 17025 and have a clear quality system set up which includes documents on management, job descriptions, deputies, internal reviews (once a year), non conformities and complaints. Where possible ÍSGEM works according to these standards, however the ÍSGEM work is not integrated in the quality management system and ÍSGEM is not internally reviewed.

Technical requirements

Personnel

Staff are employed by Matis and managed centrally by Matis HR. Review results from section head are stored by HR, but there are no formal place to store job description, CV and training records for the main food compiler. For laboratory staff these are held in the laboratory QMS system.

The food compiler discusses training needs and performance at the yearly review meeting with the section head. The performance reviews are stored by the section head in a separate folder that section head and HR has access to.

Equipment

Equipment used for ÍSGEM is limited to office equipment and PCs. Office programs are used and serviced by the Matis IT-support. There is an in house FDBMS, but the system has not been finalised. The database is run on a MS-SQL server. The DB is a relational DB with tables for component values, foods, components and references. The present system for ÍSGEM was developed when participating in the EuroFIR project so the EuroFIR recommendations were taken into account. However the system has not been fully developed. Quality evaluation is handled in Excel files and recipe calculations are also carried out in Excel.

Access to the system is login and password protected. Passwords are changed every six months. Laboratory equipment belong to the analytical laboratories

Sampling

The analytical laboratories carry out the sampling of foods. There are protocols for sampling, handling and processing of the foods and analyses. These are documented in the QMS. For each separate project Ólafur Reykdal prepares a detailed analyses protocol which includes a sampling plan. When producing the plan he seeks advice from experts, statisticians and the food industry (where appropriate).

Analyses

Most of the analyses are done at Matis which is the main food analysis laboratory in Iceland. Matis carries out analysis of proximates, ash, water, fatty acids, minerals and inorganic trace elements. Other measurements, not used for the DB, are also carried out, e.g. measurements of contaminants. All samples for vitamin analysis are presently sent abroad. The Matis laboratory staff are involved in choosing laboratories and analyses, sending the samples and checking the analyses results. The laboratory has a laboratory QMS system with SOPs detailing all the procedures including sample handling and storage, sample preparation, methods, proficiency testing, quality control and assurance. The laboratories were not reviewed in detail as they are audited regularly by professional auditors.

Publication process

Data for all components in ÍSGEM are published except for individual fatty acids, tryptophan and some inorganic elements with limited data (Cr, Mo, F, Ni). Publication time is mostly determined by project deadlines (e.g. nutrition surveys) but the website is regularly updated when new data or corrections are available.

Food composition data is published on-line on the ÍSGEM website. Special software is used to copy data from the ÍSGEM database to the website. Foods in the ÍSGEM database are marked website ready (Yes or No) so only foods marked 'Yes' are published on the Internet. To be marked as 'Yes', foods need to have at least complete data for proximates and comply with EuroFIR requirements. Food data archived in ÍSGEM need to be typical for the foods consumed in Iceland. Data used for nutrition surveys have no missing values for the components being studied. However, for other foods there are gaps. Gaps are gradually filled by borrowing data, by calculations and analysis.

Food composition data are no longer printed. The last food composition tables were printed in 2003 and are available as pdf-files on the Matis website.

Compilation process (critical control points – see EuroFIR generic compilation flowchart)

Guidelines for compilation process are included in the ÍSGEM handbook together with other important ÍSGEM information. The handbook (in mainly Icelandic) is updated once a year and is stored in an electronic folder. It is also printed out and kept in a paper folder. The handbook includes the following sections:

1. Database information
2. Rules for documentation
3. Definitions of data
4. Definitions of compounds
5. Methods for calculations of recipes
6. Quality evaluation
7. Back up of data
8. Export to excel files
9. Export to website
10. Export to text files
11. Appendices

- a) Basic documents from EuroFIR including Languag-codes and FAO
- b) List of components and units
- c) List of fatty acids groups after type of fatty acid
- d) Food groups from the Directorate of health

The identification of foods is based on requirements from the Directorate of health (needs for the dietary surveys), nutritionists and projects on food composition. The compilation flowchart adapted from EuroFIR to fit ÍSGEM is included in the flowchart. Coding of data is according to EuroFIR. Foods often get high quality index scores, but the coding is not completed as it is very time consuming.

Other information related to ÍSGEM and the compilation process is also stored in the handbook folder. This information includes comments on a compiler questionnaire, list of components (those used in the nutrition survey marked in green), technical aspects, lists of the most important codes, experiences from the coding and FAO/INFOODS guidelines for internal checks.

Seafoods analyses as an example

Seafoods are important to the Icelandic diet. Iceland has a specific fund that supports projects that increase the value of seafoods (AVS R&D Fund of the Ministry of Fisheries and Agriculture in Iceland). The sea food industry is included as external advisers in the funded projects. Matis has been supported by the fund to carry out analysis of seafoods for the ÍSGEM database.

A detailed analyses protocol and a sampling plan was developed for the project. The analytical lab (Matis staff) carried out the sampling in cooperation with the companies. There are SOPs for how to treat, process and handle the samples.

The analytical values were published in ÍSGEM when they were available. Trained temporary staff helped enter data into the database. Values were checked in the database according to a specially made work list. All data were checked afterwards by Ólafur according to a predefined protocol on which checks to do. Sum of proximates were specifically checked. A record of foods worked with each day was created.

Conclusions

The work processes for ÍSGEM are compatible with the EuroFIR technical annex and has made good use of the progress made during the EuroFIR project.

An in house FCDB management system is being developed with the aim to include all information required by Eurofir in a relational database, but due to limited resources the development work has been halted. The basic functions work well but some information is still stored in additional excel-files. In house IT-development support is an advantage for the work.

The ÍSGEM work is focused on getting high quality data for key nutrients on basic foods eaten in Iceland. Recipe calculations and aggregations are mainly done at the Directorate of Health who operate the nutrition surveys.

The work is well organised, the major restriction to progress are lack of resources. External funding has been successful and allowed nutrient analyses of key nutrients of many key Icelandic foods.

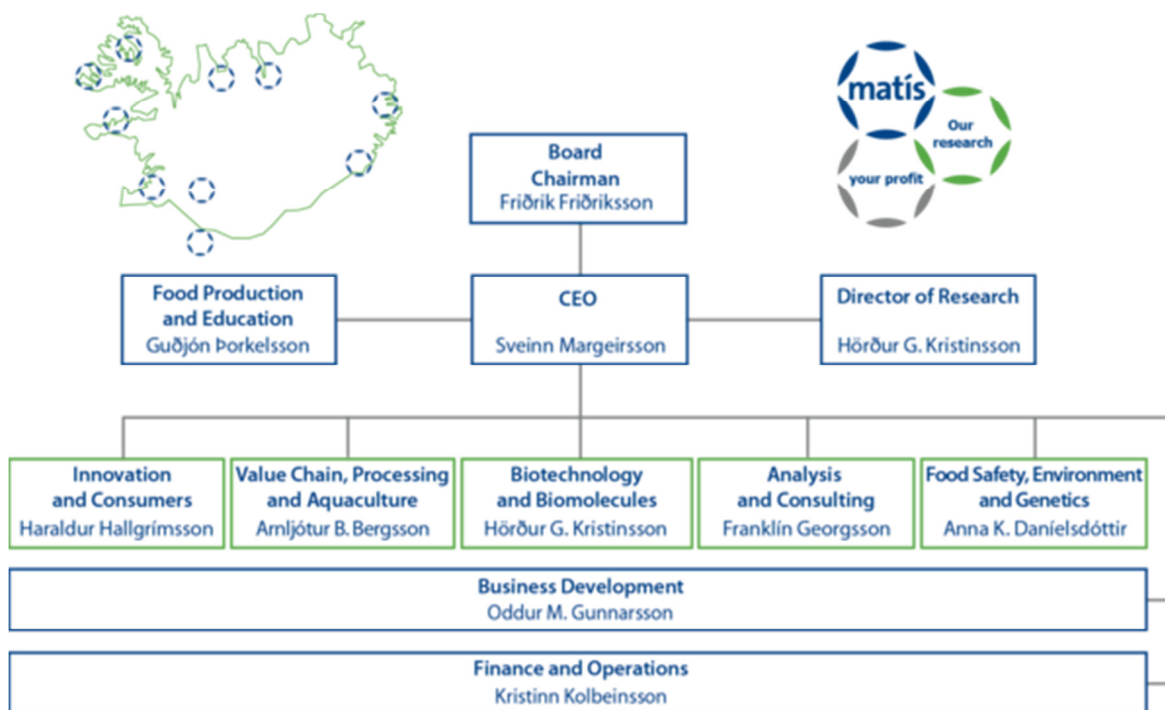
The close link to accredited laboratories ensures that samples are handled and processed according to high quality standards. The laboratories also contribute with expertise when choosing to analyse samples externally.

However the basic compilation work is mainly carried out by one person. Although work processes are well documented this makes the FCDB work vulnerable. Furthermore independent quality checks of food data cannot be carried out.

Recommendations

1. Set up a food database group and involve more than one person in the food compilation work.
2. Develop some automatic checks (would help when there is only one compiler and no one else around who can check the data).
3. Training of staff and training documentation needs to be addressed.
4. Organise an external reference group to guide the work.
5. Continue the conversion of hard copies to electronic copies to ensure safe storage of older data.
6. An excellent QMS is in place for the laboratory work. Integrate ÍSGEM into the QMS.

Appendix 1. Organisational structure of MATIS



ÍSGEM
Contact persons and organization structure

Contact persons for ISGEM

<p>Management and compiling of the database Ólafur Reykdal, Matís, 422-5098</p>	
<p>Computer scientists that have worked on ISGEM software Sigmar Karl Stefánsson, Matís, 422-5128 Sigríður Sigurðardóttir, Matís, 422-5129 Haraldur Hallgrímsson, Matís, 858-5054</p>	
<p>Development of the ISGEM system Ívar Gunnarsson, Hugsjá ehf, 568-4822</p>	
<p>Supervision of computers at Matís Opin kerfi ehf., Höfðabakka 9, 110 Reykjavík, rekstur@ok.is.</p>	

Appendix 2. Organisational structure of MATIS, cont.

Organization structure of Matis – Contact points for ÍSGEM

<p>Value chain, processing and aquaculture Arnljótur Bjarki Bergsson</p> <p>Ólafur Reykdal</p>	<p>ÍSGEM database</p>
<p>Food safety, environment and genetics Anna K. Daníelsdóttir</p> <p>Contaminants and risk assessment Helga Gunnlaugsdóttir</p>	<p>Contaminant data and database Analysis of contaminants</p>
<p>Analysis and consulting Franklin Georgsson</p> <p>Food analysis Heiða Pálmadóttir</p>	<p>Analysis for projects and customers Teaching for University of Iceland: Food composition and analysis</p>
<p>Innovation and consumers Guðjón Porkelsson</p>	<p>Use of ISGEM for calculations and labelling</p>
<p>Marketing director Steinar Aðalbjörnsson</p>	

Contact points outside Matis

<p>Directorate of Health (Public Health Institute) Hólmfríður Þorgeirsdóttir</p>	<p>Nutrition surveys Nutrition consultation</p>
<p>Unit for Nutrition Research, University Hospital Laufey Steingrimsdóttir</p>	<p>Nutrition surveys Nutrition Research</p>
<p>Icelandic Food and Veterinary Authority (MAST) Jónína Stefánsdóttir Ingibjörg Gunnarsdóttir Zulema Sullca Porta</p>	<p>Food inspection, legislation, food safety.</p>

Appendix I – Review of UZEI, Czech Republic

EUROFIR – Nexus WP1.2.2

Report from review of ÚZEI Institute of Agricultural Economics and Information, Prague, Czech Republic, 30th – 31st May 2012

Participants

Auditor:

Anna Giertlová, VÚP (FRI-SK), Beneficiary 13

FCDB Compiler organization: ÚZEI

Marie Macháčková, FCDB Compiler (Department: Bibliography and Reference Services)

Martin Kvítek (Head of Section: Agricultural and Food Library)

Dana Smetanová (Head of Department: Bibliography and Reference Services)

The audit is based on UZEI_ReviewReport_Draft_v7_20072012.doc

Background

The review of the compilation process at ÚZEI took place 30th - 31st May 2012. The review was carried out by one reviewer from EuroFIR Nexus, who is a national database FCDB Compiler. Web based documentation and Methodology of compilation of food composition data in the Czech language was provided prior to the review visit. During the first day of the visit a meeting with the Head of Agricultural and Food Library (Martin Kvítek) and Head of Bibliography and Reference Services (Dana Smetanová) was held to inform about the purpose and agenda of the visit. A short visit to the Agricultural and Food Library (AFL) at ÚZEI was part of the review visit.

Management requirements

Organisation structure

The institute consists of four divisions: Research; FADN CZ Liason Agency, Advisory Service and Education; Administration; Finance, Economy Department and Agricultural and Food Library (AFL).

An organization chart of ÚZEI showing the departmental structure in English is available online at: <http://www.iaei.cz/>

Marie Macháčková is a national food composition database compiler responsible for the compilation process and is part of the Department of Bibliography and Reference Services, which belongs to the Section: Agricultural and Food Library (AFL). The Department of Bibliography and Reference Services provides the creation of bibliographic (Czech Agricultural and Food Bibliography, FSTA, FAO AGRIS) and specialised (CZFCDB) database, reference and information services. The Czech Food Composition Data Bank

(CZFCDB) is fully funded within the CZFCDB project by the Ministry of Agriculture and is performed by 1 staff – Marie Macháčková.

The FCDB Compiler belongs to the Department of Bibliography and Reference Services and mainly cooperates with other departments of the AFL in providing or archiving reference sources for the CZFCDB. ÚZEI administrator and Economical Department are at the disposal of the FCDB Compiler within the hierarchy of ÚZEI.

Management policy

ÚZEI is state-subsidized organization established by the Ministry of Agriculture. The main activities of ÚZEI are: basic and applied research and development in the field of agricultural policy and economics; Farm Accountancy Data Network (FADN) Liaison Agency in the Czech Republic in relation to the EU; systematic development of the scientific discipline agricultural economics; dissemination of research and development results by means of educational activity; the operation of a specialized library (AFL) and in the framework of this activity the acquisition, processing, preservation and making accessible of professional literature and other forms of documentary or data information from the sphere of agriculture and food production; and others. The annual report of ÚZEI describes specific aims of the institution and describes projects and tasks in each particular year. Annual reports are available online at ÚZEI public website.

ÚZEI does not have analytical laboratories. Most of the funding for ÚZEI comes from the Ministry of Agriculture, but also from national and international projects. ÚZEI employs approximately 150 staff.

There is no formal quality assurance management framework operated at ÚZEI although there are policies that control specific areas of work (e.g. document circulation, contracts and archive documents). ÚZEI is managed by a director who approves document circulation, orders, training applications, reports, public tenders for selecting providers of food composition data, etc. The organisation is strictly hierarchical, meaning that everything is approved on each level of organisation structure from the bottom to the top. Internal policies and rules are defined internally and signed by the head of ÚZEI. Rules are mandatory for all staff. A system of dissemination of decrees to inform staff comprises: circulation of text version of new decrees within departments, signed confirmation by staff about being informed and publication of decrees at the intranet of the institute.

Collaborations

ÚZEI did not participate in EuroFIR project 2005 – 2010, but EuroFIR invited ÚZEI to cooperate on the basis of a Memorandum of Understanding signed in 2007. Since 2010 ÚZEI has been an Associate member of the EuroFIR AISBL. A full membership (since 2013) for ÚZEI was approved at the 3rd General Assembly of EuroFIR AISBL on 22nd March 2012.

ÚZEI has a good cooperation with VÚPP Food Research Institute Prague. According to the initial concept of the CZFCDB project both institutes (ÚZEI and VÚPP) were appointed by the Czech Ministry of Agriculture to establish a Centre for Food Composition Database in 2007. ÚZEI is responsible for CZFCDB. VÚPP is not a member of EuroFIR AISBL, however, since 2007 to 2011 VÚPP participated in the initialisation of the project, development of the concept, methodology of data generation and processing, development of the on-line application, initiation of contacts with EuroFIR and consultancy services to the agenda of the database. VÚPP generated food composition data based on food analyses, documented them using Excel sheets, structured according to EuroFIR requirements and implementing corresponding EuroFIR thesauri. Data were analysed at VÚPP upon sub-contract agreement, as well as some data obtained from previous project carried out by VÚPP.

In 2012 a new institution (other than VÚPP) was selected to supply of data generated by food analyses in a public tender based on the cheapest offer.

Efforts were made to collaborate with the food industry, but food producers were not sufficiently interested and little progress was made.

Description of work

A contract for work on the CZFCDB is agreed with the Ministry of Agriculture on an annual basis. Work plans are prepared with regard to budget for each specific year.

In 2008-2011, work plans were produced by the ÚZEI FCDB Compiler responsible for the compilation process in cooperation with VÚPP analysts. Two VÚPP workers worked as analysts and FCDB Compilers on CZFCDB agenda within the contract. Marie Holasová was a contact person responsible for food analyses and data documentation within the project and conceptual issues of the database and Eva Mašková performed food analyses, compilation and documentation of data from the previous projects carried by VÚPP. The ÚZEI FCDB Compiler checks the data prior to inclusion into the database and manages online publication of data. Proposed work plans of CZFCDB project are approved by the Ministry of Agriculture. Description of work for a specific year was quite general, e.g. preparation of FCDB for a specific food group. Analysis of selected food groups (e.g. traditional dishes, meat and products and bakery products) were part of the work plans. Selection of foods and nutrients for a specific year was chosen by the FCDB Compiler and analysts, who carried out food analysis. Work plans were updated according to current needs and budget.

Food composition data were gained from food analysis (performed by VÚPP), from literature sources obtained from ÚZEI Agricultural and Food Library, foreign food composition databases (preferred data are Slovak and Polish, due to the similar cuisine) and by calculations.

Data are processed within the internal methodology of compilation of food composition data that reflects requirements of EuroFIR on data documentation (food indexing, full value documentation and traceability of reference sources).

In 2012, the Ministry of Agriculture set up a list of selected foods and nutrients, which have to supplement the Czech food composition data base. The list of foods and nutrients for this year reflects labelling requirements. Customers request are rare and they do not have a direct impact on preparing work plans, however are monitored. If it is possible to realise customer requirements, they are included into the work plan for the next year.

All targets described in work plans have to be finished and delivered with the final report to Ministry of Agriculture by the end of 2012.

Two types of reports were processed each year on a biannual and annual basis, monitoring the progress of the agenda: report of the sub-contractor (VÚPP, 2008-2011) and reports written by the ÚZEI FCDB Compiler. VÚPP reports include analytical protocols with analytical results and essential parts of the reports are documented data in Excel worksheets. ÚZEI half-year report contains information about progress of the agenda, with details of what work was done and how. Final ÚZEI report contains information about realising of agenda, results, publicity of the project results. Sub-contractors reports are archived by the ÚZEI FCDB Compiler and are also included into the AFL holdings, documented and made available as other library holdings.

Reports written by the responsible ÚZEI FCDB Compiler are delivered to the Ministry of Agriculture twice a year (interim report in June; final report in December). One copy of the report is handed to the Ministry of Agriculture; the handover protocol is signed by ministry representative. Signed protocols and final reports are archived at ÚZEI according to the internal Directive and in the office of the ÚZEI FCDB Compiler.

Food composition work is reviewed by a representative of the Ministry of Agriculture on the grounds of reports, which are delivered twice a year. There is no formal performance review of the ÚZEI FCDB Compiler by a superior, although there may be performance bonuses based on outputs such as publication of articles in journals and current contents. Work plans generally contain quite broad targets. Job descriptions for individual staff members are prepared by the Head of Department, but are generic e.g. production of food composition data bank, reference services, fulfil orders of management and other. Job descriptions are updated at anytime as needed.

Food composition work is funded by the Ministry of Agriculture, which gives funds for personnel, common material and costs, food analysis and IT services within contract. Food composition work is performed by personnel, equipment and infrastructure of ÚZEI. ÚZEI management has appropriate personnel, equipment and infrastructure for producing food composition work. The CZFCDB project produced by the ÚZEI FCDB Compiler contributes to the mission and objectives of the FCDB Compiler organisation, to provide information services at the national level.

Contracts and sub-contracts

ÚZEI does not have analytical laboratories. ÚZEI has a contract with an external analytical laboratory. Analysis of food and nutrients were performed by VÚPP upon agreement in 2008-2011. The contract with VÚPP was concluded for every year. There was a list of selected foods and nutrients, which had to be analysed. Obligations of the contract were: carry out food analysis, deliver compiled data in a standardised Excel format according to the EuroFIR criteria, provide the interim/final report describing performed food analysis including sampling and participate on other activities of the Centre according to current needs. The structure of templates for data documentation using Excel sheets was developed by FCDB Compilers from both involved institutions (ÚZEI and VÚPP). Both institutions were involved in development of one database. The responsibility of VÚPP was generation of new food composition data, provision of older data from previous projects, data documentation, transfer of data to ÚZEI, participation on development of templates, consultancy in food analyses issues, selection of foods for analyses, design of sampling plans, and participation in promotion of CZFCDB. According to the contract VÚPP guarantees the outputs. The VÚPP is a respected institution in food analyses and experts performing analyses have long term experience in this field. Items of cooperation were defined in the contract between ÚZEI and VÚPP. In this context analysts from VÚPP were FCDB Compilers, because they documented analytical data in a defined structure in Excel format. Work performed each year was reviewed in reports that had to be accepted by the ÚZEI responsible compiler.

Since 2012 on the basis of new legislation, new rules for selection of a contractor were introduced. A new data supplier (other than VÚPP) was selected to carry out food analysis for CZFCDB on the basis of a public tender. The criterion for selection was the lowest price for analytical services.

There is a contract with an external IT company who created the web interface for users and the admin interface for managing data of the online version of Czech food composition database. The draft proposal was elaborated by compilers from ÚZEI and VÚPP. The IT

company is responsible for permanent functioning of the online CZFCD and for uploading of new data online and data backup. The IT company is responsible for releasing data on the website, storing and backing up of the online food composition database. This work is solely performed by the external IT company and is not managed by the FCDB Compiler. There is defined time for repair and maintenance in the contract, in case of non-functioning of the online database. Data are delivered to the IT company via e-mail in standardised Excel format and uploaded in batches, at least once a year depending on the course of data compilation. The ÚZEI FCDB Compiler is allowed to add data values or correct data online via an admin interface e.g. correct mistakes in original food name or in English; correct decimal point, if needed. This possibility is used predominantly for urgent corrections or for adding links to reference sources (e.g. bibliographical records in the CiteXplore database or freely available national food composition databases). Updates of the online database performed by the compiler are documented in order to introduce appropriate changes into the upload files ready for the upcoming batch update. Testing within a non-public test version is performed initially and after approval the updated version is published. The online data are located on server of an IT company. Communication with IT company is maintained by the FCDB Compiler.

ÚZEI also had a contract with a photographer who took pictures of foods (other than traditional dishes) available in the online database. ÚZEI is the copyright owner of food pictures. This cooperation did not continue after 2012.

Proposal for contracts are prepared by the compiler, reviewed by legal representatives and signed off by the Head of Department, the Finance Director and the Director. There is a defined structure of contract and process of approval following the hierarchical structure of ÚZEI. The circulation of contracts is defined by internal rules.

SLAs are not used at ÚZEI, due to the collaborations with other ÚZEI departments. It is performed within the hierarchy – the head of the concerning department is asked to allow cooperation and then the employer of the concerning department is contacted for cooperation.

CZFCDB does not have any other contracts regarding food composition database.

Document control

CZFCDB agenda is maintained by FCDB Compiler and updated in case of need. In the period 2007-2011 this was performed in co-operation with an analyst from VÚPP. Electronic documents used for food composition work are stored and accessed on the PC of the FCDB Compiler. There is no need to share documents with other staff. Access to the PC is restricted only to the FCDB Compiler by username and password. The IT department of ÚZEI has no specific work regarding CZFCDB, because all data and documents are only on the PC of the FCDB Compiler and not on the ÚZEI server. Due to this fact back-ups are made by the FCDB Compiler. The IT department serves only as user-support.

The FCDB compiler manually backs up all electronic files to CD disk at least four times per year or according to needs. Disks containing backed up files are stored in the compiler's office.

Hard copies

Documents relating to food composition work are also in printed form. Hard copies of data (individual records of foods included into the database), reports, description of work, copies of contracts are stored in the compiler's office at ÚZEI. Original contracts and annual reports, a handout protocol signed by a representative from the Ministry of Agriculture and other

documents are archived at ÚZEI according to archival procedures. The majority of hard copies of data sources (e.g. food composition tables and other literature sources) are handled as librarian holdings in the AFL (they have own record within the library catalogue or bibliographic databases), and they are available to the compiler.

In general there are instructions about handling of documents within ÚZEI – contracts, reports, backgrounds for accounts etc. The rules are mandatory for the staff and defined by decrees.

Within the CZFCDB documents are handled according to a general description in the Database methodology.

Review of the Quality Management System

There is no formal quality management system in place at ÚZEI, but rules mandatory for the staff have been defined by the director of ÚZEI in the form of internal decrees and guidelines for internal administration procedures (e.g. approval of orders and contracts, archive document and others). In case of need, new instructions are released to avoid disorder and ensure good quality of work at ÚZEI. ÚZEI is from time to time subject to internal and external audits (e.g. personal performance).

Technical requirements

Personnel

The ÚZEI FCDB Compiler has a job description and is responsible for tasks related to the job description. Staff can be trained according to needs and for specific tasks. Marie Macháčková (FCDB Compiler, ÚZEI) and Marie Holasová (analyst, VÚPP) were trained for one week at Slovak FCDB to use DMS - Data Management Software and nutritional software Alimenta 4.3e in 2007 and Marie Macháčková (FCDB Compiler, ÚZEI) and Eva Mašková (analyst, VÚPP) attended the Food Comp course in 2008. Training courses were supported by EuroFIR. Marie Macháčková has skills in English Language and attends an English Course, which is organised by the Ministry of Agriculture. Current training activities are based on self study from available EuroFIR documents and other literature sources. There is no formal evidence of training by personal department. It is up to staff to maintain evidence of training records.

Equipment

Equipment used for food composition work is limited to office equipment, including PCs and software for data management including DMS and nutritional software Alimenta 4.3e for recipe calculation. DMS and Alimenta 4.3e were purchased from the Slovak FCDB. Software is used according to the user manuals. DMS and Alimenta 4.3e are currently not maintained by an IT programmer.

Food composition work is performed by one person from ÚZEI in her office. The majority of equipment corresponds to library needs (tables, PCs, cabinets).

VÚPP equipment used in analytical methods is specified within documented method procedures. The measuring instruments are internally calibrated before they are used, external calibration is done in intervals of 2-3 years. Records from external calibration are stored together with device documentation. General maintenance is provided according to the needs and records stored together with device documentation.

Sampling

Samples are identified for data updates based on priorities identified by the compiler. Selection of foods for sampling was done on the grounds of the Czech food basket, e.g. high consumption of bakery products in CZ and changed food composition, due to the use of

premises; sampling of meat, different food composition data compared with older data, due to the changes in feeding and breeding, and consumer requirements, preferred lean meat; sampling of traditional dishes, which are typical for Czech region. In 2008-2011, sampling was performed by VÚPP but from 2012 sampling will be performed by a new contractor.

Purchasing and sample collection plans were produced with the aim of collecting samples that are as representative as possible within the financial limitations of the project. Sampling plan was discussed and prepared by analysts and the FCDB Compiler.

In 2008-2011 VÚPP sampled foods from these food groups: bakery products, meat and products, traditional foods, types of wheat flour.

- Sampling of bakery products:
3 products sold under the same name, originated from different bakeries, bought in capital (Prague). Sampling documentation of food products includes information how to take and prepare homogenised samples, photo documentation.
- Sampling of wheat flours:
3 products sold under the same name, originated from different mills, bought in capital (Prague). Sampling documentation of food products includes information how to take and prepare homogenised samples.
- Sampling of meat:
3 parcels of individual meat samples, bought in 3 different retail stores, removal of separable fat, representative raw sample prepared by homogenization of lean parts from 3 parcels (weight ratio 1:1:1). Culinary treatment of lean parts from 3 parcels (weight ratio 1:1:1). Sample of treated meat was prepared by homogenization.
- Sampling of traditional foods, potato dishes:
Traditional potatoes dishes prepared in laboratory 2 times according to the standard recipe. Sample was homogenised from 2 dishes. Recipes are based on standard cook book that provides recipes for foods prepared by canteens and restaurants. 2 independent experiments were realized in spring and autumn (potato dishes prepared from fresh and stored potatoes). Documentation of sampling traditional dishes includes following information: recipe, description of raw materials, cooking steps, weight losses, critical points (temperature, time), yield and photo documentation.
- Sampling of traditional foods –sauces
Dishes prepared in laboratory according to the recipe, by homogenization. Procedure record: Recipe, description of raw materials, description of the production, cooking steps, losses, critical points (temperature, time), yield, photo documentation.

Homogenised samples are stored in sealed PE packets in the freezer at -18°C until they are analysed.

Sampling is more fully described in annual report of the sub-contractor (VÚPP), which was delivered to ÚZEI upon agreement. Full documentation of sampling is available at VÚPP.

Some data is also obtained from scientific literature available at Agricultural and Food Library and from foreign food composition databases. Preferred foreign databases are Slovak and Polish, due to similar culinary practices and in the case of Slovak data similar consumers' preferences and foods available on the market.

Analysis/Data production

In 2008-2011, samples were analysed at VÚPP upon agreement. VÚPP performed basic analyses of foods and raw food materials like the basic composition – determination of dry matter, fat, proteins, ash, soluble and insoluble fibre contents and the amino acid and fatty acid spectrum. These basic analyses were complemented with the determination of lipophilic (tocopherols, carotenoids) and hydrophilic (group B vitamins – thiamin, niacin, riboflavin, pyridoxine, folic, pantothenic and ascorbic acids) vitamins. The range of nutrients was agreed as part of the project plan, dependent on ÚZEI requirements and budget. Analytical methods were performed according to AOAC methods or Czech Technical Standards. List of methods used for food analyses was part of annual VÚPP reports. Criteria for validation of data are described below. VÚPP laboratories are not accredited. VÚPP participates in a LGC Standards Proficiency Testing (PT). LGC Standards operates in the UK at Bury, Lancashire and provides PT services to laboratories undertaking chemical, microbiological and physical measurements including trials.

In 2008-2011, data from VÚPP were processed and delivered to ÚZEI in Excel sheets with template structure defined by FCDB Compilers from ÚZEI and VÚPP. The template structure of Excel sheets is compatible with EuroFIR requirements. Values were documented according to EuroFIR thesaurii. Analysts from VÚPP participated on compilation of new food composition data. At first data were checked by analysts because analysts as data producers are more experienced to attribute method indicator, value type and other method characteristics of data. Delivered data in Excel sheets were then checked by the ÚZEI FCDB Compiler. Criteria for validation of data are described below. Data documentation was also checked. Integrity of data documentation was also considered (consistent use of thesauri for the same items etc.)

VÚPP delivered the annual report regarding sampling and food analysis and data in defined time with food composition data upon agreement. The VÚPP final report is archived in ÚZEI.

The FCDB Compiler calculates algorithmically calculated values (e.g. energy value, carbohydrate total and others) by using internal algorithms of the database and creates logical zeroes, if it is appropriate. This work is done using Excel applications. Calculations in the food composition datasets delivered by VÚPP were performed by VÚPP compilers.

DMS serves for documentation of original data and calculation of average values. DMS allows documentation of a reference code for each value included into the system. Average values from DMS are transferred to an Excel worksheet, which serves as an aggregated database (second level database). The structure of food composition database in Excel sheet was approved by the EuroFIR expert Anders Møller. Data are compiled according to a standardized procedure for data documentation that is mandatory for EuroFIR partners. Implementation of the EuroFIR standard for data documentation is performed at the level of a compiled database reporting a single value for each food/component combination. Four main entities are documented: FOOD (food description), COMPONENT (component description), VALUE (main entity for value documentation using EuroFIR Thesauri for matrix, value, acquisition type and method type and method indicator) and REFERENCE (citation documentation). Indexing of foods, which is mandatory according to the EuroFIR standard, is performed with the LanguaL Thesaurus using the LanguaL Food Product Indexer by ÚZEI FCDB Compiler.

The Alimenta 4.3e software that is used to calculate recipe contains a recipe calculation module that includes yield factors and retention factors (Bognar) that can be applied at food level. CZFCDB calculated recipes by using the Alimenta 4.3e software. Recipes for school catering were published by the Czech Nutrition Society in 2007-2008. In 2010-2012 CZFCDB

cooperated with a food producer Bonduelle that ordered calculating of recipes for its promotion campaign focused on school canteens.

Food composition data are checked by VÚPP and ÚZEI FCDB Compilers according to: Validation of data (see below).

Publication process

Food composition data are checked by the FCDB Compiler prior to publishing online. Data are checked in Excel by using filters for selected criteria. Data in Excel form are later uploaded by IT company for the online version of Czech food composition database.

The currently available online dataset consists of approximately 300 foods with data from analytical labs, scientific literature, aggregated from foreign databases and calculated based on internal algorithms. Reference to each published value is clearly indicated. For Czech data sources, bibliographic references were created in the EuroFIR CiteXplore repository database in order to introduce these sources to an international audience. The agenda was performed in cooperation with I. Unwin (IDUFIC, Cambridge, UK). Links to available bibliographical records in the CiteXplore database were added in the on-line database. Links to available full texts of reference sources of referenced on-line food composition tables were also included into the on-line database and documented within the entity REFERENCE.

This year is planned to publish new foods online. Data for update of the online database have been reviewed and checked in order to include them into the on-line application to the present dataset to extend it up to 420 foods.

Data for new foods required by the MoA in 2012 will be added after data delivery, their checking and processing prior to publishing. 8 main nutrients, according to food labelling legislation have to be stated for each food. Apart from mandatory nutrients the set will contain data for ash, water, fatty acids and fractions of fatty acids.

There is no intent to publish the Czech food composition database in printed version, because it is too expensive and not useful for the current stage of the project, because of continuous compilation process and updates.

Compilation process (critical control points – see EuroFIR generic compilation flowchart)

The EuroFIR generic flowchart for the food data compilation process gives an overall description of the compilation process and identifies critical control points and SOPs needed. Procedures of the CZFCDB are described in an internal document: Methodology of compilation of food composition data, despite individual EuroFIR SOPs not having been introduced yet.

Description of compilation data is available in internal document of the CZFCDB, which was provided prior the review visit.

- Identification of relevant foods, nutrients, background information

A strict procedure for identification of relevant foods has not been established. Before 2012 foods were selected from the list of foods in Czech Food Consumption Basket (e.g. bakery products, meat and products). There were specific requirements to focus on traditional foods. Foods analyzed during previous VÚPP projects were included in the CZFCDB as well. A general list of foods or food groups and nutrients is submitted to Ministry of Agriculture for approval.

The scope of nutrients was defined in the initial stages of the project. The Czech FCDB takes account of the EuroFIR prioritized list of nutrients, requirements of legislation regarding food labelling and list of nutrients in former Czechoslovak tables.

In 2012 the list of prioritized foods and nutrients was set up by Ministry of Agriculture as a mandatory required work plan.

- Attribution of quality (index) to all original data taking into account food description, sampling and analysis

The FCDB Compiler does not assign to original data Quality index. Attribution of QI to original data is optional according the EuroFIR standard. There are insufficient personnel resources for this work at this time. All background information is archived and there will be no problem to assess quality of analytical data in the future.

- Coding of original data before entry (food, nutrients, background information)

CZFCDB uses serial number of food code. CZFCDB uses Slovak component codes which are linked with EuroFIR component codes. Each reference is coded with a unique reference code. CZFCDB documents only mandatory data so background information is not documented.

- Check on original data coding and data entry.

Coding of data and data entry is more or less made manually. Data entry is checked with list of preferred foods.

- Physical storage of original data

All sources of food composition data are stored in electronic and physical form. Electronic version of original data are stored at FCDB Compiler PC and backed up at CD disks. Original data are printed and stored in FCDB Compiler office. Data sources are managed in cooperation with the AFL.

- Selection of original data to produce aggregated data
Aggregation of data (nutrients) is performed in the DMS. Reason for aggregation of selected nutrients is documented outside the DMS, in the hard copies of records for individual foods. This procedure was implemented, because the DMS does not allow more detailed documentation.
- Selection and application of algorithms to produce aggregated and compiled data
Algorithms for calculation are defined by FCDB Compiler. Algorithms are documented in the Methodology of compilation of food composition data. Algorithms used to produce aggregated and compiled data are available at: Online Czech Food Composition Database (<http://www.czfcdb.cz/en/about-food-data/components/>).
- Validation of (aggregated and compiled) data

FCDB Compiler verifies data by:

- Checking of food name;
- Checking of edible portion;
- Checking of Nitrogen Conversion Factor (NCF);
- Checking of Fatty Acid Conversion Factor (FACF);
- Check sum of fatty acids with fat total;
- Summation of proximities;
- Check energy calculation;
- Algorithms for calculation of vitamins
- Checks of sum of minerals with ash
- Checks of saccharides
- Checks of logical zeroes

Data are checked in Excel by using filters for selected criteria.

- Determine confidence code of aggregated and compiled data

Compiler does not determine confidence code of aggregated and compiled data.

- Selection of aggregated and compiled data to be published or disseminate

In fact, practically all aggregated and compiled data are published online.

Vertical audit of data

The review concluded with a vertical audit of selected data to look at how online published data can be tracked back to data compilation processes.

Values for “Pancake from raw potatoes, fried homemade” were tracked back to documentation in Excel sheet. Data originates from Analysis performed by VÚPP. Data published online were tracked back to original reference source (final report of VÚPP), which was stored in the FCDB Compiler’s office.

Values for “Pears” were tracked back to documentation in Excel sheet. Data were produced by aggregating data coming from foreign food composition databases (Slovak and Polish). In Excel sheet were the documented aggregated values. In DMS were documented original data (Slovak and Polish data). There were documented references indicating original sources too.

Conclusions

ÚZEI is state-subsidized organization. There is no formal quality management system in place at ÚZEI, but rules mandatory for the staff have been defined by the director of ÚZEI in the form of internal instructions and guidelines for internal administration procedures (e.g. approval of orders and contracts, archive document and others). CZFCDB project is fully funded by the Ministry of Agriculture.

CZFCDB in ÚZEI has significantly progressed since 2007, when they started to build the national food composition database from scratch, within the Centre for Food Composition Database – a joint project of ÚZEI and VÚPP. In cooperation with EuroFIR, CZFCDB successfully implemented full EuroFIR value documentation. Release of the pilot Czech dataset on the EuroFIR eSearch facility confirmed that the structure of the CZFCDB is in compliance with the EuroFIR information systems. Data are managed more or less in Excel worksheets, with the risk of mistakes, when large amounts of data are managed. It is very positive that Ministry of Agriculture of the CR financially supports agenda of CZFCDB. This support covers direct analyses of foods, management and update of the on-line version of the database and other related items of the agenda. Vertical audit of data confirms that data are easy trackable to original reference source.

Permanent process of publication of data online is laudable, however user feedback will be useful to assess the online food composition database, e.g. coverage of data, searching and exploitation of data. There is missing some advisory group of experts to advise on food composition work, e.g. selection of foods and nutrients.

Recommendations

1. The Czech online database should continue to be further developed and refined in compliance with EuroFIR requirements.
2. Foods from the Czech food market should be analysed and published online to improve quantity and quality of the data.
3. Procedures of the CZFCDB are described in internal documents. It is recommended to introduce SOPs with respect to specifications for the Czech compilation process.
4. Implementation of data management software, possibly FoodCASE, should be considered to reduce manual work and to reduce the possibility of errors.

Appendix J – Review of NFNI, Poland

EuroFIR – Nexus WP1.2.2

Report from review of NFNI National Food and Nutrition Institute (*Institut Żywności i Żywienia*), Warsaw, PL 2nd – 3rd July 2012

Participants

Auditor:

Anna Giertlová, VÚP (FRI-SK), Beneficiary 13

FCDB Compiler organization: NFNI

Katarzyna Stoś (Vice Director of NFNI, Head of Department of Food and Food Supplements)

Hanna Kunachowicz (Head of Laboratory of Nutritional Value of Food Products)

Beata Przygoda (analyst, FCDB Compiler, Laboratory of Nutritional Value of Food Products)

Wojciech Kłys (QMS manager, analyst, Laboratory of Nutritional Value of Food Products)

Research workers of Department of Food and Food Supplements:

Anna Wojtasik

Krystyna Iwanow

Ewa Matczuk

Edyta Pietraś

The audit is based on D1.5_Framework_for_Certification_revised_Sep2011.docx

Background

The review of compilation processes at NFNI took place 2nd – 3rd July 2012. The review was carried out by Anna Giertlová, who is a national database FCDB Compiler VÚP Food Research Institute, Slovakia. Some information from NFNI website was available and some abstracts describing the work of the food composition team were provided prior to the review visit. During the starting meeting a discussion with the Head of Department of Food and Food Supplements (Vice Director of NFNI, Prof. Katarzyna Stoś) was held to obtain information on management processes in relation to the food composition data bank. A short visit to the Analytical Laboratories of NFNI was organized as part of the audit.

Management requirements

Organization structure and management policy

The mission of NFNI is to take care of and promote public health, through healthy diet and healthy lifestyle.

NFNI leads scientific and research activities and applies their results in the following areas:

- Risk factors of obesity and other chronic diseases, their prevention and treatment.

- Nutritional genomics.
- Epidemiology of nutrition and nutritional status of populations and trends in diets, their socio-economic conditions and the use of research results in the prevention of chronic non-communicable diseases.
- The nutritional value, food quality and safety, including dietary supplements in the prevention of chronic non-communicable diseases.
- Education and training activities in the area of nutrition.

The NFNI has an internal document NR 5/2011, which covers areas including: mission of the NFNI and its organization structure, orientation of institute, responsibilities of management, scientific board, Economical Department and other departments. This document defines the quality policy of the accredited laboratory.

The organisational chart of NFNI in the Polish language is added as Appendix 1. A more detailed structure of the Department of Food and Food Supplements is added as Appendix 2.

NFNI has approximately 110 employees. Management of NFNI consists of:

- Director of NFNI is prof. dr med. Mirosław Jarosz
- Deputy Director for Scientific Research - Iwona Traczyk
- Deputy Director for Preventive Medicine - Longina Kłosiewicz-Latoszek
- Deputy Director for Economical Affairs - Włodzimierz Sekuła

NFNI consists of six research departments. All Departments provide scientific activity and two of them: Centre of Promotion Healthy Nutrition and Physical Activity and Clinic of Metabolic Diseases provide services and consultations to their patients. The Center of Promotion Healthy Nutrition and Physical Activity is also responsible for production of the NFNI website and public education. The Scientific Board consists of employees of the NFNI and other members from organizations working in the same area (e.g. the Polish Academy of Science).

Hanna Kunachowicz is head of Laboratory of Nutritional Value of Food Products and leads three laboratories: Protein Laboratory, Mineral Laboratory and Vitamin Laboratory, which belong to this unit. The Laboratory of Nutritional Value of Food Products belongs to the Department of Food and Food Supplements. Hanna Kunachowicz and Beata Przygoda are responsible for the compilation process. The food composition team consists of 9 people (Hanna Kunachowicz, Beata Przygoda, Wojciech Kłys, Krystyna Iwanow, Anna Wojtasik, Ewa Matczuk, Edyta Pietraś, Teresa Cychowska, Gabryela Pawłowska). Members of the food composition team are analysts and also FCDB compilers. The budget for food composition work is limited, so they work on other projects and tasks as well.

NFNI is financially dependent on the Ministry of Health. Some funds are gained from donations and scientific grants from the Ministry of Science and Higher Education. NFNI also participate in EU projects. Food composition work has additional funds from the Ministry of Science and Higher Education as well as from other small sources, e.g. selling food composition datasets on CD.

NFNI staff follow rules set up in internal documents, released by the director of NFNI. The structure of organization is strictly hierarchical. Responsibilities of management, scientific board, Economical Department and other departments are defined in an internal document NR 5/2011. This document defines the quality policy of the accredited laboratory.

External cooperation

In performing tasks and projects NFNI cooperates with the Polish Academy of Sciences, with universities (e.g. the University in Olsztyn, the Jagiellonian University in Krakow), with research institutes and other research institutions, with scientific and professional associations in the country and also with similar institutions and organizations abroad. NFNI is a full member of EuroFIR AISBL. NFNI collaborates with food producers and the Polish Federation of Food Producers.

Internal cooperation

Staff of the Laboratory of Nutritional Value of Food Products collaborate with the Department of Food and Nutritional Economy on joint projects, e.g. evaluation of nutrition status of the Polish population.

Food composition tables produced by the food composition team are used by the other departments of NFNI, e.g. Metabolic Disease and Gastroenterology Clinic and the National Dietetic Centre.

The food composition team communicates with the Economical Department and IT Department via e-mail and/or phone. Supply of materials and public tenders are handled by the Economical Department by a purchasing agent.

Description of work

The food composition data bank project is funded on an annual base, but this year (2012) the budget is very limited. The work plans are annually prepared by the person responsible for the compilation process according to actual needs and preference and available budget. Decisions about preferred work plans are made by the food composition team. The work plans are first commented on and/or revised by the NFNI Scientific Board and subsequently approved by the NFNI management. Work on projects and progress is reviewed by the Scientific Board once a year and finally approved. The final annual report is submitted by the NFNI director to the Ministry of Health and Social Welfare.

Hanna Kunachowicz is responsible for the project: Production of food composition database. Actual work plans for 2012 include: recalculation of energy value of food, according to new legislation (dietary fibre has to be added in algorithms for calculation of energy value); calculation of total sugar contents for foods included in the dataset to support food labelling requirements. Hanna Kunachowicz participates on the task of applied research connected with nutritional value of food products, e.g. participation on EU working group on food labelling.

This year Beata Przygoda finished her PhD. thesis, which is focused on the effect of culinary treatment techniques on the nutritional value of food (e.g. fish, poultry). The content of nutrients in dishes changes in relation to raw materials depending on the cooking processes used. The objective of her work was to determine the yield factors and the nutrient retention factors for selected food products (fatty saltwater fish, lean poultry, vegetables) prepared using modern catering equipment (combi-steamer, accu-termal stainless steel cookware) and health oriented culinary techniques (steaming, frying without fat). For the food products prepared in traditional way i.e. fried in fat or boiled, the nutrient retention factors were verified. Based on the research finding it can be assumed that using modern catering equipment enabling steaming and frying without fat, results in high yield factors for traditional processes and high retention of most nutrients, and consequently the preparation of dishes characterized by high nutritional value. The results of this research will be used for calculation of the nutritional value of dishes in the Polish food composition database. Beata Przygoda is also working on the content of vitamin in food products. She cooperates with analytical workers: Ewa Matczuk and Gabryela Pawłowska.

Anna Wojtasik is working on the mineral content in food products. She cooperates with analytical workers: Krystyna Iwanow, Edyta Pietraś and Ewa Matczuk.

Wojciech Kłys is QMS manager of NFNI Laboratories and is working on the protein and amino acids content in food products. Wojciech Kłys participates on layout work and technical aspects of FCDB dissemination via the internet.

Krystyna Iwanow cooperates on the compilation process and verifies food composition data.

Other projects

Members of the food composition team have participated on other projects, which were related to or used Polish food composition database:

Polish National Programme for the Prevention of Overweight, Obesity and Non-Communicable Diseases through Diet and Improved Physical Activity 2007-2011 – POLHEALTH. One of the tasks within this project was analytical estimation of salt content in dinners served in different catering establishments (hospitals, elementary schools and working places).

An important ongoing project at NFNI is Swiss-Polish Cooperation Programme “Preventing overweight and obesity and chronic diseases through public education on nutrition and physical activity”, 2011-2016. The main objective of this project is to promote a healthy lifestyle and learn about nutrition value of food and proper understanding of food labelling.

Contracts and sub-contracts

The Centre of Promotion Healthy Nutrition and Physical Activity is responsible for production of the NFNI website and maintains contact with an IT company that provides services. NFNI has a contract with the IT company, which is responsible for maintaining and functionality of the NFNI website. The contract with the IT company is maintained by the IT department of the NFNI. The online food composition database is available on the NFNI website. Content of the online food composition database is prepared and checked by Laboratory of Nutritional Value of Food Products. The food composition team sends the food composition dataset via e-mail to the IT company in Excel form. Release of the dataset on the website is handled by the IT company. Supplying of all type equipment (laboratory equipment, PC – hardware and software), material, services and public tenders are managed by Dr. Włodzimierz Sekuła - Economical Department. Call for tenders must be released to procure any equipment, material or services. Criteria for specific laboratory material and equipment or services are defined according to needs of research staff.

An internal contract for analytical work is not required. The food composition team consists of analysts, so most of the analytical work for food composition database purposes is performed by them.

NFNI also has some contracts with food companies to provide analytical services.

Document control

Electronic documents used for food composition work are stored and accessed on an NFNI server. Each employee has username and password to access their own PC. Each team member has a personal workspace to store and work with files in addition to the shared workspace. Access to the food composition database in Excel is restricted to members of the working group. This access is set up by the IT department, on the direction of Hanna Kunachowicz, head of food composition team. Content, changes and new values of products are managed by FCDB Compilers (Hanna Kunachowicz, Beata Przygoda, Wojciech Kłys). The NFNI server is operated by an IT company, however all electronic files are backed up on CD/DVD disks manually by members of the working group at least once a week. Back ups are stored in FCDB compiler offices.

Hard copies

The Director of NFNI maintain contracts. Project materials (work plans, reports, results) are maintained by the Deputy Director for Economical Affairs and stored in his office. Hard copies of contracts, agreements and finished projects are archived according to NFNI archiving protocols. The archive is managed by the Economical Department.

Hard copies of food composition data, publications and copy of contracts are stored in the working group offices or archives at NFNI.

Review of the Quality Management System

NFNI's laboratories are accredited under PN-EN ISO / IEC 17025:2005. QMS and accreditation of laboratories are managed by QMS manager Wojciech Kłys.

The Quality Manual (KSIEGA JAKOŚCI) includes control of:

- Documents;
- Tenders and contracts;
- Purchasing of services and supplies;
- Customer services;
- Internal audits;
- Personnel (requirements, qualifications, experience, periodic verification, training and motivation);
- Equipment;
- Sampling;
- Validation and verification of test methods;
- Correction activity;
- And others;

The quality manual assures that food composition data produced in the NFNI Laboratory are gained within the requirements of good laboratory practice. The data compilation process is not part of this QMS.

Audits

NFNI is regularly audited by the Supreme Audit Office of Poland, every 1-2 years. Research projects are monitored and audited by the Research Agency, which funded these projects.

NFNI plans, performs and documents internal audits, which aim to confirm that the quality management system is compliant with PN-EN ISO / IEC 17025:2005. Internal audits of NFNI Laboratories are carried out by Wojciech Kłys, who is QMS manager. The compilation process is not audited.

Technical requirements

Personnel

During 2005-2010 work on food composition database was within the Laboratory of Nutritional Value of Food Products. After reorganization in 2011 the staff number was reduced and Laboratory of Nutritional Value of Food Products was included into the Department of Food and Food Supplements as an independent unit. Members of this unit are:

- Prof. Dr. Hanna Kunachowicz
- Dr Anna Wojtasik – chief of Mineral Laboratory
- Dr Beata Przygoda – chief of Vitamin Laboratory
- MSc Wojciech Kłys – chief of Protein Laboratory
- And co-workers MSc Ewa Matczuk, MSc Edyta Pietraś, MSc Krystyna Iwanow and two technicians.

The food composition team consists of 9 experienced people. Each person has some part of their work connected with food data analysis or food data compilation and this is described by

the Head of Department. Due to the many different tasks and projects taking place in the Institute, each person works on FCDB from 10 to 50% of their whole time.

Staff are employed directly by NFNI. Appropriate qualification is defined for each specific role within the organization. For food composition work a master degree in (food) chemistry or food technology, is requested to ensure competent and experienced staff.

Training

Staff may have access to job specific training provided by external organizations. There is also the possibility to participate on training provided by NFNI. An annual training plan for all NFNI staff is prepared. Each staff member has a "training card" with evidence of participation on training courses, seminars, conferences. The "training card" consists of requests to attend a training course or invitation, confirmation about participation on a training course or a certificate. Some members of the food composition team participated in the Food Composition Course in the past:

Hanna Kunachowicz – Wageningen, 1994

Wojciech Kłys - Wageningen, 1994

Agata Troszczyńska - Wageningen, 1995

Wojciech Daniewski – Bratislava, 2006

Dijana Soroka - Bratislava, 2006

(Three of the above mentioned people are no longer working in NFNI).

Currently, it is difficult for other staff to attend the Food Composition Course due to the limited funding.

Evaluation of employees is made on the individual level by the Head of Department. All staff are mainly assessed on the grounds of publication activity, which is monitored by NFNI management.

Equipment

The floor plan of NFNI includes offices and analytical laboratories. Each member of the food composition team has a PC with Microsoft Office software.

NFNI has in-house analytical laboratories. The Laboratories are accredited by PN-EN ISO/IEC 17025:2005. NFNI laboratories were visited during the review and are impressively equipped to carry out analysis required for food composition. Maintenance and calibrating of laboratory equipment is covered in Instructions in the Quality Manual. NFNI Laboratories are equipped with air conditions to sustain optimal temperature for analyses.

Sampling

Sample priorities are identified by the food composition team according to available budget. Sampling is carried out by NFNI staff by using work plans. Most recent surveys included foods from Polish production including: beef meet, fish, flours, bakery products, traditional foods, food for special dietary uses e.g. gluten-free products etc. Sampling depended on financial possibilities, e.g. sampling of meat products were funded by scientific grant and samples were taken from the whole country; flours samples were received from bigger producers with cooperation with industry; the last samples of pork meat were sampled from various Warsaw markets.

Sample processing, including cooking is also carried out by NFNI staff, e.g. in the case of study of the effect of culinary treatment techniques on the nutritional value of food.

There are general procedures describing how to receive samples for testing, register samples, label, handle and store samples prior to, during and after the tests until completion of the analysis process.

Analysis

Food composition data are gained from food analysis performed by the NFNI laboratories. NFNI laboratories execute accredited and non-accredited chemical tests of food products

and beverages. The list of accredited and non-accredited tests is part of the Quality Manual. Determination of dietary fibre in food is one of the non-accredited tests, which NFNI executes to obtain data for the Polish FCDB. Food analyses are carried out according to norms and/or documented procedures, which are part of the Quality Manual. Validation and verification of analytical methods (tests) are made according to appropriate procedures. NFNI Laboratories have a procedure for identification and correction of incorrect data produced in NFNI laboratories, as well as for checking quality control and quality assurance (PO-12 of Quality Manual). NFNI Laboratories participate in proficiency testing to monitor the quality of the analytical methods. Analytical results from NFNI laboratories are stored and archived. Analytical protocols and results from project are stored in archives of three laboratories. These documents are both in electronic and paper form and were shown during the review visit.

Some food composition data are gained from research carried out within other research projects and/or by other research institutions. Analytical services, which are not covered by NFNI, are provided by universities or other organizations within collaborative and joint projects. These data are provided to the Polish FCDB for free.

NFNI laboratories are requested by food producers or other organization to analyze food products. Results of these analyses are not used to update the food composition database due to the fact, that these data are not representative.

Data production

Food composition data of foods, which are imported from foreign countries (e.g. exotic fruits) are borrowed from the latest available edition of foreign food composition tables and publications.

Some data are calculated from a recipe. The recipes are gained directly from the Association of Bakery producers or from Book of recipes for canteens. Recipes for meat products and other food groups are received from producers and are not allowed to be published.

NFNI have many of their own retention factors and yield factors, which were found out in their laboratories. Data calculated by using retention factors are included in the Polish food composition database.

Protein content is calculated from total protein by using appropriate NCF factors defined by Greenfield and Southgate. FACF are used for calculation of fatty acids from fat by appropriate literature source. Carbohydrates are calculated by difference. Formulas for calculated vitamins (vitamin A and vitamin E) are defined in a working document of the FCDB team and are also published in Polish FCT.

Food composition data are manually entered from analytical protocols or analytical reports (from NFNI laboratories) in Excel worksheets by Beata Przygoda and Krystyna Iwanow, who are analysts and FCDB Compilers. Food composition data are checked by these two FCDB Compilers. The compilation process is not validated yet, however FCDB Compilers verify food composition data by checking: sum of proximates, sum of fatty acids, sum of amino acids, energy value etc. Original data coding and entered data are checked by another FCDB compiler. The Polish food composition database is compiled in Excel and data are protected in general way (passwords, antivirus software, back up of database). The food composition team has started to perform full value documentation according to the EuroFIR standard for data and the data has been released via the EuroFIR eSearch facility.

Publication process

The FCT were prepared by the food composition team. The FCT was reviewed by the editor's team prior to publication. The publisher of the FCT is *Wydawnictwo Lekarskie PZWL*, the largest and the oldest publisher in the area of medicine in Poland. This publisher initiates publication of new FCT. The last Polish FCT in printed form are:

- Hanna Kunachowicz, Irena Nadolna, Beata Przygoda, Krystyna Iwanow: *Polish food composition tables*, Warsaw, Wydawnictwo Lekarskie PZWL, 2005.

Also, Wydawnictwo Lekarskie PZWL from time to time asks the food composition team to prepare some specific edition of the FCT. Specific FCTs are popular with the public. In the shorter edition some of the new elements of nutrition knowledge are included:

- Kunachowicz H., Nadolna I., Przygoda B., Iwanow K.: *Nutritive Value of Selected Food Products and Typical Dishes*. Warsaw 1997, 1999, 2001, 2005, 2006, 2007, 2008, 2009, 2012;
- Kunachowicz H., Nadolna I., Przygoda B., Iwanow K.: *Let's Count Calories*. Warsaw 2002, 2006, 2008, 2011;
- Kunachowicz H., Nadolna I., Przygoda B., Iwanow K.: *Let's Count Cholesterol in Diet*. Warsaw 2006;
- Kunachowicz H., Nadolna I., Wojtasik A., Przygoda B., Iwanow K.: *Let's Count Calcium in Diet*. Warsaw 2007;
- Kunachowicz H., Nadolna I., Przygoda B., Iwanow K.: *Let's Count Vitamins in Diet*. Warsaw 2009;
- Kunachowicz H., Nadolna I., Przygoda B., Iwanow K.: *I eat healthily. Carbohydrates, glycemic index and other nutrients*. Warsaw 2011;

The content of FCT from 2005 is published online as well. Online FCT in Polish and English language are available at NFNI website:

http://www.izz.waw.pl/index.php?option=com_content&view=article&id=165&Itemid=102&lang=en and also on the EuroFIR eSearch facility. Access to the database is possible after logging and accepting the rules of access and use of the database.

The Polish food composition database is also sold for the commercial use on request of end-users. The consent has to be signed by NFNI prior to commercial use. There are records of all users, who brought the food composition database. NFNI FCDB Compilers are responsible for food composition dataset selling. Publishing of new food composition data depends on NFNI funding.

Compilation process (critical control points – see EuroFIR generic compilation flowchart)

The EuroFIR generic flowchart for the food data compilation process gives an overall description of the compilation process and identifies critical control points and SOPs needed. FCDB Compilers of the Polish Food Composition Data Base did not adopt the EuroFIR generic flowchart and SOPs. The food composition team prepared some of their own procedures important for their work, e.g. they have procedures for application of retention factors in different food matrices; SOP for calculation energy value of food. It is intended to implement the following procedures in QMS of NFNI Laboratories:

- P-01 – Calculation of the energy value
- P-02 – Calculation of the nutritional value – Dishes – Soups
- P-03 – Calculation of the nutritional value – Dishes – Fried meat
- P-04 – Calculation of the nutritional value – Dishes – Boiled meat
- P-05 – Calculation of the nutritional value – Dishes – Roast meat
- P-06 – Calculation of the nutritional value – Dishes – Roast fish
- P-07 – Calculation of the nutritional value – Dishes – Boiled fish
- P-08 – Calculation of the nutritional value – Dishes – Fried fish
- P-09 – Calculation of the nutritional value – Dishes – Boiled vegetables
- P-10 – Calculation of the nutritional value – Dishes – Stewed vegetables
- P-11 – Calculation of the nutritional value – Dishes – Canned (pickled) vegetables
- P-12 – Calculation of the nutritional value – Dishes – Raw vegetables
- P-13 – Calculation of the nutritional value – Dishes – Boiled potatoes
- P-14 – Calculation of the nutritional value – Dishes – Boiled pasta
- P-15 – Calculation of the nutritional value – Dishes – Boiled rice

- P-16 – Calculation of the nutritional value – Dishes – Boiled groats
- P-17 – Calculation of the nutritional value – Dishes – Stewed vegetable and meat combined
- P-18 – Calculation of the nutritional value – Dishes – Sauerkraut with sausage and meat, "Bigos", stewed
- P-19 – Calculation of the nutritional value – Dishes – Boiled fruit
- P-20 – Calculation of the nutritional value – Dishes – Milk dishes

These procedures were performed by the food composition team. These procedures contain examples for calculation.

The food composition team has not implemented a quality system for the FCDB, however the food composition team has its own methodology for some steps of the compilation process, that are summarised below.

- Identification of relevant foods, nutrients, background information
Food composition team is focuses on food grown/breed and produced in Poland. Food composition team tries to cover all nutrients in food. Polish food composition database has 81 parameters. During the last five years, prioritized foods were: beef meat, flours. There is no procedure describing how to select foods from abroad.
- Attribution of quality (index) to all original data taking into account food description, sampling and analysis
The food composition team does not assign Quality index to original data.
- Coding of original data before entry (food, nutrients, background information)
They have own their food coding system. Original food code consists of food groups and subgroups and serial number. Foods are coded manually in an Excel sheet. Each food has an original food code and foods are indexed by LanguaL. The food composition team does not document background information. The food composition team is intending to document a method and reference for each value. Currently, there is no link between value and method or link between value and reference. The food composition team has available only the list of references but no list of exactly which values they refer to.
- Check on original data coding and data entry.
Data are entered manually in Excel sheets from laboratory reports. Data are checked by another FCDB Compiler (correct entry of food names and values).
- Physical storage of original data
Sources of food composition data are stored mainly in physical form. Each food is recorded in physical form as a "food card". Food composition data from original reference (laboratory report, foreign database and other) are fulfilled in "food cards".

- Selection of original data to produce aggregated data
The food composition team has criteria for creating aggregated values from foreign food composition databases. The criteria for creating aggregated values are stated in written form. The data from laboratory are taken as average values or median.
- Selection and application of algorithms to produce aggregated and compiled data
Algorithms for calculation are defined by the food composition team (e.g. Protein content is calculated by using appropriate NCF factors defined by Greenfield and Southgate. FACF are used for calculation of fatty acids from fat by appropriate literature source. Carbohydrates are calculated by difference. Formulas for calculation vitamin are defined). The food composition team has a document with algorithms for calculation. Algorithms for calculation are described in FCT and are available at <http://www.izz.waw.pl/>.
The food composition team has an SOP for calculating energy value of food (P-01 – Calculation of the energy value) and many particular SOPs regarding application of retention factors, which are used (see above). Calculations are done in Excel sheets and are semi-automated.
- Validation of (aggregated and compiled) data
Data are verified, e.g. checking of food name, summation of proximate, checking sum of amino acids, checking of nitrogen conversion factor. There is no procedure for this point and validation is performed only manually.
- Determine confidence code of aggregated and compiled data
The food composition team does not determine confidence code of aggregated and compiled data.
- Selection of aggregated and compiled data to be published or disseminate
The new version of the food composition dataset is released, when production of the food composition data is finished. In fact all aggregated and compiled data are published in printed form and online. Currently the Polish FCT and online database contain approximately 930 foods and 81 nutrients per food. Today, it is not known, when the next edition of FCT will be published. It will depend on the financial situation of the institute.

Vertical audit of data

The review concluded with a vertical audit of selected data to look at how published data can be tracked back to data compilation processes.

Values for “Milk, full-fat” were tracked back to the food composition database in Excel format. It was not possible to demonstrate the values from original reference source, due to the fact, that this value was older and original document was missing/not archived.

Values for “Bread, prague” were tracked back to documentation in Excel and in printed form. Data were documented from results performed by NFNI laboratories. The “food card” for “Bread, prague” was provided. Hard copy of analytical protocol is the original reference source, stored only in the NFNI laboratories.

Conclusions

The mission of NFNI is to take care of and promote public health, through healthy diet and healthy lifestyle. NFNI is financially dependent on the Ministry of Health. Some funds are gained from donation and scientific grants of the Ministry of Science and Higher Education and other EU projects. NFNI is regularly audited by the Supreme Audit Office of Poland.

The structure of organization is strictly hierarchical (see Appendix 1). Responsibilities of management, scientific board, Economical Department and other departments are defined in an internal document NR 5/2011. NFNI staff follows rules set up in internal documents, released by the director of NFNI.

Food composition work is performed by personnel, equipment and infrastructure of NFNI. NFNI management has appropriate personnel, equipment and infrastructure for performing food composition work. The food composition team consists of FCDB compilers, who are analysts as well.

NFNI Laboratories are certified by PN-EN ISO / IEC 17025:2005 and produce data for Polish food composition database. NFNI Laboratories participate in proficiency testing to prove the quality of the analytical methods. The QMS of NFNI laboratories includes many issues (document control, contracts, personnel, training, sampling, equipment internal audits and other) and documentation and functioning of QMS of NFNI Laboratories was proved during the review visit.

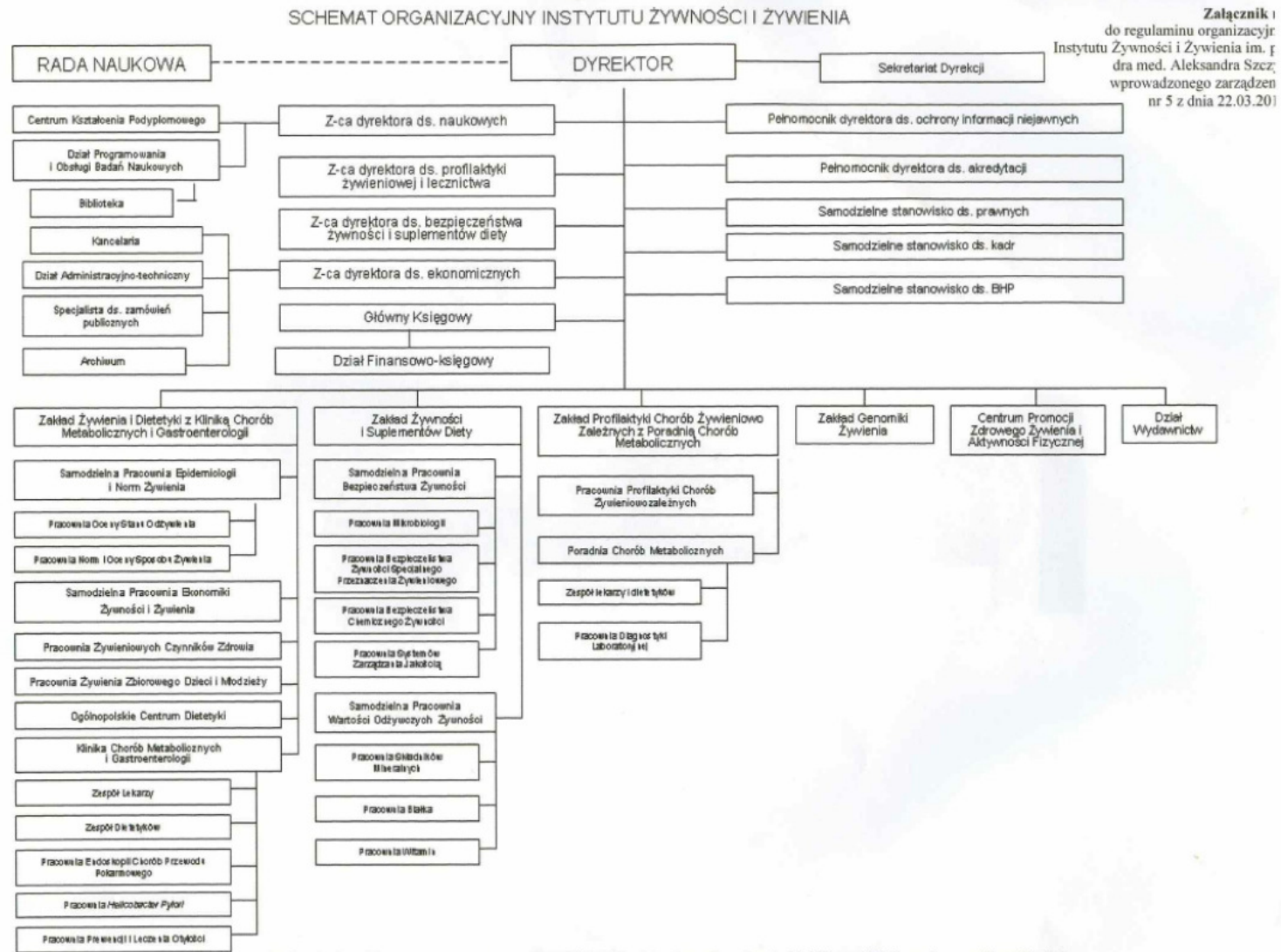
Most of the food composition data of the Polish food composition database come from analysis carried out by NFNI Laboratories, which are equipped to carry out analysis required for food composition. Due to this fact, the Polish food composition data are quite high quality, however full value documentation according EuroFIR standard is missing. Reference sources for each value are not yet documented in the food composition database. Links between value and method or link between value and reference are prepared for the purposes of production of a new food composition database. It is harder to track back older original food composition data and many of the reference sources are only in printed form. Data are documented and managed in Excel. FCDB Compilers of Polish Food Composition Data Base did not adopted EuroFIR generic flowchart and SOPs, however they have their own methodology for some steps of compilation process.

The Polish food composition data are published as FCT and at the same time online on the NFNI website.

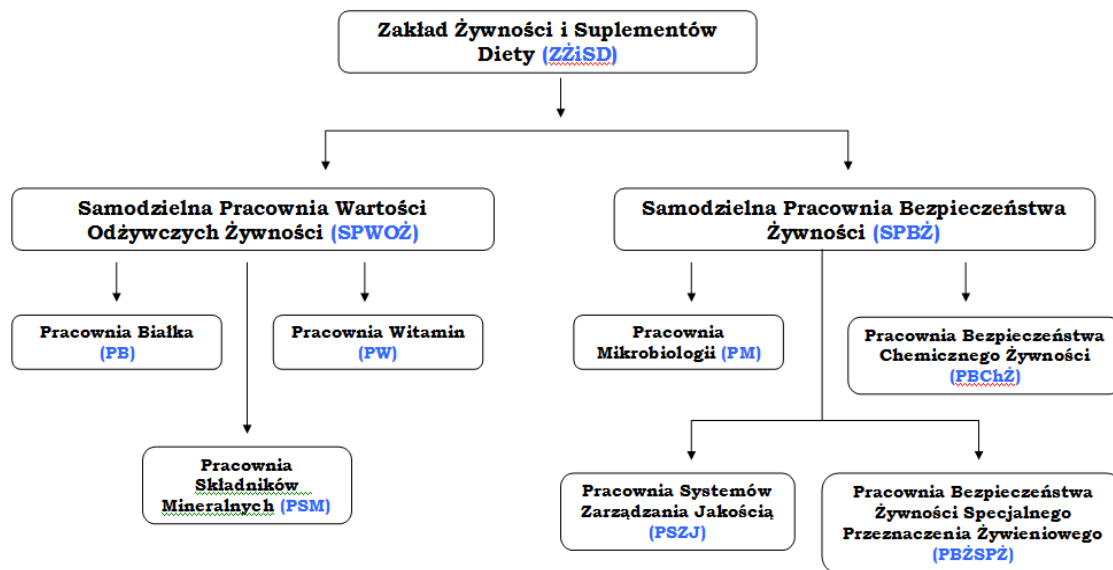
Recommendations

1. Production of the Polish food composition database should continue and foods from the Polish food market should be analysed and data compiled and published.
2. All mandatory information according to the EuroFIR standard should be documented to sustain links with European Food Composition Database (eSearch facility).
3. Archive scans or copies of original reference sources in both electronic and paper form.
4. A flowchart for the Polish food composition compilation process should be produced with CCPs and SOPs.
5. Investigate the possibility to change from Excel to a more secure database management system. Using FoodCASE as a data management system should be considered.

Appendix 1: Organization chart of NFNI



Appendix 2: Detail structure of Department of Food and Food Supplements



Explanatory notes:

- RADA NAUKOWA = Scientific Board
- ZAKŁAD DIETETYKI I ŻYWIENIA SZPITALNEGO Z KLINIKĄ CHOROÓB METABOLICZNYCH I GASTROENTEROLOGII = Department of Dietetic and Nutrition in Hospitals with Clinic of Metabolic Diseases and Gastroenterology
- ZAKŁAD ŻYWNOŚCI I SUPLEMENTÓW DIETY = Department of Food and Food Supplements
 - o SAMODZIELNA PRACOWNIA WARTOŚCI ODŻYWCZYCH ŻYWNOŚCI = Laboratory of Nutritional Value of Food Products
 - Pracownia Białka = Protein Laboratory
 - Pracownia Składników Mineralnych = Mineral Laboratory
 - Pracownia Witamin = Vitamin Laboratory
- ZAKŁAD PROFILAKTYKI CHOROÓB ŻYWIENIOWOZALEŻNYCH Z PORADNIĄ CHOROÓB METABOLICZNYCH = Department of Prevention of Civilization Diseases with Clinic of Metabolic Diseases
- ZAKŁAD GENOMNIKI ŻYWIENIA = Department of Nutrition Genomic
- CENTRUM PROMOCJI ZDROWEGO ŻYWIENIA I AKTYWNOŚCI FIZYCZNEJ = Center of Promotion Healthy Nutrition and Physical Activity
- DZIAŁ WYDAWNICTW = Editorial Unit

Appendix K – Review of IEO, Italy

EUROFIR – NEXUS WP1.2.2

Report on compiler review of IEO, Milano, Italy

Review dates: 24 - 25 September 2012

Participants

Reviewers:

Susanne Westenbrink, RIVM, The Netherlands

Compiler organisation: IEO, Italy

Patrizia Gnagnarella (BDA project manager/compiler, Epidemiology Unit)

Simonetta Salvini (Compiler, Freelance, Fiesole)

Patrick Maisonneuve (Director Epidemiology Unit)

Alessandro Misotti (Fellow, Epidemiology Unit)

Pier Luigi Deriu (IEO Quality Manager)

Grieco Giovanni (Assistant Chief Medical Officer)

The review is based on guidelines described in deliverable
D1.5_Framework_for_Certification_revised_Sep2011.docx

Introduction

The review of the IEO/BDA food composition data compilation processes at IEO took place on 24 and 25 September 2012. The review was carried out by one reviewer from EuroFIR Nexus – Susanne Westenbrink who is a national database compiler from RIVM, the Netherlands. Some information on the IEO organization and on the BDA database was available beforehand from the internet.

The review began with a welcome and an introduction of the review procedure.

The meeting started with background information on the IEO organization given by Grieco Giovanni (Assistant Chief Medical Officer). The Quality Management System was explained by Pier Luigi Deriu.

The structure and the topics of interest for the Epidemiology Unit were elaborated by the head of the unit, Patrick Maisonneuve. The afternoon and the next day were used to discuss the food data compilation process with the compiler team, represented by Patrizia Gnagnarella, Simonetta Salvini and Alessandro Misotti. Maria Parpinel, who is also one of the compilers of the food composition database could not attend the meeting due to personal circumstances. The food composition team consists of compilers from 3 organisations. Only the situation at IEO was reviewed.

Management requirements

Organization structure and management policy

The private non-profit organisation IEO (European Institute of Oncology) is a research hospital and cancer treatment centre with 318 beds. It was founded in 1987, with the aim of creating a “comprehensive cancer centre” with research laboratories and clinical services. IEO has three core activity areas: Clinical work, Research and Training. The IEO is one of Italy’s 45 research hospitals and treatment centres (IRCCS or “*Istituto di Ricovero e Cura a Carattere Scientifico*”) dealing with specific disease sectors, and is part of Italy’s National Health Service. The IEO is committed to making an active contribution to fighting cancer. Two other important pillars are the Research Campus and the cardiology hospital.

The Epidemiology Unit is part of the Research area of IEO. The BDA database (short for **B**anca **D**ati di **C**omposizione degli **A**limenti per **S**tudi **E**pidemiologici in **I**talia), being a food composition database designed for epidemiological research, is maintained at this unit. The BDA database was started in the early 1990s, originating from the cooperation between IEO in Milan, the Centro di Riferimento Oncologico of Aviano (CRO), and ISPO in Florence.

The cooperation with ISPO and CRO finished because the compiler from Florence became a freelance dietitian and the compiler of CRO moved to the University of Udine. Both compilers continue to be involved with the work on the BDA database from their current positions. As a result the BDA team consists of 3 compilers working in 3 different organisations. Two compilers are dietitians, one is a food technologist. Because the BDA database is hosted at IEO, the EuroFIR compiler peer review was held at IEO.

The IEO compiler also functions as a project manager for the BDA team. The external members work on an equal basis. All members report to the senior staff in their own

organizations, with the freelance compiler being independent in this respect. The project manager/compiler working at IEO is part of the Epidemiology Unit of IEO and reports directly to the head of that unit.

The definition of the internal and external responsibilities of the BDA working group is reported in the document „Progetto BDA (EPI.DO.4901.A)“ and „Matrice delle abilitazioni del personale dedicato al progetto BDA (EPI.DO.4934.A)“

The job description of the personnel involved with the BDA project and the relationship with the working programs is reported in the „Job Descriptions (progetto0BDA) (EPI.DO.5247.A)“.

The compiler working for IEO follows the organizational and QMS structure of the IEO institute according to the IEO quality and safety plan (Piano qualità e sicurezza 2012-2014 (CQS.PN.9.D)). Institute wide facilities such as human resources and IT support apply.

The steps performed to replace BDA personnel are reported in the document: „Percorso inserimento di un compilatore dedicato al progetto BDA (EPI.MO.4928.A)“ Two internal procedures define the steps for the reception, orientation and integration of the new employees/fellows in the division/units of the IEO Institute (Giornate di accoglienza ed orientamento all'IEO (DRU.PG.94.D) and Orientamento ed inserimento di nuovi collaboratori nelle Unità Organizzative (DRU.PG.3424.B)).

The organizational structure of IEO is added in appendix 1 and of the epidemiology unit in appendix 2. The position of the epidemiology unit and the BDA is indicated with circles. For this review only the organisational structure and QMS of IEO is reviewed. It was not possible to also include information for the organisations of the two other compilers.

BDA policy-making processes takes place within the BDA team and need to be incorporated in the policy and working plans of each of the participating organizations. For the IEO compiler the BDA policy is validated and included in the annual working program and signed off by the head of the Epidemiology unit of IEO. It was not completely clear from the discussions how far the working program for BDA reflects the need of the IEO organization with respect to updates and extensions needed for specific research projects.

Income generation

The IEO compiler and the compiler from Udine University are paid by their organizations. The IEO compiler spends 30%-50% of her time working on the BDA database. The other part is spent on work for other projects. This is not reflected in an earmarked yearly budget, which easily leads to varying priorities within or over the years. The research budget in general is limited. Extra activities or money needed to outsource some of the work to be done is difficult to obtain. When extra income can be generated this can be used for additional activities for the food composition database. One way to generate additional income is by asking for money for the Excel copies of the published dataset. The procedure is to ask for a donation, which is a tax efficient approach. There is no longer a printed version of the BDA food composition table. No other publications in print or electronically are produced that generate income for the food composition database work. The BDA database work is not sponsored by the food

industry.

BDA working objectives

The BDA food composition activities are the topic of the EuroFIR compiler peer review. The BDA team is responsible for the compilation process for the BDA database. The objectives of the compiler team which are documented in the document entitled “Progetto di aggiornamento della banca dati di composizione degli alimenti per studi epidemiologici in Italia-BDA” are:

- Development, update and management of BDA food composition database for Italy
- Distribution of the data to potential users, that are researchers from IEO and Udine University as well as dieticians and other users in the field of food and nutrition.

The annual working plan fixes the annual objectives concerning the BDA project. BDA meetings are planned to evaluate the work progress in relation to the objectives and the working plan.

Products from the BDA database are:

- a searchable website with BDA data in Italian and English (<http://www.ieo.it/bda2008/uk/diritti.aspx>)
- an Excel file with the published dataset, which is provided if a financial donation is given.

Collaborations

To maintain the BDA database IEO is collaborating with the University of Udine and with a freelance compiler. All facilities for the BDA database e.g. software and hardware are organised by the IEO. Hosting the BDA website is organised through the IEO IT department by contracting an external company. The compiler team is not aware of costs, contracts etc. Compilers collaborate with other departments within and external to their organisations when needed for the food composition database or for other projects. No budget is available for analytical work, so the compilers do not collaborate with laboratories.

Originally an advisory board was set up to advise and support the BDA work, but currently no advisory board or stakeholder group is in place.

The BDA group is part of SIAGRO, a project coordinated by INRAN Rome and funded by MiPAAF (the Italian ministry for agriculture, food and forestry policy) in the frame of QUALIFU (Food and Functional Quality). The role of BDA is to create a network of laboratories that will be able to provide composition data of Italian food, to offer up-to-date and complete information about simple and complex food. Activities are in progress coordinated by Maria Parpinel (University of Udine).

IEO is full member of EuroFIR AISBL. Through EuroFIR and the EuroFIR compiler network links are made with national compiler organizations similar to IEO. IEO participates in the EuroFIR-NEXUS project. The BDA compiler team cooperates with INRAN, which is the national food data compiler for Italy, in providing Italian data for the EFSA Food composition project (CFT/EFSA/DMC/2011/03). Since BDA is mainly

designed for epidemiological studies, coverage of commonly consumed foods is extensive in BDA.

Customer requirements

Customers of the BDA database are primarily the research departments of IEO and University of Udine. Customer requirements are met through direct cooperation within and between these institutes. There seems to be no very formal structure to investigate and fulfill the needs of these users. This was more an issue when the database was under construction. However, the compilers can also work on specific datasets if needed for research purposes. Examples for this are the data on flavonoids and carotenoids that were compiled, but are not published on the BDA website.

The other groups of customers include dietitians and software companies that request an Excel copy of the published dataset, as well as the users of the searchable website. Questions or requests are received mainly by email. All emails receive an answer within a week. Emails concerning queries on (new) foods or values published are collated in a separate folder and are taken into account when the team works on the update of the food group it concerns. Simple questions receive an answer free of charge. If users ask for more complex issues, an official collaboration and/or a request for payment is discussed.

Description of work

The working plan is written on a yearly basis by the project manager / IEO compiler. The working plan includes work on other projects as well and does not include activities to be carried out by the external compilers nor financial aspects related to the work of external compilers. The number of hours to spend on the BDA database is not specified very precisely nor are the deadlines for the milestones. Priorities are frequently assigned to other projects, in part due to the lack of finances to work on the BDA database. As a result it takes a long period of time to update food groups and to finalize the next version of the database as a whole. A document concerning quality and management is written to contribute to improvement of the BDA project (“Obiettivi di miglioramento”).

Working plans for the other 2 compilers were not discussed during this review. It is however known that the other 2 compilers also have limited time to spend on the BDA database, due to other project work or due to lack of funding to pay for the work (in case of the freelance compiler).

All documents concerning working plans and performance reviews are available and collated in the IEO document repository on the computer.

Contracts and sub-contracts

All contracts needed to maintain the BDA database are organised through the IEO organisation. Contacts/licences for computers and software include the institute wide standard software for Word, Excel and Access. The BDA website is maintained in Access, so no specific contracts are needed for the DBMS. To maintain the BDA website an external company is contracted at the institute level that maintains all websites from IEO. The compiler team does not have information about the content of these contracts or the costs of the work.

The BDA team is not involved in analytical work, so no contracts are needed for that.

Document control

For document control and archiving, IEO procedures are followed whenever applicable. An internal IEO document (Gestione della documentazione (DSA.PG.0004.E)) describes how to manage and archive IEO documents.

The BDA document management is described in a document entitled: Gestione della documentazione per il progetto BDA. The documents specifically related to the BDA Group are listed in the file "list of doc BDA&IEO.xls".

Electronic documents used for food composition work are stored and accessed via the IEO document repository on the computer network and are managed according to standard networking protocols controlled by the IEO IT Department. Access to the workspace with the BDA files is restricted to the IEO compiler and the head of the Epidemiology unit through username/password controls. Data is backed up at the IEO servers by the IEO IT department according to IEO regulations. This means that all documents including the BDA database are backed up four times per day on magnetic tapes. Data can be retrieved up to 3 weeks ago. The website is backed up every day and once monthly and once yearly. In case of failure of the IEO server system a recovery system is in place.

The two other compilers work from their own offices and apply the procedures that are applicable in their situation. The team has no shared workspace and documents are exchanged by email.

After producing the first version of the document for the IEO/BDA QMS, IEO will take into account version numbering for future versions of the documents.

Review of the Quality Management System

IEO has a QMS in place that is built from several elements. In January 2003 IEO obtained the accreditation of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) as a healthcare organization for the clinical departments. Some other units such as pharmacy distribution and laboratories are ISO 9001 certified. Three elements of ISO 9001 (documentation system, auditing system, non-conformity system) apply to the whole institute. The epidemiology unit -including the BDA database and the compiler employed at IEO- is not included in any of the certifications, except for the 3 ISO 9001 elements mentioned. This means that several aspects related to QMS are not yet (fully) in place in this unit.

At IEO a performance review for the employees is held yearly according to two internal procedures (Valutazione del personale amministrativo (DRU.PG.478.D) and „Valutazione del personale amministrativo (con rapporto diretto ad un Direttore-Responsabile) DRU.PG.480.D“). In this review the results of the previous working plan are evaluated and the plan for next year is discussed and established. Plans and performance review reports are signed by both the compiler and the head of the Epidemiology department.

Internal procedures are in place regarding evaluation of non-compliance and corrective

actions. They are explained in the document “Gestione delle Non Conformità (AMD.PG.0036.D)”. When a non-compliance is identified, a procedure is activated filling in the AMD.MO.0291.G form. Briefly, an analysis is started to evaluate the problem and to suggest an action to avoid the adverse effects. The corrective action is applied and after a period of time the non-compliance is checked to evaluate the efficacy of the intervention and the removal of the non-compliance.

Internal and external responsibilities of the BDA working group is documented in „Matrice delle abilitazioni del personale dedicato al progetto BDA (EPI.DO.4934.A)“.

The BDA project is reviewed by internal audits as reported in “Progetto BDA (EPI.DO.4901.A)” and “Audit Interni IEO (DGE.PG.0038.D)” according to the IEO quality and safety plan (Piano qualità e sicurezza 2012-2014 (CQS.PN.9.D)).

Objectives are set up for the BDA project on yearly basis. Likewise progress is evaluated yearly (objectives, milestones, follow-up and changes) and reported in the document “Obiettivi di miglioramento.doc” When the deadlines are not met, or the objectives are not achieved, the activities are rescheduled.

The BDA team has started to build a QMS that focuses on the compilation process to assure quality of their data. The EuroFIR flow chart was adopted. Standard operating procedures (SOPs) are written in Italian and detailed according to the working procedures of the BDA team (see the chapter on the compilation process). The SOPs are linked to a generic document giving an overview of the BDA working process. Next to the SOPs detailed instructions on some aspects are written to assure standardized working processes. The SOPs which are part of the IEO documentation system within the IEO QMS were constructed following the IEO standard for SOPs and are accessible through the IEO intranet.

In the framework of this compiler peer review, the elements presented during the review were the steps of the generic flow chart; the SOPs written for critical control points and some specific working instructions and detailed descriptions of steps in the compilation process. Procedures and documents that relate to the IEO institute wide procedures, e.g. project planning, staffing, contracts and document repository and archiving were briefly discussed and are mentioned throughout this report.

List of documents related to the BDA compiler organization is shown in appendix 3.

Technical requirements

Infrastructure

The infrastructure is described in the chapter on Organization structure and management policy

Personnel

One compiler is employed full time by IEO. The BDA team will be enforced by a fellow who is also employed at IEO and who is trained as a dietitian. Job descriptions and CVs

are available within the Epidemiology unit. Working plans and performance reviews are held with and signed off by the head of the Epidemiology unit. Support from the human resources and the IT department is available for IEO staff members. The situation of the compiler employed by University of Udine was not discussed. For the freelance compiler this chapter is not applicable.

Training

IEO employees are entitled to follow 12 days of training per year. Training records are available and training programmes are filled in and approved by the head of the Epidemiology unit on a yearly basis. No information is available for the situation of the other two compilers.

At IEO finances are more limited at the moment and grants are more difficult to get, which makes it difficult to get permission for training. The IEO compiler is trained as a dietician and by following post graduate training she stays accredited as a dietician. This is however not mandatory from the IEO organisation.

Technical competencies have been a selection criterion for BDA compilers. Two compilers and the fellow are trained as a dietician; one compiler is trained as a food technologist. Two of the compilers have followed the International Food Composition Course in Wageningen. Since finances for training are insufficient for the Food Composition Course, the fellow can only attend the course when a grant can be obtained.

Equipment

Equipment used for IEO food composition work is limited to office equipment, including PCs and software for data management.

Office software such as Word, Excel, Access and internet access is used and serviced through the IEO IT team. Access to files and the food composition database is restricted to the IEO compiler and the head of the Epidemiology unit through username /password controls. Protection against viruses is arranged through McAfee software.

The IT department is available to facilitate both hard and software for the computers.

This department also assists in performing complicated queries and database maintenance. No other applications are developed or applied. No specific SLA (service level agreement) is in place for this cooperation.

Database management system

The BDA database management system is built in Access and includes relational tables for foods, components, references, EuroFIR technical annex and modules for some calculations. Historical data is kept in separate files outside the database. IEO has a user interface that secures data management sufficiently to a certain extent. It is for example not possible to use identical food or component codes more than once.

A number of processes are performed outside the database by using Excel, which requires both exporting and importing data from the database. The transfer is validated by double checking the data and by randomly checking the correctness of the export/import procedures. Examples of processes outside the DBMS are the calculation of fatty acid profiles, retinol equivalents and recipe calculation. To perform consistency checks the help of the IT department, that uses Web Applications developed with c#.net Framework 1. to perform queries, is needed. The BDA DBMS allows for both manual

and electronic data entry. To check data entry, data forms are printed on paper, mostly per food item and this is checked with the original data source. EuroFIR value documentation is now included in the BDA system as well.

FoodCASE

The BDA team has investigated the possibilities to transfer their food composition data to FoodCASE. Although the need to have a full DBMS is recognised, it is not possible to change to FoodCASE due to financial restrictions. In the current situation, no additional costs are made to maintain the Access database. Finances for the yearly costs of the FoodCASE licence and the technical support, are not available. Furthermore in one aspect, changing to FoodCASE is considered be a step backwards because in FoodCASE data entry can only be done manually.

Analytical work (including sampling)

IEO has no budget for analytical work. Therefore, sampling and analyses is out of the scope of this review. The database is filled with data originating from other sources such as other food composition tables, scientific literature, food industry, similar foods and calculations. Data from the INRAN food composition table, which is mainly analytical data of Italian foods, is incorporated in the BDA database.

Data production

BDA is a database for generic foods that comprises data from other food composition databases, scientific literature and data from the food industry, as well as calculated and estimated data. A few generic items are calculated by weighted means (weight is based on consumption data). Very few brand data is included in the database and they are quoted. Manufacturers' data have been used very seldom, and mainly to fill gaps. No agreements have been set up with manufacturers concerning responsibilities.

Data are compiled and entered by one compiler. Data check is always performed by another compiler. Validation of the data is done after all new data has been entered and checked for correct data entry: this step is performed by one of the three compilers.

Publication process

After all steps including data entry and aggregation as well as data checks and validation are done by the compilers, the data is ready for publication. The BDA database allows for multiple selections of data to produce datasets for the BDA website or other users if needed. The BDA website currently contains data on 1406 foods and 153 components.

The database is updated food group by food group and a full update requires a long period. The previous version of the BDA website was launched in 2008. It is not yet known when the next release can be planned. Instead of waiting for a full update of the BDA database before publishing a new version on the internet, BDA has decided to follow the approach to publish a new version after a limited number of food groups have been updated. This is an opportunity to do some advocacy for the database in newsletters, national food journals etc. Furthermore this approach prevents the updated data being out dated before publication.

Guidelines for the publication process are reported in the document “Selezione di dati aggregati e compilati per la loro diffusione o pubblicazione (EPI.IO.4920.A)”.

Compilation process (critical control points – see EuroFIR generic compilation flowchart)

For the BDA compilation process the EuroFIR generic compilation flowchart is adopted without changes. This is visualized in appendix 4. Each step is described in Italian shortly with reference to IEO SOPs for the BDA compilation process (see below). Critical control points (CCP) are defined for the BDA compilation process. Most CCPs are equal to the CCPs in the EuroFIR generic flow chart. For each step that is considered a CCP a detailed SOP is written, including listing of risks as well as preventive or corrective actions that can be taken. During the review it was discussed that the steps as defined in the generic flow chart equal the order in which the BDA team works to a large extent, but not completely. To improve the BDA quality approach, adapting the order of the steps in the BDA flow chart is planned for next year. The written SOPs and additional procedures with detailed working instructions / manuals were available during the review to show traceability and repeatability of the process.

The steps of the compilation process as recognized by the BDA team are listed below. Each step for which a SOP is written is also mentioned with the Italian name and the IEO SOP number given between brackets.

- | | |
|---------|---|
| Step 1 | Decision on which foods/nutrients need to be added / updated |
| Step 2 | Collection or production of original data |
| Step 3 | Identification and comprehension of the data in the data sources
<i>Identificazione dei dati di composizione (EPI.IO.4923.A)</i> |
| Step 4 | Use of data |
| Step 5 | Attribution of quality (index) to all original data
<i>Attribuzione dell'Indice di Qualità a tutti i dati originari (EPI.IO.4921.A)</i> |
| Step 6 | Coding of original data before data entry
<i>Codifica dei dati originari prima dell'inserimento (EPI.IO.4925.A)</i> |
| Step 7 | Original data entry /keybording /importation |
| Step 8 | Check on original data entry
<i>“Verifica dei dati originari ed inserimento dei dati” (EPI.IO.4922)</i> |
| Step 9 | Decide whether data are correct or not |
| Step 10 | Storage of original computerized data |
| Step 11 | Physical storage of original data |
| | <i>Gestione della documentazione per il progetto BDA (EPI.PI.4931)</i>
<i>“Archiviazione dei dati di origine (EPI.IO.4924)”</i> |
| Step 12 | Extraction of all original data available for each food / component pair |
| Step 13 | Selection of the original data to be further used to determine aggregated data
<i>SOP “Selezione dei dati da aggregare” (EPI.IO.4929).</i>
<i>See Section 2.4. in the publication Salvini S et al (1998).</i> |

- Step 14-15 Selection and application of algorithms to calculate (weighted) means, recipes, derived nutrients
“Selezione e applicazione di algoritmi specifici per il calcolo dei dati” (EPI.IO.4930).
Section 2.4. in the publication Salvini S et al (1998).
- Step 16 Validation of aggregated and compiled data
“Convalida dei dati aggregati e calcolati (EPI.IO.4926.A)”
“controlli informatici testo.doc”.
- Step 17 Correct errors / inconsistencies that were identified during validation
- Step 18 Determine confidence code of the aggregated and compiled data
- Step 19 Storage of aggregated and compiled computerized data
- Step 20 Selection of aggregated and compiled data to be disseminated as published databases or tables
SOP Selezione di dati aggregati e compilati per la loro diffusione o pubblicazione (EPI.IO.4920.A)
- Step 21 Storage of data selected for dissemination
 Gestione della documentazione per il progetto BDA (EPI.PI.4931)
- Step 22 Dissemination of data

Feedback from users

Feedback from users is collected through the contact with core users at IEO and University of Udine. Feedback from other users like dietitians and software companies is mainly collected through the dedicated email address of BDA. For more details, see customer requirements.

Contact with the food industry

To update the BDA database the food industry is contacted whenever needed. Up till now this is done to a limited extent. From 2013 onwards, a network of Italian food industries should start providing some data on a structural basis.

Dissemination of data

IEO is a private non-profit organization that is only partly funded by the Italian government and tax money. This also accounts for the BDA database. Finances to update the database and for additional activities such as a new release of the BDA database on internet is limited. See the chapter on the publication process for more details. Moreover BDA datasets are provided on request to users through Excel files. To generate some extra income the users are asked to pay a donation for the Excel file.

EuroFIR

IEO is full member of EuroFIR AISBL. The BDA food composition data is documented in accordance with the EuroFIR technical annex. The IEO dataset is included in the EuroFIR eSearch facility. Updating the EuroFIR eSearch data is not possible due to technical (and financial) restrictions, as IEO has no functionality to produce xml datasets.

References

Salvini S, Parpinel M, Gnagnarella P, Maisonneuve P, Turrini A (1998) Banca Dati di Composizione degli Alimenti per Studi Epidemiologici in Italia. ed. Istituto Europeo di Oncologia, Milano.

Conclusions

IEO is a research hospital and cancer treatment centre with a QMS in place for the clinical departments and some other units. The Epidemiology unit, which hosts the BDA database, is not included in any of the certifications, except for three ISO 9001 elements that apply to the whole institute.

The BDA compiler team has started to build a QMS that focuses on the compilation process to assure quality of their data. Therefore, the EuroFIR flow chart is adopted. Standard operating procedures and detailed working instructions are available and relate to the working process of the BDA team.

Procedures concerning job descriptions, annual working plans, performance reviews, training, IT support etc. are organised according to the IEO infrastructure.

IEO uses Access for their database management system. The compiler team is well aware of the limitations of working with Access instead of a database management system (DBMS) and manages to maintain their data well within these limitations. They manage to keep good track of the status of the update and work in a structured way that assures that duplicated work or forgetting steps is avoided. A number of steps from the compilation process (e.g. recipe calculation and calculation of most derived components (but not energy) are done outside the Access database. For consistency checks on the data, detailed instructions are available but the help of the IT department is needed to perform some of the queries. Not having a DBMS means that part of the work of the compilers is done manually rather than by the computer.

IEO has no budget for analytical work. The database is filled with data originating from other sources such as other food composition tables, scientific literature, food industry, similar foods and calculations. Data from the INRAN food composition table, which is mainly based on analysis of Italian foods, is incorporated in the BDA database.

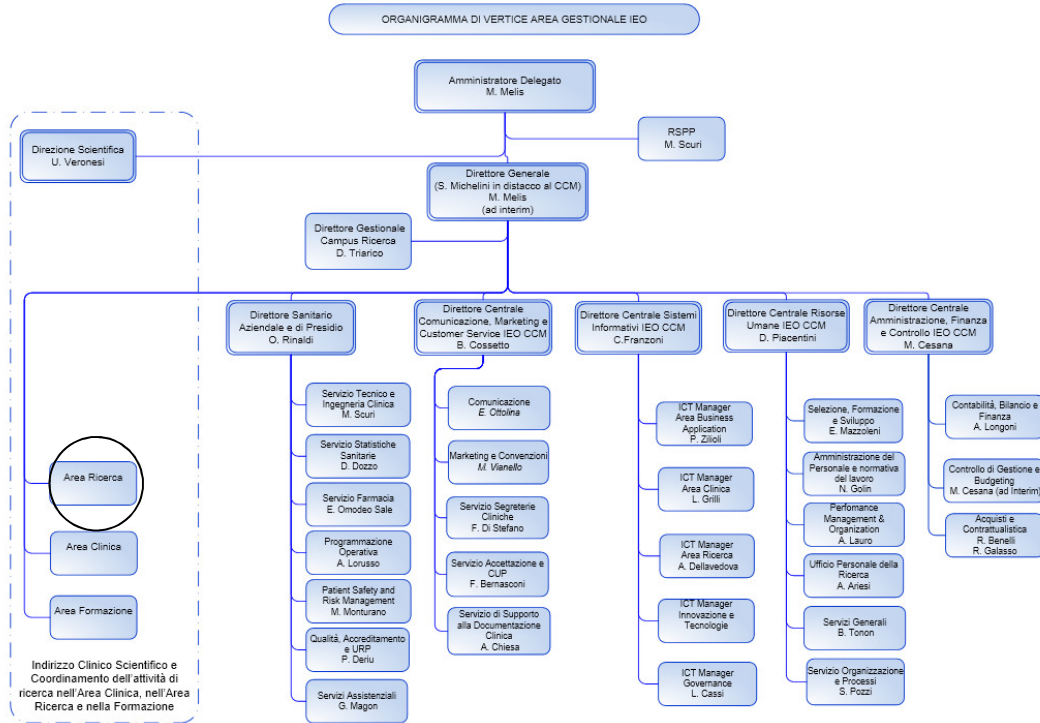
Data entry and data compilation is done by one compiler and data is checked by the second compiler, which is a good approach. Because the three compilers do not work in the same city the data needs to be exchanged between them. This is done by exchanging Excel files (mainly by email) or the access database. This approach carries the risk of losing documents, which may be copies or in some cases original data sources.

The BDA compiler team prepared this review very well. The compilation procedures were discussed in a structured and detailed way, which was possible because of the flow chart and the detailed procedures available. The BDA compiler team was very open and shared all information and documents that was asked for.

Recommendations

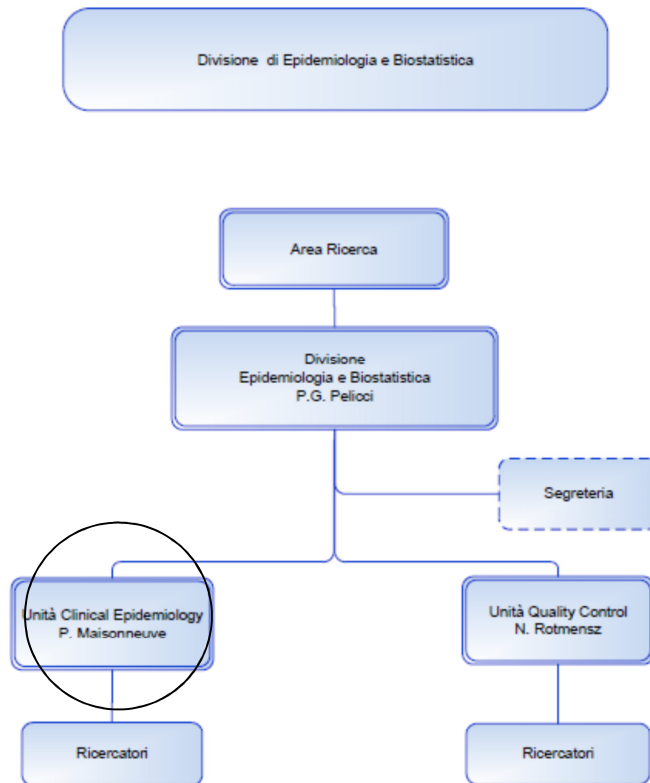
1. To make the work and the importance of the IEO/BDA database more visible and to enlarge the support for the work of the IEO team it is recommended to form some sort of network / advisory board or group of stakeholders within the contributing organizations or beyond.
2. It is recommended to adjust the EuroFIR generic flow chart to the IEO specific work flow wherever needed. A generic document is written as an umbrella document for the SOPs. However the detailed instructions can be made more generic, because at the moment it focuses on some specific food groups / components only. A more generic document would help to avoid redundancies of the reported information in several documents.
3. Since the limited budget makes it difficult to work on additional issues like functionality of software, the website or training, seeking additional funding wherever possible, within the restrictions of the organizations involved in the BDA database work, should be encouraged. Attending the Food Composition Course has been possible with a grant from a food company in the past; it could be worthwhile to explore this type of funding once more.
4. To compiler organizations that work with Access database systems it can in general be recommended to investigate the possibilities of moving to FoodCASE as a new relational food database management system. It was clear from the discussions at IEO that this option had been discussed within the team. Financing the fee for the license and the software support is a major problem, as well as contributing to any additional functionality. If the transition to FoodCASE is not an option, it is recommended to invest in the functionality of the current Access database. Several queries could be built and implemented to further computerize the compilation process (e.g. recipe calculation, consistency checks). It is also advised to contact other compiler organizations (e.g. NUBEL Belgium or ANSES France) to learn how these compilers have implemented (semi) automated functionality within an Access database.
5. To avoid the risk of sending datasets and original documentation between the three compilers, it is recommended to explore the possibilities of having the database available through the internet or to have an internet area where shared documents can be stored and edited.

Appendix 1 IEO organization structure including The Epidemiology unit



Appendix 2.

Organization structure of the Epidemiology unit including the BDA compiler team



Organigrammi IEO - Ottobre 2012

The positions of the two external BDA compilers from Udine University and freelance are not included in the organogram, but are described in the document entitled: *“Progetto BDA” (EPI.DO.4901.A)*

Appendix 3.
List of documents related to the BDA compiler organization

Acronvm	Division-unit	Type of document	Acronvm	ID	Version	Document Name	Comments
AMD	CeO	Form	MO	291	G	Rilevazione e Gestione Non Conformità-Area di miglioramento	IEO documents used by the BDA project
AMD	CeO	General Procedure	PG	36	D	Gestione delle Non Conformità	IEO documents used by the BDA project
CQS	Quality and Safety Committee	Plan	PN	9	D	Piano qualità e sicurezza 2012-2014	IEO documents used by the BDA project
DGE	General Direction	General Procedure	PG	38	C	Audit interni IEO	IEO documents used by the BDA project
DRU	Human resources department	General Procedure	PG	94	D	Giornate di accoglienza ed orientamento all'IEO	IEO documents used by the BDA project
DRU	Human resources department	General Procedure	PG	3424	B	Orientamento ed inserimento di nuovi collaboratori nelle Unità Organizzative	IEO documents used by the BDA project
DRU	Human resources department	General Procedure	PG	478	D	Valutazione del personale amministrativo	IEO documents used by the BDA project
DRU	Human resources department	General Procedure	PG	480	D	Valutazione del personale amministrativo (con rapporto diretto ad un Direttore-Responsabile)	IEO documents used by the BDA project
DSA	Medical Office	General Procedure	PG	4		Gestione della documentazione	IEO documents used by the BDA project
EPI	Epidemiology and Biostatistic	External Document	DE	2417		D1.8.19-EuroFIR Standard Technical Annex	BDA project document
EPI	Epidemiology and Biostatistic	Generic Document	DO	4932	A	Categorie merceologiche BDA	BDA project document
EPI	Epidemiology and Biostatistic	Generic Document	DO	4936	A	Definizioni ed acronimi BDA	BDA project document
EPI	Epidemiology and Biostatistic	Generic Document	DO	5247	A	Job Descriptions (progetto BDA)	BDA project document
EPI	Epidemiology and Biostatistic	Generic Document	DO	4934	A	Matrice delle abilitazioni del personale dedicato al progetto BDA	BDA project document
EPI	Epidemiology and Biostatistic	Generic Document	DO	4901	A	Progetto di aggiornamento della banca dati di composizione degli alimenti per studi epidemiologici in Italia-BDA	BDA project document
EPI	Epidemiology and Biostatistic	Generic Document	DO	4933	A	Sistema di codifica alimenti BDA	BDA project document
EPI	Epidemiology and Biostatistic	Generic Document	DO	4935	A	Tabella componenti BDA/EuroFIR	BDA project document
EPI	Epidemiology and Biostatistic	Operating Instruction	IO	4924	A	Archiviazione dei dati di origine	BDA project document
EPI	Epidemiology and Biostatistic	Operating Instruction	IO	4921	A	Attribuzione dell'Indice di Qualità a tutti i dati originari	BDA project document

	Biostatistic	Instruction					
EPI	Epidemiology and Biostatistic	Operating Instruction	IO	4925	A	Codifica dei dati originari prima dell'inserimento	BDA project document
EPI	Epidemiology and Biostatistic	Operating Instruction	IO	4926	A	Convalida dei dati aggregati e calcolati	BDA project document
EPI	Epidemiology and Biostatistic	Operating Instruction	IO	4923	A	Identificazione dei dati di composizione	BDA project document
EPI	Epidemiology and Biostatistic	Operating Instruction	IO	4929	A	Selezione dei dati da aggregare	BDA project document
EPI	Epidemiology and Biostatistic	Operating Instruction	IO	4920	A	Selezione di dati aggregati e compilati per la loro diffusione o pubblicazione	BDA project document
EPI	Epidemiology and Biostatistic	Operating Instruction	IO	4930	A	Selezione e applicazione di algoritmi specifici per il calcolo dei dati	BDA project document
EPI	Epidemiology and Biostatistic	Operating Instruction	IO	4922	A	Verifica dei dati originari ed inserimento dei dati	BDA project document
EPI	Epidemiology and Biostatistic	Form	MO	4927	A	Obiettivi di miglioramento 2012	BDA project document
EPI	Epidemiology and Biostatistic	Form	MO	4928	A	Percorso inserimento di un compilatore dedicato al progetto BDA	BDA project document
EPI	Epidemiology and Biostatistic	Internal Procedure	PI	4931	A	Gestione della documentazione per il progetto BDA	BDA project document
EPI	Epidemiology and Biostatistic	Protocol	PT	4914	A	Aggiornamento BDA - Categoria Merceologica Cereali	BDA project document
EPI	Epidemiology and Biostatistic	Protocol	PT	4913	A	Aggiornamento BDA - Categoria Merceologica Frutta	BDA project document

Appendix 4.

IEO flow chart

See separate document entitled: *FINALE-certificazione-eurofir-2012.ppt*

Appendix L – Review of INRAN, Italy

EUROFIR – NEXUS WP1.2.2

REPORT ON COMPILER REVIEW OF INRAN , ROME, ITALY

REVIEW DATE 6 SEPTEMBER 2012

Participants

Reviewer:

Isabel Castanheira, INSA , Portugal

Compiler organization: INRAN, Italy

Luisa Martella , Food database compiler,
Emanuela Camilli, food database mana
Aida Turrini , EuroFIR Project manager for INRAN

Reference Document

Roe, M., Finglas, P., Lindroos, A.-K., Castanheira, I., Giertlová, A.,
Westenbrink, S. Bell, S., Beernaert, H.(2011) EuroFIR Report on framework for
certification scheme (D1.5)

Introduction

The review of the food composition data compilation processes at INRAN took place on 6th September 2012. The review was carried out by one reviewer from EuroFIR Nexus – Isabel Castanheira, senior research scientist and head of Reference Materials Laboratory at INSA, Portugal. Documentation and information was provided before the visit with web based documentation about INRAN (www.inran.it) and the INRAN printed tables and food composition database available at the INRAN web site and through the EuroFIR e-search platform.

The review started with the approval of the agenda (annex 1) by participants. The INRAN FCT review (Management requirements, Technical requirements and Compilation Process) was done with the presence of both compilers Luisa

Marletta and Emanuela Camilli. The EuroFIR project coordinator Aida Turrini was present at the opening and closure of the meeting.

INRAN. - Istituto Nazionale di Ricerca per gli Alimenti e la Nutrizione (National Reserach Institute on Food and Nutrition)

INRAN FCT web site

(http://www.inran.it/646/tabelle_di_composizione_degli_alimenti.html)

Management requirements

Organization structure

INRAN, Istituto Nazionale di Ricerca per gli Alimenti e la Nutrizione (National Research Institute for Food and Nutrition) is a governmental research organisation, founded in 1936, under the aegis of the Italian Ministry of Agriculture, Food and Forestry Policy. INRAN responsibilities in relation to the FCT have been institutionally defined by law since 1946. The institute published the first edition of the Italian food composition tables in 1946. INRAN's competences and custody of FCT was re-established by Law in 1999 (D.L. 29 October 1999, n. 454). The institute covers others areas providing strategic and applied research in the fields of Food Science and Nutrition. Furthermore INRAN combines and integrates several scientific disciplines, including the sensory and consumer sciences. The mission and vision of INRAN are available at INRAN web site (www.inran.it) and its focus is on development of studies and research to support Italian agro-food. A clear organisational structure was provided giving details of management structure and departmental structure (annex 1). INRAN also provides advice and guidance to the food industry to help improve product quality and stimulate product and process innovation. The staff includes 200 full or part-time employers. Now the Institute consists of three scientific areas: Food Science, Nutrition, Applied Food Science, as well as Administration and Management.

Management policy

The organizational constraints at INRAN, which is undergoing reorganisation to be merged with C.R.A, are the main pitfalls to a regular management review during 2012.

There is no specific budget item being allocated for activities related to compiling food composition data but ministerial funding flows through a wide-range of projects. Funding is acquired from a number of other non-ministerial sources and management decisions are project based.

Collaborations

EuroFIR

INRAN is full member of EuroFIR AISBL and Aida Turrini is a member of the EuroFIR AISBL Executive Board. Through EuroFIR AISBL links are strengthened with national compiler organizations producing and maintaining FCDB around the world. INRAN is a member of the EuroFIR- NEXUS project

and agreed to join the overall plan of compiler visits under the compiler peer review scheme.

National and International research projects

INRAN, which is the national food data compiler for Italy, provides Italian data for the EFSA Food composition project (CFT/EFSA/DMC/2011/03). INRAN cooperates with all other Italian organizations that provide databases dealing with food and nutrition. INRAN is member of several national, European and international projects (EU research projects) focussing on different aspects of food quality. INRAN/Aida Turrini leads WP 3 (Sampling) in the Total Diet Study Exposure project funded by EU.

Other collaborations

INRAN developed their activities through several collaborations: a) with producers and consumers focusing on updating the composition of food produced and consumed in Italy; b) requested by companies or official organizations to evaluate typical foods and specific food product categories. These collaborations encompass: a) BIOVITA project (Database of Italian traditional food, food label of origin); b) QUALIFU-SIAGRO project (implementation of Database: Italian traditional recipes)

Description of work

The INRAN, food composition working group carried out food composition analysis under various projects with industry, local associations, and international organisations. The work is delineated according to projects descriptions of work (schedules, objectives, milestones and staff allocations).

The management of food composition data has been developed “to match as closely as possible the research typology and fulfill the Italian and international expectations in terms of data quality to give confidence (reliability and credibility). The work in terms of quality management is a hybrid dedicated to both compilation and analytical activities incorporating the requirements of EuroFIR (compilation) and Good Laboratory Practices and ISO 17025 (analysis) in place at INRAN.

Contracts and sub-contracts

Internal and external contracts are in place. Internal contracts are related to work plans and focus on contract personnel (fixed term). Only external collaborations are regulated by written contract and most of the work is managed by formal contracts. All contracts are reviewed by the “UNITA Affari generali e amministrativi “ management team and legal representatives and are formally signed off by the General Director. Signed copies of contracts are held within INRAN and are stored electronically as scanned Pdf files and stored at UNITA Affari generali e amministrativi “.

Document control

Since FCT is not part of Quality Management System, the document control process was designed to support the compilation of data and to guarantee the

traceability and origin of nutrient values, covering storage of data and updating procedures in electronic or hard copy version.

Review of the Quality Management System

The laboratories at INRAN work according to Good Laboratory Practice standards although up to now they have not integrated a formal Quality Management System.

Technical requirements

Personnel

Personnel involved in food composition studies have an adequate combination of academic and professional qualifications. Each member of staff has a work plan ensuring the competence for operation of specific equipment, performing tests, evaluating results and signing test reports.

A job description is available for each member of staff. Training needs are identified and training programmes are evaluated according to quality practices and principles in place at INRAN. Three categories of training are defined and complete by staff: initial, ongoing and professional development. Compilers from the team have attended to the International Graduate Course on Production and Use of Food Composition Data organized by FAO and EuroFIR in Wageningen. Records on training were checked and are kept up to-date on the relevance of qualifications gained in terms of experience and professional qualifications.

Equipment

INRAN has impressive laboratory facilities covering broad areas of food chemistry devoted to several areas of sample processing (collection and preparation, homogenization, freezing, freeze-drying), analysis of traditional and specific foods. Equipment covering all areas of work is calibrated on a regular basis in compliance with laboratory quality requirements. A detailed program of calibrations, maintenance and checks with specialized standard procedures for each class of equipment is in place. An acceptance criterion was established to monitor equipment performance and maintenance. IT provision and software is maintained and developed by contracted suppliers.

Sampling

INRAN pays particular attention to sampling and sampling plans. Most of the sampling plans are part of funded projects and are designed to take into account variability within foods. Specific sampling plans are produced when necessary and cover geographical origin, seasonal variation and take into account the ratio of edible and non-edible portions. Three sampling plans were designed for a) meat& fish; b) milk and cheese; c) eggs; fruits, vegetables and cereals. The sampling plans describe the main source of variation, e.g. for sampling foods of animal origin instructions are provided on breed; sex; age; feeding and type of farm; technological treatments and cooking methods. Information on pooling of samples from different origins is described for each assay.

Protocols for sample identification, sample collection and sample handling are also in place.

Analyses

Most of the analyses are done at INRAN laboratories under Good Laboratory Practice standards. INRAN carries out analysis of water, ash, total nitrogen, protein, total lipids and dietary fibre by AOAC methods. SFA/MUFA/PUFA is analysed by GLC preceded by a Folch extraction. Starch is determined as total by the Englyst method or using an enzymatic assay kit. Total sugars are measured by the Koziol method and individual sugars by HPLC. Minerals are measured by ICP-OES. Vitamins are measured by HPLC methods with the exception of folate which is determined by the microbiological method for total folate. The laboratories have in place SOPs for sample handling and storage and laboratory sample preparation. Analyses are carried out under internal quality control procedures accepted by EFSA. INRAN laboratories participate in proficiency testing schemes on a regular basis. Data checking (repeatability criteria) is part of the data validation process.

Publication process

INRAN has three editorial products: INRAN printed tables, INRAN CD and INRAN web site linked to the EuroFIR e-search platform.

The latest edition of FCT includes original experimental data (70%) with the remaining 30% of data from a careful selection of scientific literature, official reports from laboratories and grey literature. Borrowed data is not often used. INRAN FCT contains information for 790 foods consumed in Italy including beverages, raw foods, processed foods and recipes. Recipe calculations are used mainly for traditional foods. Data is available for 67 components in the majority of foods however there is a lack of information for vitamins and trace elements in some foods. Publication of data is mostly determined by project deadlines and contract requirements, nevertheless a criteria for data selection before publication is in place.

Compilation process (critical control points – see EuroFIR generic compilation flowchart)

The EuroFIR generic flowchart is followed on informal basis. SOPs are not available although a formal management of compilation process is defined and includes almost all steps. The attribution of quality index to all original data taking into account the seven criteria is not yet in place. Steps of the compilation process are controlled as follows:

1. Decision on which foods nutrients are updated is based on stakeholders' consensus
2. Analytical programmes are part of research projects
3. Identification of relevant foods and nutrients is decided taking into account existing data and survey requirements
4. FCT has in place systems for food description and food coding
5. Most food values are original data produced by INRAN
6. Checking the original data is carried out on regular basis
7. Storage of data is guaranteed both in electronic or hard copy form

8. Extraction of all original data take into account the original data source
9. Quality procedures exist to aggregate data from different sources
10. Values are expressed according to the EuroFIR thesaurus
11. Validation of aggregated and compiled data is supported by compiler experience and training
12. Inconsistencies are detected and corrected through compiler experience and knowledge
13. Compiled and aggregated data is stored in computer files
14. Selection of aggregated and compiled data is defined by consensus between compilers and stakeholders
15. Data selected for dissemination is storage in computer files

Vertical review of data

Garlic

A Vertical audit was applied to trace back documentation of nutrient values in key foods analysed for the Biovita project. This was done using a casual key food summary report and traced back to raw data and ancillary information (certificate of analysis).

Results of analysis for proteins, vitamin C, total dietary fibre and individual sugars of two garlic samples from 180 bulbs from two different geographical areas of Lazio were traced reviewed.

The approach was in casuistic form. The results confirm that data is complete. It was possible to identify all steps of the analytical process, statistical analysis of data, aggregation of data and associated documentation for each single value.

Conclusions

The INRAN food composition team has been developing impressive work to create new analytical data following the quality criteria designed during the EuroFIR project. The analytical data and software programs have been developed and are currently being tested for food composition data production. The food composition data production work is done under appropriate Quality requirements. The team seems to control all the activities from selection of foods and nutrients up to publication of data.

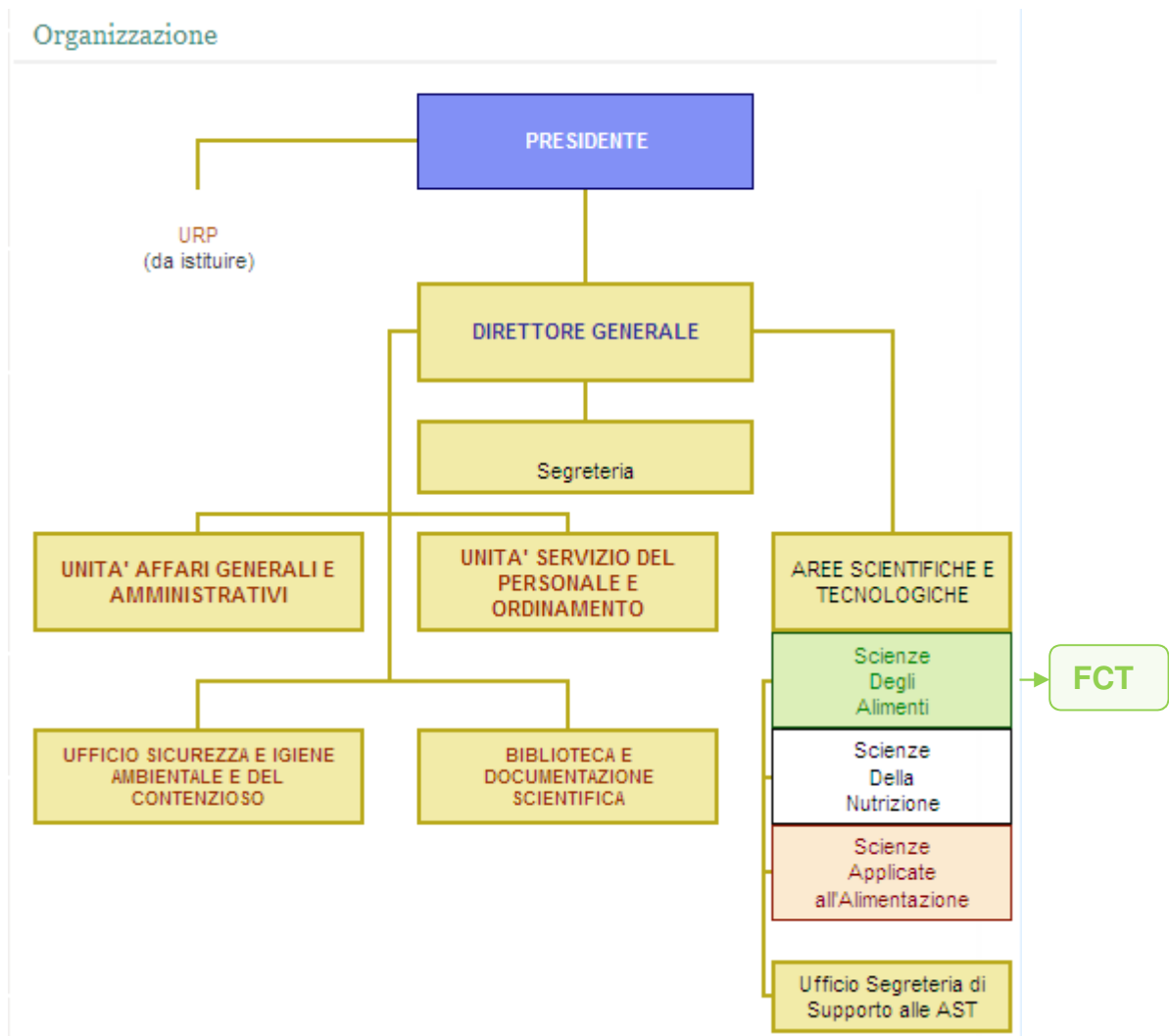
Sources of data are mainly analytical data (70%) in agreement with sampling and analytical protocols produced. Only 30% of data originated from literature and grey and official literature used refers to products available in Italy.

INRAN FCT is used by dieticians, nutritionists, epidemiologists, health operators, nutritional surveillance, consumers, consumers associations, food industries and agriculture sectors.

Recommendations

1. The INRAN online database should continue to be developed, making use of analytical data generated under quality assurance and metrological principles.
2. The focus on foods that are produced in Italy or that are traditional and an important feature of the diet should continue, using analytical data generated by INRAN or published in scientific literature.
3. Food composition study SOPs and guidelines should be completed and should be specific for INRAN processes.
4. Attention should be given to creating a specific budget to allocated activities related to compilation processes.

Appendix 1. Organisational structure of INRAN



Appendix 2. Organisational structure of FCT

FCT
INRAN

06.09.2012

FCT Contact persons and organization structure

Contact persons for INRAN

Management and compiling of the database	Aida Turrini
Computer scientists that have worked on INRAN software	
Development of the INRAN system	
Supervision of computers at INRAN	

- 1. Proposal agenda**
- 2. Management requirements**
 - 2.1. Organization structure and management policy
 - 2.2. Description of work
 - 2.3. Contracts and subcontracts
 - 2.4. Document Control
 - 2.5. Review of Food Databanks Quality Management System
- 3. Technical requirements**
 - 3.1. Personnel
 - 3.2. Equipment
 - 3.3. Sampling
 - 3.4. Analysis
 - 3.5. Publication
- 4. Compilation Process (critical control points and generic compilation flowchart)**
 - 4.1. Identification of relevant foods nutrients and background information
 - 4.2. Attribution of quality index
 - 4.3. Coding on original data coding and data entry
 - 4.4. Physical storage of original data
 - 4.5. Selection of original data to produce aggregate data
 - 4.6. Selection and application of algorithms to produce aggregate and compiled data
 - 4.7. Validation (of aggregate and compiled) data
 - 4.8. Selection of aggregate and compiled data to be published or disseminate
- 5. Conclusions**

Appendix M – Review of UGR, Spain

EUROFIR – NEXUS WP1.2.2

Report on compiler review of UGR, Granada , Spain

Review date: 3rd December 2012

Participants

Reviewer:

Isabel Castanheira, INSA , Portugal

Compiler organization:UGR , Spain

Emilio Martinez de Victoria Muñoz, EuroFIR Project Manager for UGR ,
Maria Alba Martinez , Food database compiler
Ignacio Mariunez de Victoria, Computer Scientist

Reference Document

Roe, M., Finglas, P., Lindroos, A.-K., Castanheira, I., Giertlová, A.,
Westenbrink, S. Bell, S., Beernaert, H.(2011) EuroFIR Report on framework for
certification scheme (D1.5)

Introduction

The review of the food composition data compilation processes at UGR took place on 3rd December 2012. The review was carried out by one reviewer from EuroFIR Nexus – Isabel Castanheira, senior research scientist and head of Reference Materials Laboratory at INSA, Portugal. Documentation and information was provided before the visit with web based documentation on BEDCA (in Spanish, www.bedca.net) and the scientific papers and food composition database available at EuroFIR e-search platform

The review started with the approval of the agenda (annex 1) by participants. The UGR review (Management requirements, Technical requirements and Compilation Processes) was done with the presence of Project Coordinator Emilio Muñoz and Maria Alba Martinez. The team member responsible for software, Ignazio Carazo, was presented to demonstrate bedca software and at closure of the meeting.

UGR.- University of Granada

BEDCA – Base de datos Espanola de composicion de alimentos – Spanish food composition database web site (<http://www.bedca.net>)

Management requirements

Organization structure and Management policy

In 2004, Spanish EuroFIR partners at the Universities of Barcelona (CESNID) and Granada (INYTA) and users and advisory group (UAG) members at the Spanish food safety authority (Agencia Española de Seguridad Alimentaría, AESA) set up a working group, a 'Spanish network' (BEDCA). It is a network of public research centers, administrative and private institutions, which aim to develop and maintain the Spanish FCDB. Partial funding for this initiative has been granted from the Spanish government. The association was formally created on 16th February 2011 and is located in Granada. The association is governed by a General Assembly and by an executive board " junta directive". The General assembly meets once a year and the executive board " Junta Directiva" is composed of the president, secretary, treasurer, and six members. This association has the principal aim to develop the Spanish Food Composition Database. The BEDCA network has the following objectives:

1. To promote the establishment of an organization by the creation and maintenance of a reference FCDB for Spain.
2. To identify and evaluate the main sources of data, existing at the present time, and other potential sources.
3. To collaborate with EuroFIR on the establishment of a European data platform for food composition.
4. To design and develop a web site that serves as an internal communication platform for the network as well as for the dissemination of its activities.

Collaborations

EuroFIR

UGR is full member of EuroFIR AISBL. Through EuroFIR AISBL, links were strengthened with national compiler organizations that manage FCDB around the world. UGR is a member of the EuroFIR- NEXUS project and agreed to join the overall plan of compiler visits under the compiler peer review scheme.

National and International organisations

The association BEDCA, is the national food data compiler for Spain. BEDCA cooperates with all other Spanish organizations that produce data dealing with food and nutrition. The Main collaborations are with CESNID; Universidad Complutense de Madrid; Universidad de Córdoba ; Universidad de Murcia; Universidad de Barcelona; Hospital Puerta de Hierro; Instituto de la Grasa de Sevilla.

Description of work

The work developed by BEDCA, is only dedicated to support the activities of the compilation process. The management of food composition has been developed to match as closely as possible the research typology and fulfill the Spanish and international expectations in terms of data quality to give confidence (reliability and credibility).

The method chosen to realize the compilation of the BEDCA was the indirect method, defined as a method of the compilation, evaluation, unification and management of existing data from several sources (FCTs Spanish and non-Spanish, scientific articles, food companies, doctoral thesis, etc.).

The work is developed with a quality framework that matches EuroFIR criteria, although there is no formal quality system in place either for laboratories or for the compilation process. Participants in the Spanish network BEDCA were provided with and obtained extensive and complete compiled information on the Spanish food composition data. These sources have different origins: Spanish FCTs, food companies, scientific articles, and others and are present at Table 1

Table 1
Information provided for each BDECA partner on main origins of types and management of FCDB.

	CESNID	Universidad Complutense de Madrid	Universidad de Córdoba	Universidad de Murcia	Universidad de Barcelona	Hospital Puerta de Hierro	Instituto de la Grasa de Sevilla
<i>Sources of data</i>							
Food composition tables	75%	95%	0%	0%	0%	0%	0%
Food companies	6%	0%	0%	0%	0%	0%	0%
Scientific articles	18%	0%	0%	0%	0%	0%	0%
Other sources (e.g. own labs)	1%	5%	100%	100%	100%	100%	100%
<i>Value types</i>							
(a) Analytical	31%	15%	100%	90%	90%	100%	100%
(b) Estimated or calculated	23%	85%	0%	10%	10%	0%	0%
(c) Unknown origin	46%	0%	0%	0%	0%	0%	0%
<i>Management of the FCDB</i>							
Spreadsheets (e.g. Excel)	-	Yes	Yes	-	Yes	Yes	Yes
DBMS (e.g. Access, Oracle, etc.)	-	-	Yes	-	-	Yes	-
Software designed for this purpose	Yes	Yes	-	-	-	Yes	-
Others (e.g. paper)	-	Yes	Yes	-	-	-	-

Contracts and sub-contracts

The BEDCA work is developed under contract. The database system has been coordinated and funded by a joint initiative between the Ministry of Science and Education and Ministry of Health.

Document control

Since BEDCA does not have a formal Quality Management System, the document control system was designed to support compilation of data and to guarantee the traceability and origin of nutrient values, covering storage of data and updating procedures in both electronic and hard copy versions. Document

control is designed to fulfil the requirements of value documentation as a EuroFIR concept.

Review of the Quality Management System

Since a QMS is not in place at BEDCA the review of the Quality Management System was not carried out

Technical requirements

Personnel

Personnel involved in food composition studies have adequate combinations of academic and professional qualifications.

Maria Alba Martinez, a BEDCA member attended the International Graduate Course on Production and Use of Food Composition Data organized by FAO and EuroFIR in Wageningen.

Equipment

Equipment is mostly restricted to computers to accommodate software and fulfils the requirements for software and computation systems needed for the compilation process.

Sampling

Since BEDCA builds its database by an indirect method, taking data from existing sources, a sampling plan is not implemented at BEDCA.

Analyses

Analyses are done at different Spanish laboratories under Good Laboratory Practice standards. Analyses are carried out for 35 components distributed through the BEDCA member organisations. Data comes from different sources and there is no system of checking method accreditation although laboratories all work to GLP standards.

Publication process

The Spanish Food Composition Databank is published on line. This system provides basic information about the foods, components, values, methods and sources related with the food composition. Data is updated regularly when new data or corrections are available.

Compilation process (critical control points – see EuroFIR generic compilation flowchart)

The EuroFIR generic flowchart is followed on an informal basis. SOPs are not available although a formal management of compilation process is available and includes almost all compilation steps. The attribution of quality index to all original data taking into account seven criteria is not yet in place. Steps of the compilation process are considered as follows:

1. Decision on which foods and nutrients are updated is based on BEDCA members' consensus.
2. Analytical programmes are part of research projects undertaken by BEDCA members
3. Identification of relevant foods and nutrients is decided taking into account food and nutrients surveys based on the information available at the Ministry of Health
4. FCT has in place systems for food description, and food coding based on Languag and other EuroFIR thesauri
5. Checking the original data is carried out on a regular basis using software processes
6. Storage of data is guaranteed in both electronic or hard copy in all compiler locations
7. Extraction of all original data takes into account the data source
8. Values are expressed according to EuroFIR thesauri
9. Validation of aggregated and compiled data is supported by experience and knowledge of compilers
10. Inconsistencies are detected and corrected through compiler experience and knowledge
11. Compiled and aggregated data is stored in computer files
12. Selection of aggregated and compiled data is defined by consensus between compilers and stakeholders
13. Data selected for dissemination is stored in computer files

Vertical review

Orange Juice

A vertical audit was applied to trace back documentation of nutrient values in key foods in the BEDCA database. This was done using a casual key food summary report and traced back to raw data and ancillary information (certificate of analysis).

Results of analysis for Vitamin A (Beta carotene), Vitamin C, and Folate of orange juice samples from the CESNID Food Composition Table published in 2004 were traced back.

The approach was in casuistic form. The results confirmed that data is complete. It was possible to identify all steps of analytical processes, statistical analysis of data, aggregation of data and associated documentation for each single value.

Conclusions

The Spanish Food Composition Data base originated from different Spanish food composition tables as a EuroFIR initiative. The building of the unified Spanish Food Composition Database was supported by effective communication between different organisations. The new communication scenario was derived from the presence of several databases which have different designs and the need for requesting food information in real time. The solution is based on the choice of a suitable "client-server" architecture for the system, and the design of a generic query language to build queries that can be translated into specific SQL queries in each database.

The BEDCA team, has been developing impressive work to gather Spanish data from several sources and to create a Spanish Food Composition Data Base following food classification and description systems developed during the EuroFIR project. The software programs have been developed and are currently applied to food composition data production. The team seems to control all the activities from selection of foods and nutrients up to published of data.

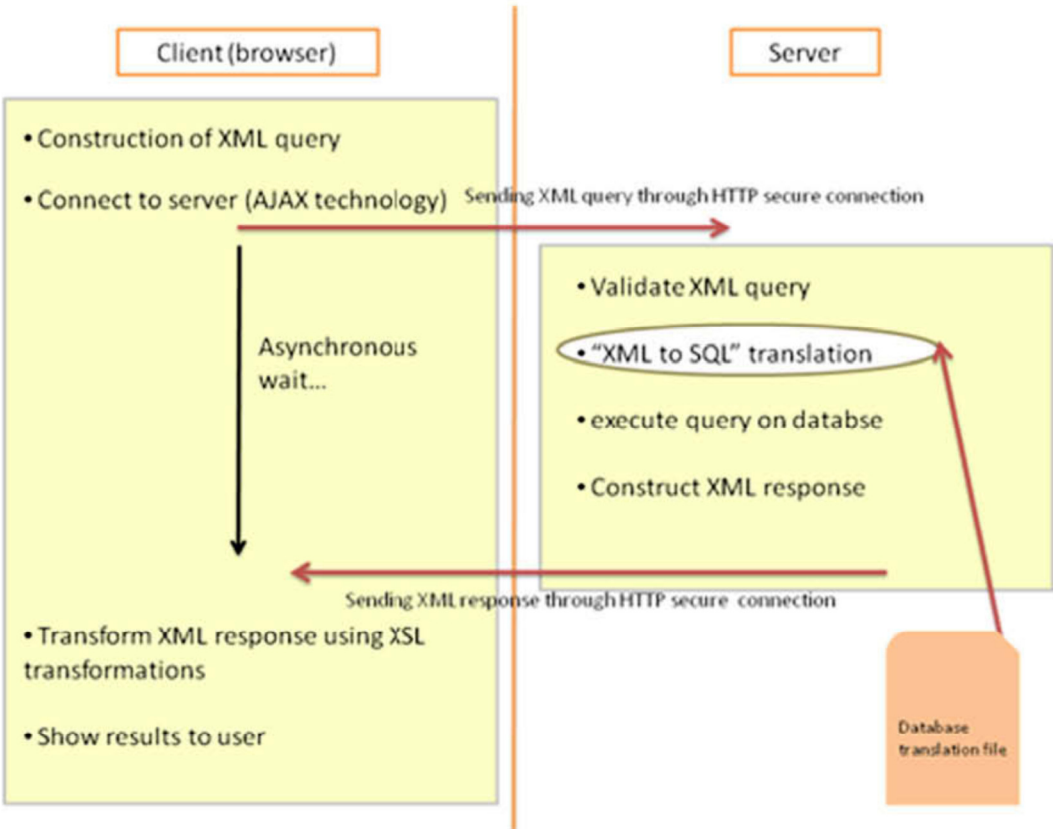
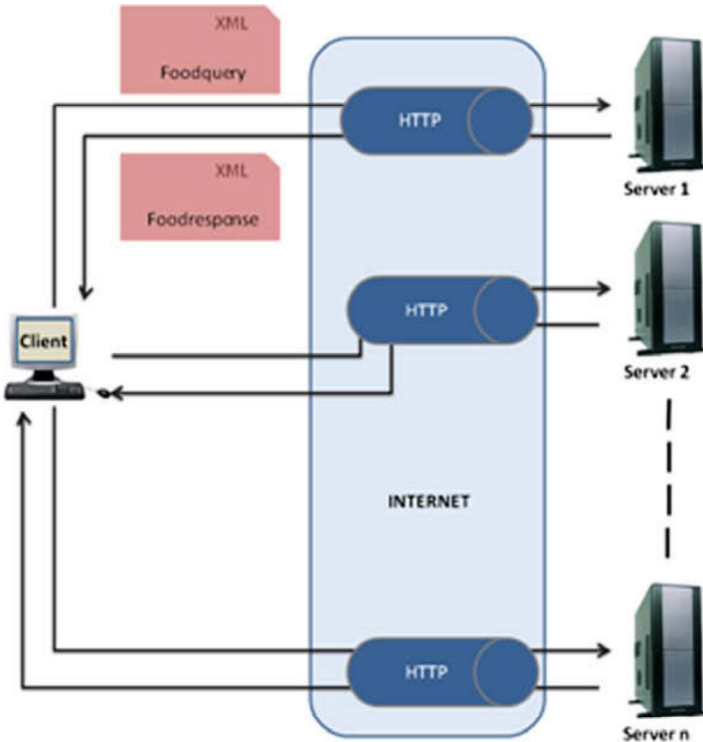
Sources of data are analytical data, estimated or calculated and data originating from literature (grey and official literature) and refers to products available in Spain.

BEDCA is used by dieticians, nutritionists, epidemiologists, health operators, nutritional surveillance, consumers, consumers associations, food industries and agriculture sectors.

Recommendations

1. The BEDCA online database should continue to be developed, making use of analytical data generated under quality assurance and metrological principles.
2. The use of software engineering methods specifically developed for the Spanish situation should continue.
3. The focus on foods that are produced in Spain or that are traditional and an important feature of the diet should continue, replacing data from unknown or less relevant sources.
4. SOPs and guidelines specific to the Spanish compilation process should be completed.
5. Attention should be given to creating a specific budget allocated directly to activities related to the compilation process.

Appendix 1. BEDCA Client Server diagram



Appendix 2. Organisational structure of BEDCA

Contact persons and organization structure

Contact persons for BEDCA

Management and compiling of the database	Maria Alba Martinez
Computer scientists that have worked on BEDCA software	Ignacio Martinez
Development of the BEDCA system	
Supervision of computers at UGR	

Agenda UGR Visit
7th September 2012

- 1. Proposal agenda**
- 2. Management requirements**
 - 2.1. Organization structure and management policy
 - 2.2. Description of work
 - 2.3. Contracts and subcontracts
 - 2.4. Document Control
 - 2.5. Review of Food Databanks Quality Management System
- 3. Technical requirements**
 - 3.1. Personnel
 - 3.2. Equipment
 - 3.3. Sampling
 - 3.4. Analysis
 - 3.5. Publication
- 4. Compilation Process (critical control points and generic compilation flowchart)**
 - 4.1. Identification of relevant foods nutrients and background information
 - 4.2. Attribution of quality index
 - 4.3. Coding on original data coding and data entry
 - 4.4. Physical storage of original data
 - 4.5. Selection of original data to produce aggregate data
 - 4.6. Selection and application of algorithms to produce aggregate and compiled data
 - 4.7. Validation (of aggregate and compiled) data
 - 4.8. Selection of aggregate and compiled data to be published or disseminate
- 5. Conclusions**

Appendix N – Review of NFSA, Norway

EUROFIR – NEXUS WP1.2.2

Report on the compiler review of the Norwegian Food Composition Database at the National Food Safety Authority (Mattillsynet), Oslo, Norway

Review date – 26 February 2013

Participants

Reviewers:

Anna Karin Lindroos, National Food Agency, Sweden

Veronica Öhrvik, National Food Agency, Sweden

Compiler organization:

Ellen Kielland, compiler, National Food Safety Authority

Jorån Østerholt Dalane, compiler, National Food Safety Authority

Anette Hjartåker, University of Oslo

Astrid Nordbotten, National Food Safety Authority

Atle Wold, National Food Safety Authority, steering committee

Lars Johansson, Helsedirektoratet, steering committee

Rønnaug Aarflot Fagerli, National Food Safety Authority, steering committee

The review was based on guidelines described in deliverable
D1.5_Framework_for_Certification_revised_Sep2011.docx

Introduction

The review of the food composition data compilation processes at Mattillsynet (Norwegian Food Safety Authority, NFSA) took place on 26 February 2013. The review was carried out by Anna Karin Lindroos, head of the Food Data Division at National Food Agency, Sweden and Veronica Öhrvik responsible for the Swedish Food composition database. Anna Karin Lindroos is also a director of the EuroFIR- AISBL. Before the visit the reviewers had access to web based information on the Norwegian food composition database and other related information (<http://www.matportalen.no/>). NFSA has the administrative responsibility for the Norwegian food composition database and this review therefore focuses on the work at NFSA.

Matvaretabellen (MVT) is the Norwegian Food Composition Database (FCDB)
Mattillsynet - Norwegian Food Safety Authority, NFSA

Management requirements

Organization structure and management policy

The Norwegian food composition table (MVT) is managed by the Norwegian Food Safety Authority (NFSA), the Norwegian Directorate of Health and University of Oslo (Appendix 1). NFSA has the administrative responsibility for management of the MVT.

The Norwegian Food Safety Authority (NFSA) is a governmental body, whose aim is, through regulations and controls, to ensure that food and drinking water are as safe and healthy as possible for consumers and to promote plant, fish and animal health (appendix 2).

The mission of the NFSA is to promote:

- Safe, healthy food
- Safe drinking water
- Healthy plants, fish and animals
- Excellence in animal welfare and respect for fish and animals
- Environmentally friendly production
- Health, quality and consumer interests throughout the food production chain

The food composition work is located within the the division of **Sales to consumers** at NFSA. The division, headed by Atle Wold, consists of around 16 employees with university degrees in nutrition, law, veterinary science, engineering, toxicology and food technology. Staff are mainly funded by government money.

The compilation team consists of Ellen Kielland, Jorån Østerholt Dalane and Astrid Nordbotten at NFSA (1.5 full time employee (fte) and 0.5 fte at the University of Oslo. The university position is funded by NFSA.

Ellen Kielland has an MSc in nutrition and is responsible for the development, maintenance, quality assurance and dissemination of MVT.

Jorån Østerholt Dalane has an MSc in nutrition, and works 50% with food compilation on short term contracts (her current contract is for 6 months).

Astrid Nordbotten has an M Sc in chemistry and works four weeks each year with the food composition data work. She is mainly assisting in the contacts with the labs. Astrid works at the division of **Supervision development**.

Mission statement

The mission of the MVT including work tasks and when the steering committee should be involved is stated in a document by the The Norwegian Directorate of Health and NFSA.

The division of *Sales to consumers* carry out food controls and analytical projects for MVT be carried out in collaboration with control projects within the division. One example is a recent project on baby foods where nutrient content is compared with the declared content on the nutrient labels.

Links with other departments

The analytical projects are carried out in close collaboration with the division of *Supervision development*.

Sampling is mainly carried out in collaboration with the regional offices of NFSA.

The NFSA has an administrative department that supports all departments and divisions. The support includes human resources, IT, finances and communications. The communications team helps the food compilers to add information on Matportalen.no (where MVT is published). HR takes care of everything related to employment of staff. There are no internal service contracts as it is the role of the administrative staff to support the NFSA departments and divisions.

Links to other organisations

The Ministry of Health and care services provides the policy documents for monitoring the Norwegian diet.

Norwegian Directorate of Health – partly finances MVT (appendix 1) and are engaged in the steering committee (Lars Johansson and Anne Hafstad). The steering committee (Atle Wold (NFSA), Rønnaug Aarflot Fagerli (NFSA), Lars Johansson and Anne Hafstad meet with Ellen Kielland twice a year.

University of Oslo - The food composition work is closely linked with the dietary survey work at the University of Oslo (Figure 1). There is a compiler group consisting of Anette Hjartåker, Thea Bergvatn, Elin Björge Lökken, Monica Hauger Carlsen, Ellen Kielland and Jorån Østerholt Dalane. The reference group meets every month for two hours to discuss the work and practical issues. There are detailed minutes with action points from each meeting.

Other collaborations including links to other compiler organisations

NFSA are full members of EuroFIR AISBL. NFSA are part of the Nordic food analysis network with the purpose to collaborate on analytical projects for the Nordic food composition databases and to jointly apply for money to carry out nutrient analyses. The network is funded by the Nordic Working Group for Diet, Food & Toxicology (NKMT).

NFSA collaborates with marketing trade organisations, food industries (Gilde/Nortura, Fjordland, Tine) and Statistics Norway (mainly for sales data).

Description of work

The NFSA team is responsible for the overall planning and monitoring of the food composition work. Works plans are set each 6 months in the compiler group. The work plan is presented for and approved by the steering committee.

Customer requirements are achieved in three different ways:

- The instructions from the Norwegian Directorate of Health
- Feed back from consumers
- Feed back from industry

Analytical reports in English or Norwegian are published on the NFSA webpage and the EuroFIR webpage. A new version of MVT is released each year (starting from last year).

Individual plans are set each year and confirmed by the head of division. The individual plans for each staff member are available internally. The working plans are followed up in the division each sixth months and with the head of division each sixth week if needed. The progress of the compilation work and plans for the following six months are reported to and approved by the steering committee twice a year.

Staff competences are focused on nutrition but there is a well used network with complementing competences such as chemistry, IT, law and risk assessment available.

For new employees a general introduction course is given at NFSA. NFSA also offers internal courses in e.g. IT.

Contracts and sub-contracts

There are external contracts with the University of Oslo (MVT finances and work), Norwegian Directorate of Health (MVT finances), the National Institute of Nutrition and Seafood Research (NIFES, analyses) and Bouvet (manage online version of MVT). External contracts signed by head of division Atle Wold.

Document control

Electronic documents related to the food composition work are stored in ePhorte4, an internal document system with automatic version control. Hard copies of data and publications are stored at different places. Signed contracts are all stored in ePhorte4 (the Norwegian official document system). Reports and old analytical protocols are stored at NFSA. There is work going on to scan old food composition tables and publish them on the public webpage. After the food composition tables are published on the webpage the printed versions will be stored at the National Archives of Norway.

The internal network and all electronic files are automatically backed up every day. The database is backed up every day. The IT department is responsible for this work.

Instructions and guidelines are not included in a quality management system. Date is used for version control of these documents. Minutes from the compiler group meetings and the steering committee meetings include decisions on

changes in the instructions (e.g. changes in factors) but there is no system for tracing these changes.

Review of QMS

NFSA has a quality management system and an electronic system for SOPs. The food compiling team does not use the quality management systems. There is an overview document outlining all the different food compiling processes. This document has links to the different instructions. All food compiling instructions are approved by the reference group prior to use.

Internal audits are carried out at NFSA and the food compiling work could be reviewed by the internal auditors. So far this has not happened. There is a quality manager in the organisation who makes follow-ups of the audits. There are also procedures for corrective actions.

NFSA is also regularly audited by EFTA Surveillance Authority but it is unlikely that the food composition work would be included in these audits.

Technical requirements

Infrastructure

See Organization structure and management policy

Personnel

There are no job descriptions for individual staff members. But individual plans are made for each year and confirmed by the Head of Division (see description of work).

Job specific training includes the FoodComp course and computer courses e.g. in Excel as the database is managed in Excel. An administrative system for formal training records called Gitek is automatically linked to the employee's CV. When a new staff member is employed the CV is added into Gitek and thereafter updated by the employee when appropriate. However, this is not always done and the food compilers have not updated their specific training in Gitek. There is no general introduction of the food compilation work to new employees but the book Food composition Data, Production, Management and Use (by Greenfield and Southgate) should be read prior to start.

Performance reviews are done each year. A standardised questionnaire is filled in and signed by the Head of Division and the employee. The Head of Division reports that the yearly performance review has occurred to the Head of the Department of Control.

Staff cover is a weak point. Currently there is one staff member with control over the whole compilation process and a temporary position. The position at University of Oslo also supports the work but as this position is not fulltime it has been difficult to get someone on the position to stay long term. A large effort has been done to put together all important information about the compilation process to simplify introduction of new staff and for cover.

Equipment

There are no labs at NFSA so the equipment used for food composition work is limited to office equipment, including PCs. All food compiling, including language coding, factors for calculations etc is managed within Microsoft Office Excel spreadsheets. MVT is included in the KBS database) or which there is a data management system (see appendix 1).

IT maintenance and development is carried out by staff at ICT. Specific IT support for MVT is carried out by one staff member, who is familiar with the MVT work. For the public food composition database a specific web-database has been developed. The database was developed and is managed by Bouvet, an external IT company.

Sampling

A sampling plan is prepared for each analytical project by the two compilers and one analytical chemist at NFSA with advice from the compiler group. The sampling plan, including choosing foods, analytical methods and budget is approved by the steering committee.

Sample identification is made using sales data and market shares. Sales data is expensive and therefore data from market trade organisations are used occasionally.

Sample collection is carried out either by the regional offices of NFSA or by the lab. There are guidelines for sample collection and sample handling available. For sampling in collaboration with regional offices there are oral agreements between head of departments/divisions. For sampling by the lab there is a written contract.

Analyses

NFSA have an agreement with the National Institute of Nutrition and Seafood Research (NIFES) for analyses, when NIFES haven't got the required methods they arrange sub-contracts with other labs. NFSA have two detailed documents specifying the quality demands on the work carried out by the lab: (I) includes sampling, sample handling and traceability, analytical method and performance including accreditation, participation in proficiency testing and validation for the specific food matrix and results delivery and (II) detailed demands on method quality for fatty acids including which fatty acids to report and results delivery.

The delivered results is checked by the two compilers and the analytical chemist at NFSA. Results are followed up with the lab and if necessary repeat analyses are performed.

Publication process

MVT 2012 consists of more than 1300 foods, which are published online and managed through an external web based database (<http://www.matvaretabellen.no/>). The previous version of MVT was published in

2006 both online and as a printed version. From 2012 onwards a new on-line version of MVT will be published each year.

Not all compiled foods will be published online and publically available, MVT is part of the larger food composition database KBS (Kostberegningssystem –diet calculation system) used for dietary surveys. KBS comprise of about 2400 foods. Which foods to publish online are decided by the compiler group.

Compilation process (critical control points – see EuroFIR generic compilation flowchart)

NFSA has guidelines for the compilation process including different quality checks, calculations, priority of foods etc. The document refer to EuroFIR SOPs where appropriate.

The compilation process

1. Identifying a new food

There are guidelines approved by the steering committee for how to identify a new food.

New foods are identified based on dietary surveys and per capita evaluations. Prioritising of the foods is discussed and decided at the reference group meetings.

2. Assigning nutrient data to the food

Foods are mainly analysed but food composition data is also borrowed from industry and other FCDB. There are specific guidelines on how to value borrowed data and a priority list for FCDB to borrow data from. An instruction based on EuroFIR SOP's 3-6, 14-16 is used when entering data to the food composition table.

3. QI

Quality index are not used in the compilation work.

4. Food codes

A unique food code based on the food classification (11 food groups) system is used to identify food items. A new food can either be created from scratch or be based on an existing food code i.e. when a food item is updated with new data the same food code is used. By using an existing food the accompanying information can be copied and then checked and changed accordingly.

5. Calculations and algorithms

Recipe calculations are mainly made at University of Oslo in KBS and therefore not included in this review. Internationally used factors (Food composition data by Greenfield and Southgate) is used for calculations of protein and fatty acids. Other factors are based on the Nordic Nutrition Recommendations 2004.

6. Data checking

Compiled data is controlled by another person than the compiler. Unit, used factors, calculations of carbohydrates, sum of macronutrients and fatty acids

and reasonability of values are checked according to an instruction based on EuroFIR SOP's 3-6, 14-16.

7. Validation of the food information

Validation of food data is done prior to entering information in excel (see chapter „Analysis“). New data are compared with old data to assure that the food data are reasonable.

8. Correction of errors

Errors are corrected prior to release of a new version. There is no system for correcting errors but old versions of the database is available at the website so there is version control that enables one to identify changes.

9. Database checking before release.

Spot check of food composition data is done prior to a new release, the controls are documented and signed with name and date. In addition, the excel sheet is controlled e.g. right values in right column.

A shorter information regarding updates in the new version is launched at the website together with detailed information about which food codes are new, revised and deleted in a separate Excel sheet.

Conclusions

The planning and decision making processes of the MVT work are clear and structured and EuroFIR SOPs are implemented in the work. Additional instructions have been written for how to borrow data, analytical projects and quality controls of nutrient data.

The food composition team is very active and NFSA has during the last years produced several new analytical reports and scientific publications.

A lot of new food composition data of high quality has recently been produced and published.

New versions of MVT are published regularly in a user-friendly public web-based food composition database. The food composition data can be downloaded to both excel and an open office programme. Associated information such as scientific publications and analytical reports are also available on the web-site. In addition, scientific publications and analytical reports are published on the EuroFIR webpage.

MVT has a steering committee that meets twice a year. A status report is delivered before each meeting where the work plan for the following time period is decided.

The main compilation work is carried out at NFSA but half a position (paid by NFSA) is located at the University of Oslo where the national dietary surveys are also carried out. The food compilers at NFSA meet with the compilers at the

University of Oslo every month. The meetings are documented in detailed minutes with action points. The close collaboration with the national dietary survey is an advantage for both parties.

There is a clear mission statement for the Food composition database.

The administrative support and infrastructure at NFSA is excellent and includes IT, communications, finances and HR. The NFSA also has a specific document control system.

The food composition team makes good use of the complementary competencies available at NFSA, University of Oslo, the Norwegian Directorate of Health and the Norwegian Scientific Committee for Food Safety (VKM).

The use of Excel instead of a food composition database management system makes the work vulnerable, time consuming and the demands on quality controls and competency of staff are high. There are also difficulties with version control and traceability of data.

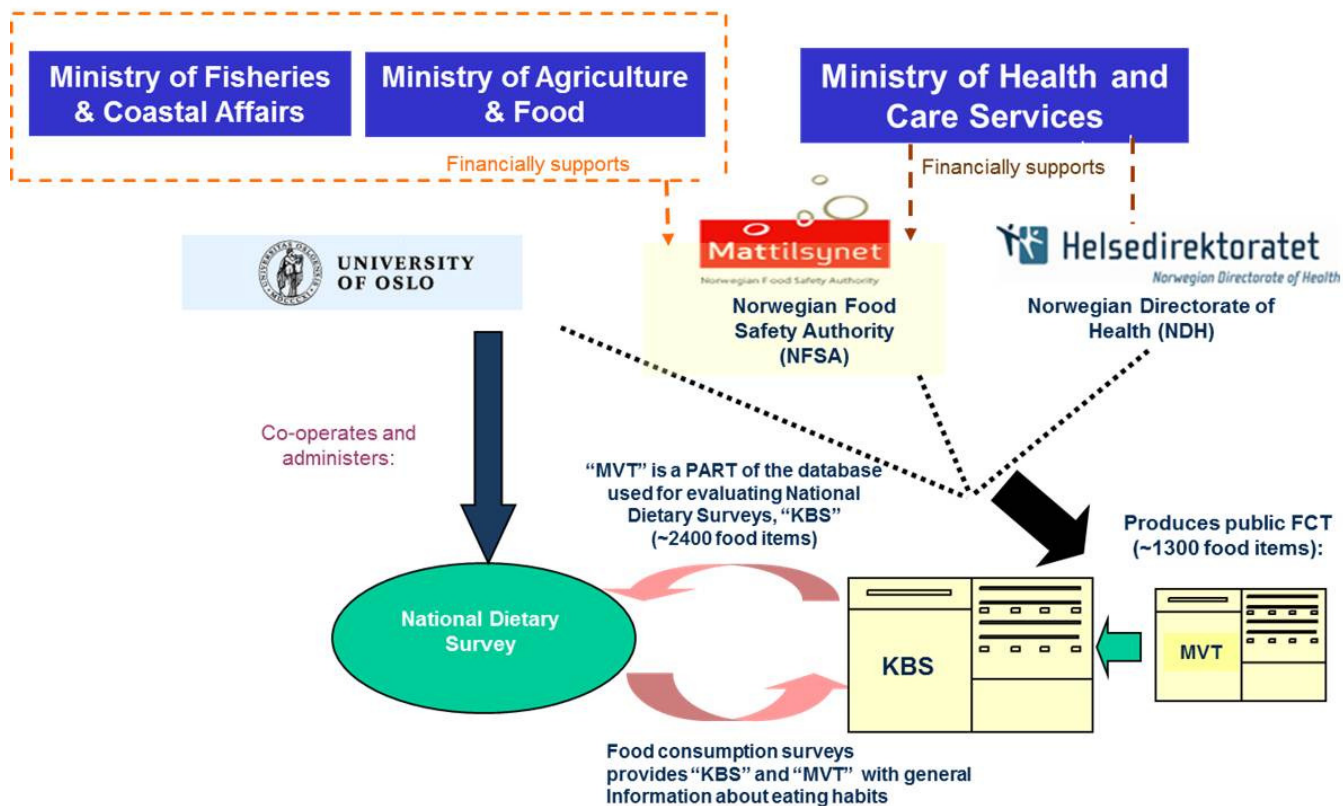
The management of the food composition database is mainly carried out by one person which makes the work very vulnerable.

There is no induction programme for new compilers and training is not documented.

Recommendations

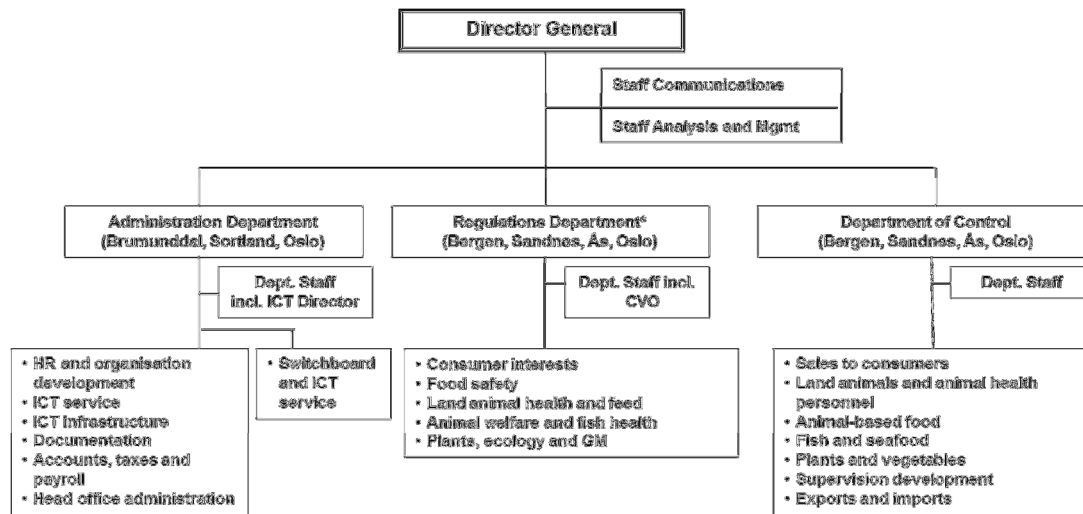
1. To improve and guarantee a high quality of the food composition data we strongly recommend that a food composition database management system is introduced.
2. Until a food composition database management system has been introduced we recommend that efforts are made to secure traceability of value changes and to make the work in the Excel spreadsheets safer by e.g. locking the spreadsheets.
3. The main documentation should be included in the document control system and quality documents and instructions in the quality management system.
4. To make an induction programme for the food compiling work for new employees.
5. To keep track of training by uploading all new training in the HR system Gitek.
6. We recommend that errors that the compilers consider significant are corrected between the database releases. We suggest that the compilers at NFSA report significant errors to the reference group and if the reference group agrees the errors could be corrected directly instead of waiting for a new version of the database to be published.

Norway: Relationship between National Food composition Table/Database and Nutrition Survey



Organisation of Norwegian food composition database (MVT) work.

Appendix 2



Organizational structure of NFSA. Division of Sales to consumers is located in the Department of Control .

Appendix O – Review of IMR, Serbia

EUROFIR – NEXUS WP1.2.2

Report on compiler review of IMR, BELGRADE, SERBIA

Review date: 7th MARCH 2013

Participants

Reviewers:

Mark Roe, IFR, United Kingdom

Compiler organisation: IMR, Belgrade

Dr. Mirjana Gurinović, compiler team leader

Agneš Kadvan, software developer

Jasmina Debeljak Martačić, compiler

Milica Kojadinović, compiler

Jelena Milešević, compiler

Marina Nikolić, compiler/statistician

Snježana Petrović, compiler

Maria Ranić, compiler

Slavica Ranković, compiler

Marija Takić, compiler

Ivan Stancic, Delta Electronic, network manager

Dr Marija Glibetić, Head of Centre of Excellence in Nutrition and Metabolism, was not present during the review but participated in arranging the review and providing documentation.

The review is based on guidelines described in deliverable
D1.5_Framework_for_Certification_revised_Sep2011.docx

Introduction

The review of food composition data compilation processes at the Institute of Medical Research (IMR), Centre of Research Excellence in Nutrition and Metabolism (CRENM), Belgrade took place on 7th March 2013. The review was carried out by Mark Roe, a national food composition database compiler from IFR, UK. The CRENM compiles the Serbian food composition database (SFCDB) but is not funded specifically for that purpose. Data is produced and procedures are developed with funding obtained from collaborative projects that are related to production and use of food composition data.

Management requirements

Organization structure and management policy

IMR is a Serbian governmental research institute in the field of biomedicine and is part of the University of Belgrade. IMR's mission is to contribute to the health of the community through progress in science, particularly in the area of medical research. IMR consists of eight research teams with a total of more than 50 full-time researchers with different educational backgrounds in medical and life sciences. The CRENM is one of the eight research teams and is responsible for compilation of the SFCDB.

CRENM is led by Dr. Marija Glibetić (Head of Laboratory) and includes a Research Group Leader (Dr. Mirjana Gurinović), 15 members of faculty and additional postgraduate staff employed to work on specific research projects. CRENM includes teams focused on lipid analysis, cellular and molecular biology and immunology, nutritional intervention studies, public health nutrition, statistics and mathematical modeling and a group working on the Serbian food composition database and development of user software applications.

CRENM has a mission 'To enhance the quality of Serbian/regional food data by adding or exchanging existing data with the best possible analytical data'. The aim is for the SFCDB to contain a minimum of 1100 foods and 200 composite dishes (commonly used and traditional) with a minimum of 75% of analytical data from Serbia and/or the west Balkan region. The SFCDB currently contains 1046 foods and 116 composite dishes and the Balkan regional database contains 2071 foods and 200 composite dishes.

Description of work

CRENM has been certified as a 'Centre of Excellence' by the Serbian Ministry of Science and Technology (SMST) for the period 2010 – 2014, after which a further qualification, based on outputs including publications, project funding and measures of esteem, will be required. The ministry provides funding for staff and facilities but not specifically for development of the SFCDB. There is a general outline of work that is submitted to the Ministry and includes reference to food composition but the SFCDB is funded by work included in externally funded projects. The main source of funding has been EU projects including:

- EuroFIR Network of Excellence (2006-2010)
- EuroFIR Nexus (2011-2013)
- EURRECCA Network of excellence - Harmonising nutrient recommendations

across Europe with special focus on vulnerable groups and consumer understanding (2007-2011)

- BaSeFood - Sustainable exploitation of bioactive components from the Black Sea Area traditional foods (2009-2011)
- CHANCE - Low cost technologies and traditional ingredients for the production of affordable, nutritionally correct, convenient foods enhancing health in population groups at risk of poverty (2011-2014)
- EFSA project : Updated food composition database for nutrient intake, 2012
- EFSA tender CFT/EFSA/DCM/2012/02 “Dietary monitoring tools for risk assessment” (2012-2013)
- BACCHUSS Beneficial effects of dietary bioactive peptides and polyphenols on CVD health in humans (2012-2016)
- EURODISH - Study on the need for food and health research infrastructures in Europe (2012-2015)

Each project has a specific description of work and CRENM either leads or contributes to specific areas of the project. Many of these projects include tasks that relate either directly or indirectly to developing the SFCDB either by adding or improving data or by developing software interfaces for compilers and/or users. Examples of projects linking into development of the SFCDB include the EFSA funded project to develop an updated food composition database for dietary monitoring that allowed existing Serbian data to be checked and refined with additional documentation and expanded to include additional composite dish information and information on dietary supplements. The CHANCE project included collection of consumption data that is being used to identify priorities for adding foods to the SFCDB. There is no funding for analysis of food samples so data is taken from product labels, produced from recipe calculations, borrowed from other food data bases or taken from scientific literature with published results from analytical values.

In addition to core faculty staff, other researchers are employed using funding related to specific projects and work on tasks associated with those projects. However there is overlap between projects and work is managed based around project and task requirements and timelines. The Head of laboratory is responsible for allocating work to researchers to ensure that objectives are met within budget allowances. Researchers have specific job descriptions based on actual research projects they are working on. Twice a year (January and June) the head of Centre is responsible for writing progress reports for project team achievements and for individual researcher performance with recommendations for continuation of research activities. Progress will be reviewed by the SMST but will be based on outputs (e.g. publications, funding, student numbers) and will not include specific review of work related to food composition. However outputs associated with projects must meet the descriptions of work and associated milestones and deliverables and most outputs will be subject to either external peer review or review by project work package leaders and co-ordinators. Researchers are assessed individually based on their contributions to CRENM outputs.

Collaborations

CRENM has collaborations with many food composition compiler organisations in the Balkan region and coordinates activities in the CEEC network. Memorandums of understanding are in place to allow joint work and data sharing between the Serbian

national database and the CEEC regional database. IMR is a member of EuroFIR AISBL and was involved in the EuroFIR Network of Excellence project from 2006 to 2010 and is currently a beneficiary of the EuroFIR Nexus project. The strong collaborations with European partners have enabled CRENM to be involved in EU funded research projects that have enabled development of the SFCDB and development of applications for users. CRENM have regularly taken advantage of training opportunities that have been available through collaborative projects.

Contacts have been established with food producers and retailers in Serbia as part of the EU funded CHANCE project. Companies were sent questionnaires related to production of foods important in the Serbian diet and those contacts will be maintained and extended where possible. IMR also has links to industry through the Serbian Chamber of Commerce.

Contracts and sub-contracts

Contracts are available for all projects carried out and are signed by the CRENM Head of Laboratory and/or by the appropriate senior management at IMR. Examples of contracts for the SMST funded 'Centre of Excellence' and contracts for EU funded projects were provided. All contracts are filed and maintained within CRENM and IMR.

CRENM has a sub-contract in place with Delta Electronic, who provide a service to maintain servers and IT networks that are outside the scope of those provided centrally by IRM. The contract was established based on previous experience and expertise. A service contract with 'Go Daddy.com' exists for provision of domain hosting for the SFCDB and was established following comparison with other providers of similar services. The SFCDB was originally hosted through a Serbian company but was moved to improve reliability.

Memorandums of understanding have been signed between IMR and partners in the CEEC network to allow for collaboration and data sharing within the Balkan regional network.

Document control

Electronic documents are handled through the IMR network system that is centrally administrated. Files are accessible by individual users and can be stored in shared network drives by staff associated with each project team. Files associated with the SFCDB are not all stored on the central network and each user also generates some files on their own PC with backups being stored on USB memory. Completed projects are moved to shared drives but there are potential data vulnerabilities during data production and it is not clear exactly how data files are shared and tracked by version. Files on central servers are backed up monthly with a procedure for partial back up of documents that have been modified. The SFCDB is maintained on a 'Go Daddy' server and is accessed by compilers who work on the 'live' database. The database is backed up as part of the Go Daddy hosting service, including back up to a separate file server.

Hard copies of all 'important' files are kept at IMR and are stored in the CRENM offices in folders that are filed by project. Hard copies of original documents, e.g. signed documents, are scanned and are also stored electronically. Documents are

kept for a minimum of five years.

Review of the Quality Management System

IMR and CRENM do not have formal quality management systems in place but many procedures are in line with standards that would be required by ISO9001. Documentation and SOPs are available for key management processes and there are systems in place for coding and storing biological samples and data that are generated during projects. When the CRENM was established there was a review of top level documentation by the SMST. The CRENM will be the subject of a further review by SMST when the current funding program ends and will include a report on progress.

Technical requirements

Personnel

Compilers are employed by IMR through funding either from SMST or other funded projects. Each staff member is assigned to specific projects and tasks related to their area of expertise and interest. There is a system to allow for deputizing and for additional staff resources to be moved to projects and tasks to cope with short term changes in workload. Performance of staff is assessed in relation to project outputs and staff are assessed against output standards required by SMST.

Training

The CRENM employs staff with a wide range of skills related to nutrition and biochemistry and training specific to food composition is available to staff. 6 members of CRENM have been supported by EuroFIR to attend the International Postgraduate Foodcomp Course run by Wageningen University. Compilers have also made use of a range of training courses, workshops and exchanges that have been offered through EuroFIR. The EuroFIR projects and compiler network have also enabled access to reference documents e.g. EuroFIR technical annex that have informed design of the SFCDB. Records are kept of all training and certificates gained.

Sampling, analysis and equipment

The SFCDB is compiled using data from scientific literature and other sources (e.g. manufacturers) and by recipe calculation. No data is generated from samples collected and analyzed by CRENM projects. Equipment used is restricted to office and IT systems and are maintained either by IRM or by sub-contractors responsible for server systems.

IMR database management system

CRENM has a food composition database management system (FCDMS) that has been developed during the EuroFIR Network of excellence project and is fully aligned to the EuroFIR technical annex and CEN standard for food composition data. The database is a web database (MySQL web server). The FCDMS is developed in Visual FoxPro (v 9.0) and with ODBC connection the compiler side application establishes the connection with the web database. The user interface was developed by CRENM specifically for management of the SFCDB and the regional database.

Food description using Languag indexing is fully integrated into the FCDMS. Documentation is required for fields that are designated as 'mandatory' in

the EuroFIR technical annex but in some cases it means that the process of entering values with documentation is very time consuming for compilers. While documentation is very important the process could perhaps be made easier by considering the use of 'default' values being automatically added for some fields and then being reviewed as a separate process.

The FCDMS also includes modules for recipe calculation, exporting data in xml format and reporting in formats suitable for printing.

Access to the database is restricted to compilers and all changes made to data are recorded with details of when the change was made and by which member of the compiler team. Access to the regional database is also controlled by username and password and the unique USB memory stick ID that determines the user identification parameters (country, username, password control). The SFCDB and the CEEC database are separate databases on different servers. The SFCDB is a subset of the CEEC database but Serbian data can only be changed within the SFCDB. The CEEC database is maintained and updated by the compilers for each member country.

Data production

Data is being collected through work included in externally funded projects and compilers are continually adding data. Generally data is either calculated by recipe or is from manufacturers' information, e.g. product label data. Recipes are based on 'standard' recipes that are referenced from sources including 'The European Cookbook' and other collections of recipes that reflect common consumer practice. Priorities for data are identified from consumption survey data that has been produced during relevant research projects. Values are entered by one compiler and are then checked and validated by a second compiler. A paper process is used for value checking and validation and copies of all paperwork is stored centrally in the CRENM office. Many values are also borrowed from other food composition datasets and these borrowed values are all checked against the original published data.

Documentation, including references, is stored in files organized by food group and is available to all compilers.

Publication process

The SFCDB is not yet publically available and is only available through CRENM, CEEC and via EuroFIR. Publication of an eBook in collaboration with EuroFIR is planned. Subsets of the SFCDB may be produced and published for use within a project, e.g. the CHANCE project included production of a user dataset matched to the requirements of a food frequency questionnaire produced for the project. Any data made available is fully controlled by CRENM.

Feedback from users

There is no formal procedure to collect feedback from users, however comments from any data users are collected and reviewed to improve quality and usability of the data. Members of the CRENM compiler team are also users of the SFCDB during projects that use food composition data and their feedback is used directly to improve the database. An expert user group could be formed to represent key user groups,

e.g. researchers, industry, health professionals, consumers and could be a useful mechanism for providing feedback and advice on improving usability of the data.

Compilation process (critical control points – see EuroFIR generic compilation flowchart)

IMR has produced a flowchart of the compilation process that specifically relates to SFCDB. SOPs or other forms of documentation are available for most processes used in data compilation including all processes identified by EuroFIR as critical control points that may significantly impact on data quality.

SOPs include:

SOP 3: Identification and comprehension of the data in the data sources

SOP 5: Attribution of quality index to all original data

SOP 6: Coding of original data before data entry

SOP 8: Check on original data coding and data entry

SOP 11: Physical storage of original data (physical records)

SOP 13: Selection of original data to produce aggregated data

SOP 14/15: Selection and application of algorithms in order to produce aggregated and compiled data

SOP 16: Validation of aggregated and compiled data

SOP 19: Storage of aggregated and compiled computerized data

SOP 20: Selection of aggregated and compiled data to be disseminated as published databases or tables

Other procedures and manuals include:

- Procedure for updating data in FCDB
- Procedure for defining technical requirements of the FCDM system
- User manual for the web-based Food Composition Data Management (FCDM) software for FCDB creation (national/regional)
- User manual for the eSearch administration and maintenance module
- User manual for the EuroFIR FoodExplorer tool
- User manual for the EuroFIR FoodBasket tool
- Network structure and procedure for back up of FCDB

Conclusions

CRENM have developed the SFCDB since 2006, based on guidelines developed during the EuroFIR network of excellence and Nexus projects. The SFCDB is compatible with the EuroFIR technical annex and the CEN standard for food composition data and is maintained and developed using a database interface developed by CRENM. SOPS and user manuals are available for key steps of the compilation process and documentation of data produced is stored systematically.

CRENM are also key partners in the Central and Eastern European Countries (CEEC) network and the database interface developed by CRENM is used for both the SFCDB and the CEEC regional database.

The CRENM compiler team has made good use of training opportunities, particularly workshops and exchanges available through EuroFIR, and CRENM has developed a team of skilled and knowledgeable compilers.

The SFCDB does not contain data produced by analysis of samples specifically for the food composition database but consists of data compiled from relevant literature sources, manufacturers' data and calculated by recipe. The quantity of data is limited but the focus of compilation is data that originates from and is applicable to foods consumed in Serbia.

The SFCDB is planned to be published as an ebook but is otherwise only available through the EuroFIR Food Explorer tool or through the CEEC network.

Recommendations

1. CRENM should focus on expanding the SFCDB to include analytical data where possible with a focus on foods that are produced and consumed in Serbia.
2. Development of SFCDB relies on projects that fund work related to production and use of food composition data. Funding specifically for food composition data production and management should be sought to help maintain a concentrated focus on building the content of the SFCDB according to needs identified by the compiler team rather than needs matched to project requirements.
3. Links with the Serbian food industry, including manufacturers and retailers, should be improved to enable access to data that can be used to inform collection of new data and to validate existing data.
4. Consideration should be given to publishing the SFCDB to a wider group of users.
5. A steering group or expert group could be established to advise on development of the SFCDB. Such a group could provide valuable links to user groups including, industry, academics, health practitioners, food industry and consumers and could provide feedback on proposed developments and on data produced.
6. The process of documenting values entered into the FCDBM system could be reviewed with a view to streamlining the process and reducing the time needed to enter and review data.

Appendix P – Review of MRI, Germany

EuroFIR – Nexus WP1.2.2

REPORT ON COMPILER REVIEW OF MRI, Karlsruhe, Germany

REVIEW DATES: 12 March 2013

Participants

Reviewers:

Susanne Westenbrink, RIVM, The Netherlands

Compiler organisation: MRI, Germany

Bernd Hartmann (BLS project manager/compiler, Department of Nutritional Behaviour)

Carolin Schmidt (Compiler, Department of Nutritional Behaviour)

Katja Stang (Compiler, Department of Nutritional Behaviour)

The review is based on guidelines described in deliverable
D1.5_Framework_for_Certification_revised_Sep2011.docx

Introduction

The review of the BLS food composition data compilation processes at MRI took place on 12 March 2013. The review was carried out by one reviewer from EuroFIR Nexus – Susanne Westenbrink who is a national database compiler from RIVM, the Netherlands. Some information on the MRI organization and on the BLS database was available beforehand from the internet and from documents provided by Bernd Hartmann.

The review began with a welcome and an introduction of the review procedure.

The meeting started with background information on the MRI organization given by Bernd Hartmann. Details on the food data compilation process were discussed during the afternoon.

Management requirements

Organization structure and management policy

Max Rubner-Institute, the Federal Research Institute of Nutrition and Food, consists of eight departments that are located in 5 cities across Germany. The departments are divided in four 'horizontal' cross product departments and four 'vertical' production-chain-oriented departments. The organogram of the organization is given in appendix 1. The cross-product department of Nutritional Behaviour is located in Karlsruhe. The food composition database (Bundes Lebensmittel Schlüssel-BLS) as well as the German National Nutrition Survey (Die Nationale Verzehrsstudie, NVS II) are managed by this department. The number of employees of MRI is about 660 of which about 220 persons work in Karlsruhe. Departments such as human resources and IT are located in Karlsruhe and serve the whole institute. No separate organogram is available for the BLS team, since it is not a separate entity within the department of Nutritional Behaviour. More information on MRI can be found at <http://www.mri.bund.de/en/de/max-rubner-institut.html>.

The main purpose of the BLS team is to maintain the BLS database for the purpose of the German National Nutrition Surveys. When this review took place, the BLS

team consisted of a project leader and a compiler, both nutritionists. From March 15th 2013 the team will be extended with another full time compiler, who is a nutritionist and experienced with BLS through non-permanent previous job contracts. From April 2013 a food chemist will join the team with a 50% appointment.

The MRI has a hierarchical structure in which the compilers report to the BLS project leader. The project leader reports to the head of the department of nutritional behavior, who finally reports to the president of MRI. Decision making follows the same route, although it depends on the magnitude of the decision if the head of the department or the director of the institute needs to sign off.

Personnel

Contracts, job descriptions as well as CVs are available for every employee. In the job description also back up of the staff is described naming the persons who replace each other in case of vacation or illness. It was not clear during the discussion if the job descriptions are amended when the allocated persons leave or change jobs within the organization.

Employees are entitled to follow training funded by the ministry on a yearly basis. Nowadays the budget for training of the compiler team is part of the annual BLS budget, which gives more room to facilitate actual training needs. Some organizational training is offered within MRI. Other training is followed from external training facilities. Two members of the compiler team have followed the International Food Composition Course in Wageningen. The third compiler is planning to come to the 2013 Food Composition Course. The food chemist team member will take care of basic training in the analytical field for the other team members.

Performance reviews are held annually. Staff members were trained to do these reviews. In between less official mid-year reviews are held. During the performance review plans, goals, achievements and working priorities are discussed. Reports of the reviews are written and kept with the files of the employees.

Income generation

The work done at MRI is almost fully funded by the (Federal Ministry of Food, Agriculture and Consumer Protection). The government formulates questions that need to be answered by MRI. There is some free space to work on other topics. MRI can also work with external organizations, which can be other governmental bodies, but also to some extent private parties. A very important prerequisite is that MRI remains independent. Any conflict of interest needs to be avoided.

Part of the income may come from EU funded projects like the EuroFIR and EuroFIR NEXUS projects and the 2012 EFSA project to deliver food composition data.

Additional income is also generated by the BLS team by selling licenses to access the BLS online searchable database to commercial companies and individual users. This income can be used by the BLS team freely e.g. for food analyses, but not for hiring staff. However, administration linked to acquiring the income from licenses costs an estimated 10-20% of the available BLS time. When the data is needed for scientific purposes, such as the German National Nutrition Survey, EuroFIR AISBL and EFSA the data is given free of costs.

The BLS database work is not sponsored by the food industry.

BLS working objectives

The main task for the BLS team is to keep the BLS database updated and fit for purpose for the national food consumption surveys. Recently 4000 new food were added to the database for this purpose. MRI including the BLS team get many ad hoc queries from the ministry, which need to be answered with priority. Requests from other users of the BLS data are taken into account as well, if they fit to the requirements of the main task of the team. The compiler team occasionally works on other projects (such as EuroFIR NEXUS and EFSA projects). Another example is the recently finalized project to determine nutrient retention factors for vegetables, which was a 3-year project, financed from MRI internal budgets.

Working plans are made based on brainstorm sessions with the BLS team and the head of the department to determine the goals on a yearly basis. The head of the department signs off plans. Following internal discussions, the head of the department decides on prioritizing tasks as proposed by the project leader. The head of the department also decides if the team can participate in external projects. The president of MRI is always informed about collaborations and for large projects he is the person to decide on participation.

Collaborations

To maintain the BLS database the compiler team is in the first place collaborating with the colleagues of the German national nutrition surveys, to have an up to date database available for these surveys. The national nutrition survey team is responsible to indicate which new foods are needed in the database.

Furthermore, there is collaboration with other MRI departments, e.g. the Department of Safety and Quality of Fruit and Vegetables, the Department of Safety and Quality of Meat, the Department of Safety and Quality of Cereals, the Department of Safety and Quality of Milk and Fish Products, and the Analysis Division. Each laboratory is involved to answer questions concerning the foods for which they are specialized to do food analyses.

Since 2008, a collaboration with Souci Fachmann Kraut (SFK) has existed. All analytical data (about 800 foods) from SFK is made available for BLS and is now incorporated in the database. In return the Souci Fachmann Kraut team is given the analytical values produced by the food analyses for BLS.

MRI is also member of EuroFIR AISBL and BLS in this way is in contact with several food database compilation teams in Europe.

The BLS team is seeking cooperation with other governmental organizations in the field of food analyses. Since the sister organization of MRI, Federal Office of Consumer Protection and Food Safety samples food nationwide for analytical purposes in a representative manner, it would be more efficient if the samples could also be used by MRI or at least a cooperation could be arranged.

There is no advisory board/steering group organized around BLS with members from external organizations.

Customer requirements

Apart from the German national nutrition surveys, the BLS has 1500 paying customers, such as dietitians and nutritionists, food industry, software companies and individuals. In general, there is tight contact with these user groups, both through the technical queries they have for the BLS team as well as through the feedback on the data. For example the need to provide energy values including the energy from dietary fibre was also expressed by the users.

Description of work

The working plan is written on a yearly basis by the BLS project leader. The working plan includes work on other projects as well. Time is reserved to answer ad hoc questions from the ministry, which cannot be detailed in the working plan on beforehand. Progress is evaluated on a yearly basis.

All documents concerning working plans and evaluations thereof are available on the MRI server.

Contracts and sub-contracts

Several contracts are in place for the work of the BLS team. All contracts needed are organized through the MRI organization.

Office software (Word, Excel and Access) is licensed on an institute wide basis.

In 2008 a contract was signed with Souci Fachmann Kraut to exchange data (see collaborations for more details).

Cooperation contracts have been established with the food industry (big companies and lobby groups), who have their own area in the BLS portal to upload label information. The contracts are still valid, but since data collection for the national nutrition survey was finalized the food industry does not seem to recognize the importance of providing data anymore and do not provide many new data currently. It is the aim of the BLS team to revive this cooperation.

Cooperation with laboratories in the MRI institutes is done without the need of a contract. However, details of the work are discussed and documented in descriptions of work and protocols.

When analyses are needed from an external laboratory a call is set out following EU regulations. The procedure depends on the budget involved. A specialized independent German organization takes care of the call for tender and the selection of the laboratory.

MRI is an associate member of EuroFIR AISBL. For a German governmental organization it is not possible to become a full member of a private organization. To participate in EU projects such as EuroFIR NEXUS, EFSA projects, EuroDISH and others contracts are available.

To develop the current DBMS a contract was signed for the first 2 years. For maintenance, this was changed into a frame work agreement. To use FoodCASE an agreement with Premotec will be signed that includes the use of FoodCASE, the ownership of the software, service and conditions to extend the functionality of FoodCASE.

A contract is in place to host the cooperation and calculation platform through the Federal Office for Agriculture and Food (BLE) that has a department specialized in securing data.

Document control

Electronic documents are stored and accessed via the MRI computer network and are managed according to standard networking protocols by the IT department. There seem to be no MRI SOPs for document control.

Institute wide documents are stored in folders that are accessible to all employees. Documents related to the work of the Department of Nutritional Behaviour are accessible to staff involved in the work only. Documents are arranged in folders on the server for the department.

The access to the BLS database management system is restricted to the BLS team, in particular the calculation area. The portal of the BLS is freely accessible to all MRI departments and to other users with a license agreement to read the data. The cooperation platform of the food industry has access to their own restricted areas to add or change data.

The MRI IT department is responsible for maintaining the network and the server. Documents on the MRI server as well as the BLS data are backed up every night plus every two weeks.

Hard copies of the original data sources are kept in a locked fire free cabinet.

Review of the Quality Management System

MRI has no formal QMS certification, such as ISO 9001, in place. However, at MRI several aspects of such standards are in place. Procedures are in place to detail aspects of the organization such as contracts, job descriptions, performance reviews, training facilities, document control, back up procedures, procedures concerning (institute wide) working plans, workflow, financial procedures, decision making, signing off procedures, archiving, QESH (Quality, Environment, Safety & Health) issues, etc. Related documents are stored properly and are also (more or less easily) available for the BLS staff. It is the experience of the compiler team that it is not always easy to retrieve these documents. Asking a colleague about MRI procedures is quicker and easier. For specific issues, EU regulation is followed, for example to set out a tender.

The internal MRI laboratories that BLS works with have no ISO 17025 certification in place. However, the BLS team knows that these laboratories take place in ring tests /proficiency testing and use standardized analytical methods. External laboratories MRI works with are certified for ISO 17025.

No standard operating procedures are in place for the BLS regarding evaluation of non-compliance and corrective actions. However when a non-compliance is identified an analysis is started to evaluate the problem and solutions are proposed and evaluated again later.

MRI is preparing for an institute wide formal review to be carried out by another governmental organization in October 2013. This will also include the work of the BLS compiler team.

The BLS team will start to build a QMS that focuses on the compilation process to assure quality to their data. The EuroFIR flow chart will be the starting point and will be adapted to BLS procedures. Standard operating procedures (SOPs) are planned to be written. However, some documentation on processes within the food data compilation process are already available.

Technical requirements

Infrastructure

See Organization structure and management policy

Personnel

See Organizational structure/personnel

Training

See Organizational structure/personnel

Equipment

Equipment used for MRI food composition work includes office equipment, PCs and software for data management.

Office software such as Word, Excel, Access and internet access is used and serviced through the MRI IT team.

The BLS database management system is specialized tailor made software, including the BLS cooperation platform and the BLS Online Portal that is maintained at BLE (see contracts).

To cook foods prior to analyses and for the study on retention factors a research kitchen is available. An oven is available that measures both core temperature and humidity during the cooking process. The oven thermometers as well as weighing scales are calibrated regularly. The BLS team is not involved in this.

Database management system

The BLS database management system is a tailor made relational database management system built 2006. The software is written in JAVA. It contains metadata on components, values and references. The parameters needed for the EuroFIR technical annex and Quality index parameters are not included. Extensive calculation modules are included to calculate several types of recipes, included nested recipes. For recipe calculations yield and retention factors can be applied. Historical data is kept in separate versions of the database and all changes on the data can be retrieved through the audit trail.

The database contains both analytical data from analyses commissioned by BLS and from scientific literature for about 1200 foods. Analyses are usually done in duplicate, triplicate or more. Results are usually provided in Excel format and mean or median values are calculated by the BLS team. Only the mean or median values are imported into the BLS database as original values. Not including all original data holds a risk of losing information. Additionally there is the risk of introducing possible errors due to the application of Excel files. BLS has an import module so manual data entry is not needed. The imported data is checked by the compilers through manual comparison of the data and later on through checks by the database itself through comparing the new calculated data with former data and listing the differences.

Most of the food composition data is calculated from recipes. The database has no missing values. When analytical values are missing for the ingredients of recipes, missing values can be filled in by taking over from similar foods or can be calculated using the component profile of other foods (fatty acid profiles, amino acid profiles and carbohydrate profiles).

New components can be added if needed. Derived components are calculated using standardized algorithms.

The BLS database management system secures the calculation of derived components and recipes automatically, following any modification of related foods or components.

All results are checked 'manually' to see if the results are realistic. Comparisons are made with previous versions of the BLS database, with foreign food composition tables and by calculating data from the national nutrition survey with both the previous and the updated version of the BLS.

Some algorithms are included to check for consistency of data.

FoodCASE

MRI is in the process of deciding about transferring the BLS database to the FoodCASE software. One of the advantages of FoodCASE is the availability of the EuroFIR standard and quality index modules. MRI is discussing the need for additional modules to FoodCASE in order to be able to compile the BLS data as needed. Some of the BLS modules must be added to FoodCASE e.g. the calculations using the component profiles and the electronic import module.

Important prerequisites for MRI are that the ownership of the software is arranged by contract in such a way that MRI stays independent and can continue using FoodCASE in case of any problems. Final decisions need to be taken in the first half of 2013. MRI is willing to share efforts and results with other FoodCASE users.

Analytical work (including sampling)

In general, MRI is able to do some food analyses every year. Foods are selected for analyses depending on the needs of the national nutrition surveys or to improve some data for which values are derived from similar foods or to replace some outdated data.

Analyses are carried out by MRI laboratories mainly and sometimes by external laboratories. BLS does not need to pay salaries of the MRI laboratories, only the samples and grants to the equipment. The drawback of this system is that BLS needs to wait until the laboratory has capacity to do the work.

Sampling is usually done by BLS staff or trained persons from the MRI institute. For sampling detailed working plans are written including e.g. information on the samples to buy, locations for purchase, the amounts needed etc. For sample preparation, detailed descriptions are written regarding cooking methods and recipes to apply.

BLS is familiar with the expertise of the MRI laboratories. The laboratories use accredited methods or their own modifications. MRI laboratories are not ISO 17025 certified but take part in ring tests for specific components. For external laboratories, certification is taken into account in the selection procedure.

Sample handling with respect to homogenization and storage is taken care of by the laboratory. Analytical results are provided to the BLS team in Excel documents for all single measurements. All results are scrutinized before data is imported in to the BLS database. In case of any unexpected values the laboratory is consulted to check the values. If needed analyses are repeated to correct or verify the initial results. The BLS team calculates mean and median values and selects either the mean or median value to include in the database.

Data production

The BLS database is a database for generic foods mainly for the purpose of the national food consumption surveys. The cooperation platform enables the food industry to upload food composition data of brand data. However, the foods are published as generic foods, and brand data is stored as meta data which is mainly used for reasons of comparison. Currently the food industry is not very active in keeping their data updated.

After scrutinizing the data available in the BLS database selected values are selected by flagging for further calculations.

Besides calculations modules the BLS contains modules to take over values from similar foods and to calculate the composition based on profiles of fatty acids, carbohydrates and amino acids, as available from other food items. To fill in missing values, also values are taken from other sources such as the SFK database, literature, other foreign food composition tables and the food industry.

The BLS DBMS contains a module to check and automatically make corrections to the data. However, this is not trusted completely since what happens to the values is not fully retrievable. In addition, procedures are available to check on data consistency including error reports. These reports limit the work of checking all values individually. In addition, procedures are present such as identification of outliers by comparison of different versions of the BLS datasets and by calculating nutrient intake with older and new versions of the BLS dataset. Part of the data checking is still done in Excel because this allows for various alternative ways of sorting and looking at the data.

For more details see the food data base management system.

Publication process

After all steps of the compilation process from data entry to calculation and validation are finalized the data is ready for publication. Datasets are provided to the national nutrition survey team and published at the BLS searchable website. The next version of the website will be released in April 2013. Although the food industry would be in favor of updates every 6 months, MRI has decided for less frequent updates because a more stable version is needed for food consumption research.

The BLS database currently contains data on 14,814 foods with 131 components per food.

Products from the BLS database for general use a searchable website (BLS Online Portal) with data in German and English (<http://www.blbdb.de/index.php?id=1&L=1>), as well as a downloadable dataset in Excel. A license agreement is needed to have access to the database.

Compilation process (critical control points – see EuroFIR generic compilation flowchart)

The BLS team has no quality management system in place, although many elements of quality management are available at the level of MRI. It is the aim of the BLS team to prepare a flow chart describing the food data compilation process in the near future. The EuroFIR flowchart will be used as the basis and will be adapted to the workflow of the BLS team. Descriptions of work will then be re-arranged into standard operating procedures for the critical steps of the process. Critical control points, hazards and preventive and corrective actions will be described. For practical

reasons the BLS team will start this task after the database has transferred into the FoodCASE software.

Several steps of the compilation process are detailed in working procedures, instructions, papers, algorithms and steering files, but these documents were not yet arranged into a quality management system.

The steps of the compilation process were discussed throughout the day and details are mentioned in the previous chapters of this report. An overview of the compilation process for BLS is given in appendix 2.

Feedback from users

Feedback is received from the national nutrition surveys. This includes the request to add new foods as well as the checking of new versions through the data of the German National Nutrition Survey. The high number of licenses yields several feedbacks, which is taken into account as far as possible. In this way the BLS team has a fairly good idea on the opinion and needs of users. See also customer requirements.

Contact with the food industry

See contracts, cooperation and data production.

Dissemination of data

See the publication process.

EuroFIR

MRI is associate member of EuroFIR AISBL. See for more information in the paragraph on contracts.

The BLS dataset is provided to EuroFIR for the FoodExplorer software, but is not publicly available due to restrictions of licensing. Only a limited number of foods (\pm 1000) in the BLS database are indexed with LanguaL codes. Within Germany a classification system was developed based on facets and descriptors. LanguaL descriptors are linked to this German system. The BLS team is waiting for the final version of the German classification system, so both this system and LanguaL can be linked to the BLS codes.

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Conclusions

MRI is not certified by ISO9001 or ISO 17025 or any other standard for their offices and laboratories. However, several elements of such standards are in place at the institute wide level (e.g. job descriptions, annual working plans, performance reviews, training).

The BLS team recognizes the relevance of building a quality approach according to the EuroFIR standard for the food data compilation work, but did not start to formalize this yet. It is planned to adapt the EuroFIR flowchart to the workflow at MRI and to add standard operation procedures for the critical steps of the BLS workflow. This work will start from March/April 2013.

The BLS database is filled with data originating from analyses commissioned by MRI as well as from other sources such as the Souci Fachmann Kraut database, other food composition tables, scientific literature, food industry, similar foods. A large part of the data is calculated.

Analyses are performed on a regular basis (in general each year) and are planned and documented in a detailed way. Laboratories are selected on the basis of their expertise on both components and food groups. BLS seeks cooperation with other German organizations for more representative and efficient sampling.

The BLS data is managed through a relational database management system (DBMS) that secures most steps of the compilation process. The DBMS contains several sophisticated modules for calculations to fill in missing values. With the help of the DBMS the BLS team manages to keep track on the process of updating the large number of foods (± 15000), which are necessary for the evaluation of the German National Nutrition Survey (NVS II), in a structured way.

The current DBMS needs to be replaced by modern software that includes the EuroFIR standard. MRI intends to use the FoodCASE software in the near future (2013). Several of the limitations of the current system are expected to be solved with FoodCASE. However additional modules need to be added to FoodCASE to continue data management at the same level as the current DBMS.

The BLS compiler team was very open and willing to share information and documentation and answer all questions regarding their work. Following the outline of the review, the compilation procedures were discussed in a structured and detailed way.

Recommendations

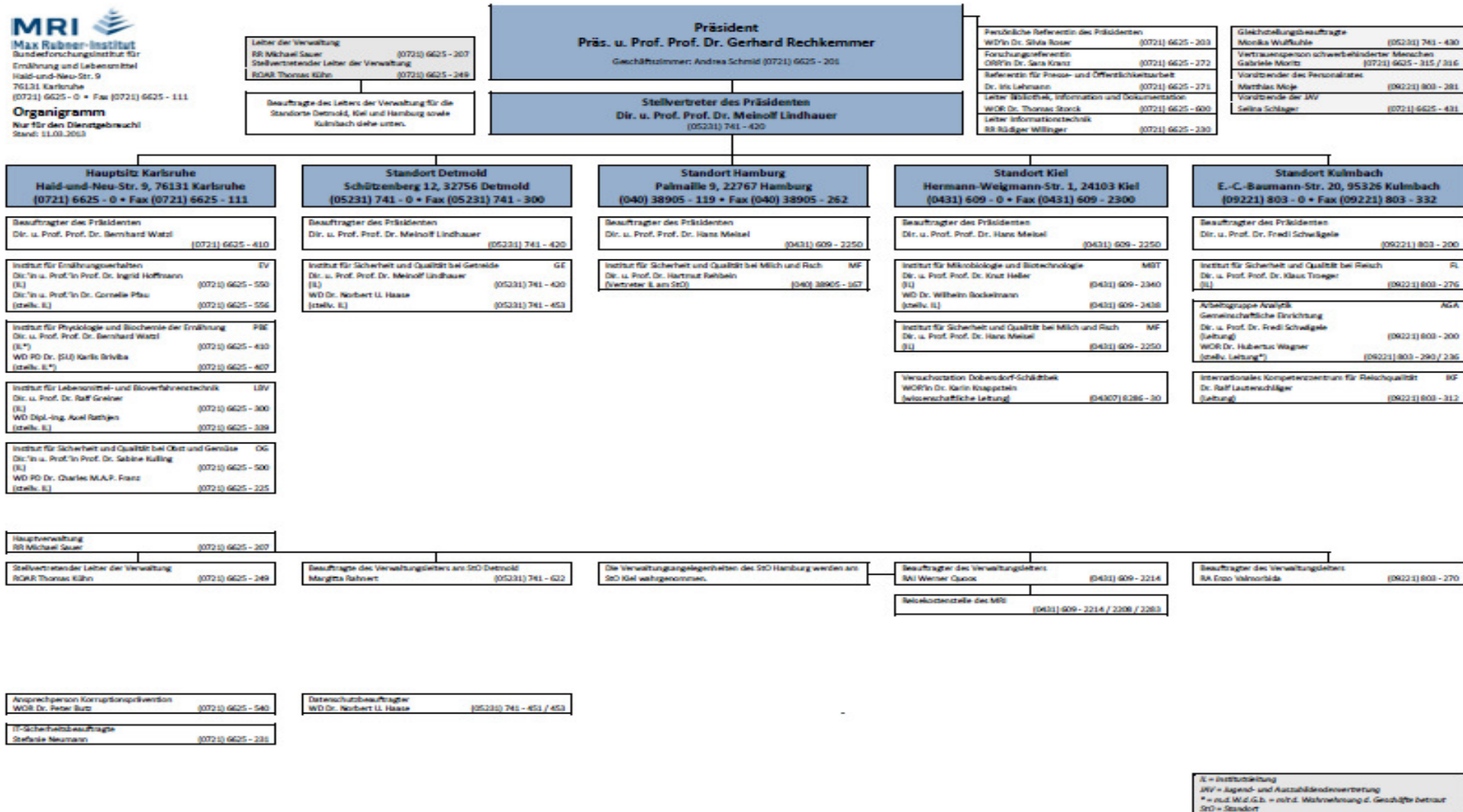
1. It is recommended to include all original analytical data in the BLS database, not only calculated mean or median values. When calculation of mean and median values can be done within the DBMS the use of procedures performed outside the DBMS can be limited.
2. It is recommended to include more queries for data checking linked to the production or error reports to limit manual work and ad hoc checking of data.
3. It is recommended to start building a quality approach for the BLS work. The BLS food data compilation process can be described by adapting the EuroFIR generic flow chart. It is recommended to write standard operation procedures including

critical control points, hazards, preventive and corrective measures at least for the critical steps. A standardized approach will assure that all BLS staff work in a similar way.

4. It is recommended to further investigate the possibilities to collaborate with other German organizations in food sampling in order to create efficient (time and money saving) procedures for food analyses.
5. It is recommended to consider the installation of an advisory board or steering group to advice on policy and content of the BLS database.
6. It is recommended to work together with other countries that plan to use FoodCASE, in order to share the resources needed to extend and improve the functionality of FoodCASE.

Appendix 1

MRI organization structure including The Nutritional Behavior Department



Appendix 2.

Steps of generating the BLS data (Hartmann et al. (JFCA, 2008) page 116

