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Development of Standard Operating Procedures for the Use of a Food Composition Database in the Field of Nutrition surveys

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List of abbreviations

BLS

Bundeslebensmittelschlüssel

EuroFIR

European Food Information Ressource

FCDB

Food Composition Database

HACCP

Hazard Analysis Critical Control Point

SOP

Standard Operating Procedure

Introduction

The goal of this thesis was the creation of Standard Operating Procedures (SOPs) in the field of Food Composition Databases (FCDB) focusing on their use within nutrition surveys. Detailed standardized rules were to be elaborated to facilitate working with a FCDB and nut.s nutritional software [DATO DENKWERKZEUGE, 2010].

A SOP is a list of instructions and explanations, developed to reduce errors to a minimum and to achieve high quality results. Processes are being analyzed, restructured and described clearly.

The complexity of processes, related to working with a database, explains the necessity of developing SOPs for the use of a FCDB in the field of nutrition surveys. These processes need to be regulated, due to the fact that their complexity is a major source of errors.

SOPs are a good tool to bring clarity into the confusing amount of work steps related to database work.

The final version of the SOPs is planned to be used in daily database work at the Department of Nutritional Sciences at the University of Vienna. Those people working with the FCDB and nut.s nutritional software [DATO DENKWERKZEUGE, 2010] will have to read and follow the elaborated instructions.

The SOPs have been developed in due consideration of the following points:

- Finding a way to describe the necessary work steps as clear and unambiguous as possible
- Improving internal work processes
- Finding a possibility to reduce complaints and errors to a minimum
- Improving internal communication
- Clarify areas of authority

A general overview of the origin of food composition data is given in the “Literature review”. This chapter also deals with basic information on SOPs, the definition of quality (especially data quality), processes and procedures. Since this work is based on the SOPs developed by the EuroFIR-project, these are described in this chapter as well.
The chapter “Material and Methods” is dealing with the development of the present SOPs and the included flowcharts and documents. The testing phase of the first draft of SOPs is also explained in this chapter.
The problems and ambiguities that appeared during testing are explained in the chapter “Results”. Since the elaborated SOPs present the result of this thesis, they can be found in this chapter, including flowcharts and documents.
The results of this thesis are discussed and compared with results from literature in the chapter “Discussion” and finalized by a short “Conclusion”.

Literature Review

Sources of data in Food Composition Databases

Food composition data are essential for different areas like scientific research, education and public health, clinical practice as well as food industry. The application of such data ranges from general uses, which affect most users, to uses concerning only a particular area [WILLIAMSON, 2006].

Data are used at the international level, for example in food trade, as well as at the national level by governments or agricultural researchers. Furthermore, food composition data are needed at a regional level and of course for the individual, when it comes to counseling or developing individual diet plans [RAND et al., 1991].

Since food composition data are indispensible in many areas and, in the end, affecting nearly every individual somehow or other, it is necessary to assure quality of data and therefore food composition databases.

Types of databases

When it comes to obtaining data for a food composition database it is necessary to understand the purpose of the corresponding database. A distinction can be drawn between Reference databases and Special-purpose or Application databases.

A Reference database is primarily designed to provide basic material and is therefore often used as data source for the construction of Application databases. A Reference database is complete in documentation of sampling, sources, production of data and description of included foods and nutrients. Data therein may be analytical data, compiled and aggregated data as well as a combination of these.

An Application or Special-purpose database is targeted on treating a specific problem or a specific application. It may contain data from a single Reference database, from several Reference databases or complement reference data with additional data. Usually Application databases are less complicated (due to the fact that there is no primary data or extensive description) and easier to handle than Reference databases [RAND et al., 1991].

Food composition data

There are different ways how food composition data can be obtained. The quality of these data depends on the mode of data acquisition [GREENFIELD and SOUTHGATE, 2003].

Analytical values

Analytical values are the preferred method of gathering food composition data for specific foods, although it involves disadvantages like expense and expenditure of time [RAND et al., 1991].

Analytical values do not necessarily have to be originally analyzed for the compilation of a particular database. They can be taken from published literature or laboratory reports. This category also contains original calculated values [GREENFIELD and SOUTHGATE, 2003].

Sampling

Sampling, in terms of food composition work, describes the collection of an example of a food for analysis. This sample is taken out of "the population of interest", more precisely, the total amount of the food of interest.

The number of examples that need to be collected depends on the desired precision [RAND et al., 1991].

Food samples need to represent those foods consumed by the population for whom the database is developed. A basic requirement for developing quality data is documentation. In the case of sampling, documentation must include the biological and natural variability of foods, such as different seasons, geographic location, farming and cultivar. When calculating the composition of the whole population of a food, some error should be assumed, due to the inconsistency and heterogeneity of foods [GREENFIELD and SOUTHGATE, 2003].

Sources of foods

- Bulk commodities: Data obtained from bulk commodities obtain high quality, due to the fact that they involve a large number of analyzed samples. They are often used to test for contamination or misuse of chemicals or as basis for the calculation in food disappearance statistics. The sample taken should really represent the bulk commodity. Therefore random sampling is recommended.

- Wholesale foods and commodities: Sampling can be compared to sampling used for bulk commodities.

- Retail foods: Retail foods are foods as delivered to the consumer. Most foods included in FCDB (in industrialized countries) are retail foods. Samples of primary products have to be representative of the whole range of sales outlets. The primary sample should proportionately correspond to the amount of food in different outlets.

- Field, garden or wild foods: Field and garden foods are of great importance in non-industrialized countries. They are much more variable and mostly consumed seasonally as fresh and afterwards preserved in different ways.
  Wild foods have to be taken into account for special population groups consuming large amounts of wild plants and hunted animals.

- Foods as consumed: Those are foods at the stage of consumption, which means cooked foods including mixed dishes. The multitude of different recipes and modes of preparation makes it difficult to select representative samples. A common method is the simulation of the preparation in a laboratory. Collecting cooked dishes from a particular number of households would be more representative, but bares a lot of logistical problems. Collection from the hotel and restaurant industry or public institutions is much easier. Still compilers have passed on to using calculations from recipes more often [GREENFIELD and SOUTHGATE, 2003].

Variability in nutrient composition

Sampling, as well as the design of analytical and sampling protocols, not only depends on the different sources of food samples, but also on the variability of foods themselves. The nutrient composition of foods depends on the geographical position, the season, the maturity and the cultivar or breed. Those factors have to be taken into consideration [GREENFIELD and SOUTHGATE, 2003].

Sampling methods

- Random sampling means, that every item in the population of foods has the same chance to be included in the sample for analysis. Since this is hard to realize, stratification is a more common method.

- In Stratified sampling the whole population is divided into strata, considering the most important variations.

- Selective sampling is often used for analyzing contaminants. A sampling plan dictates which material should be included or excluded.

- Convenience sampling is not really useful for food composition database work. Samples are taken depending on their accessibility, cost or usefulness [GREENFIELD and SOUTHGATE, 2003].

Original calculated values

Some nutrient values can be calculated from one or more nutrients that have already been analyzed. Schakel and colleagues [1997] summarized examples for such calculations as follows:

- Calculation of energy values on the basis of protein, fat, carbohydrate and alcohol using Atwater factors.
- The protein value can be calculated from the nitrogen content, using, for example, a conversion factor of 6.25 g protein per gram nitrogen.
- USDA tables, for example, use Carbohydrate values calculated by difference for 100g of food. Other methods are calculating the Carbohydrate amount from the sum of sugars, dietary fiber, starch and oligosaccharides or from the sum of sugars, dextrins, glycogen and starch.
- It is possible to calculate the dietary fiber content of a food from the sum of insoluble and soluble fiber.
- Vitamin A is often calculated from the sum of beta-carotene equivalents and vitamin A activity of retinol.
- Beta-carotene equivalents can be calculated when the quantity of each carotenoid is already known.
- Vitamin E: Different conversion factors are available for the calculation of alpha-tocopherol equivalents from the activity of tocotrienols and tocopherols.
- When a food contains only one type of fat, it is possible to calculate fatty acid values from the proportion of the contained fat and its fatty acid profile.
- It is possible to calculate the amino acid content for a food with only one protein from the protein-containing ingredient, comparable to the calculation of fatty acids [SCHAKEL et al., 1997].

Imputed values

Data for a food or nutrient cannot always be generated or found in the literature, but in some cases can be estimated from analytical values that were originally maintained for a similar food. This may be a biologically similar food (e.g. values for green beans can be used for peas) or another type of the same food (e.g. different ways of preparation, like cooked or steamed) [GREENFIELD and SOUTHGATE, 2003; RAND et al., 1991].

Imputed values can also be calculated from partial analyses of foods (e.g. chloride can be calculated from the value of sodium) or can be derived from comparing different conditions of the same food [GREENFIELD and SOUTHGATE, 2003].

In the majority of cases, some adjustments or calculations are necessary, because the food found is not so similar to the needed food that data can be adopted without any adjustments. Therefore, it is necessary to adjust for the differences between the food of interest and the substituted food [RAND et al., 1991].

Using data from a different, but similar, food requires consolidated knowledge of the nutrients and foods to guarantee data close to the food of interest [RAND et al., 1991].

Usually, it is advisable to use nutrient values from a food within the same family or genus, although genetic similarity does not necessarily result in nutrient similarity. Attention should be paid to the part of a plant (like root, stem or leaf), the color of a vegetable, (because it can suggest the vitamin content), growing conditions, location, maturity, processing (e.g. heating, canning, freezing, drying, mechanical separation), use of additives or the cut of meat [RAND et al., 1991; SCHAKEL et al., 1997].
Furthermore, it is necessary to consider which part of a food is edible, because there are differences between and within cultures [RAND et al., 1991].

Calculated values

Values are often calculated for mixed dishes or recipes as well as to obtain values for cooked foods on the basis of raw foods or differently prepared foods. In this process yield factors and retention factors are being applied [GREENFIELD and SOUTHGATE, 2003].

Yield factors: Heat processing leads to changes in the weight of foods. These changes can be caused by

- an increase of the water content
- a reduction of the water content
- fat uptake and water reduction [BOGNÁR, 2002]

The amount of the change depends on several factors, like ingredient, preparation method, temperature, time and equipment [BOGNÁR, 2002].

These yield factors are defined as the weight of the already prepared food divided by the weight of the unprepared food [RAND et al., 1991].

Retention factors: Food preparation with the aid of heat leads to changes in food constituents (nutrients), like for example vitamins. In most cases, changes in nutrient contents come along with changes in weight (increase or reduction of water content, uptake of fat) and are calculated parallel to the yield factors [BOGNÁR, 2002; RAND et al., 1991].

Borrowed values

Borrowed values are data originally created by someone else [RAND et al., 1991]. Other databases and tables are sources of borrowed values. In many cases the original data source is not available. Borrowed values have to be justifiable and therefore appropriate reference to the original data source is necessary [GREENFIELD and SOUTHGATE, 2003].

Assumed zero

Some nutrient values are presumed as not being present in a detectable amount and therefore are reported as zero [RAND et al., 1991].

Standard Operating Procedures

A Standard Operating Procedure (SOP) is a set of instructions with the objective of guaranteeing data and product quality. The use of SOPs minimizes discrepancy and standardizes processes in a way that leads to stable quality, even if there are changes in personnel [LAPITAJS and WESTENBRINK, 2008; EPA, 2007].

Definitions

To understand the relevance of SOPs it is important to define some terms in the beginning.

Quality

The term "quality" is of Latin origin (lat. qualitas, -tatis f.) and is often translated as composition or constitution (of an item).
Quality connotation is known since ancient times, and its interpretation and definition has changed over the years [KAMISKE and BRAUER, 2008].
A possible classification of quality into three main criteria is the following:

- Quality at work means, that conditions of employment and motivation of employees influence the quality of a product.
- Quality in competition: Good product quality leads to a competitive advantage.
- Quality of requirements includes the term "fitness for use", which means that quality begins with the customers reasons for buying a specific product [DOPPLER, 1999].

Quality is the consistency of a product or service with the customer's requirements and expectations, compared to competing products or services [PFEIFER and SCHMITT, 2007].

The ISO 8402-94 standard defines quality as: The set of characteristics of an item that give that item the ability to satisfy expressed and implied needs. The ISO 9000:2000 standard defines it as: The ability of a set of intrinsic characteristics to satisfy requirements [DOPPLER, 1999; PFEIFER and SCHMITT, 2007].

Nonperformance of quality requirements is treated as failing, and can usually not be compensated by overcompliance of another requirement [PFEIFER and SCHMITT, 2007].

Only the superior quality of a product assures a company's existence of long duration. Nowadays quality implies every employees understanding of what is necessary to meet customers' requirements. It is therefore necessary to scrutinize and, if necessary, rearrange existing corporate structures [KAMISKE and BRAUER, 2008].

"Quality has to be managed" [PFEIFER and SCHMITT, 2007]. This declaration highlights the necessity of a Quality management system. A quality management system is a process that classifies each quality-related activity as follows:

- Definition and Documentation of the process
- Determination of quality standards
- Check for compliance with quality regulations
- Initiation of corrective measures, if necessary
  [DOPPLER, 1999]

A method focused on total customer satisfaction, is TQM (Total Quality Management). TQM focuses on persistent quality improvement by integration of all processes and functions of a company in the quality management process [ROSS, 1999].

Quality control measures are used to prevent the appearance of failure, because deficient products would lead to higher costs for the company [ROSS, 1999].

Data quality

As in every other field of work, quality of a product (in this case quality of data in food composition databases) cannot be judged by looking at the final result only. It is necessary to go back to the origin of the nutrient values. Quality of food composition data starts with the sampling process [BURLINGAME, 2004].

The main objective in sampling is the generation of representative food samples and to make sure that there are no changes in food composition between the collection and the analysis of the sample. Further it is important to document the natural variability due to different seasons, geography, husbandry and cultivar [GREENFIELD and SOUTHGATE, 2003].

Size and number of samples are fundamental values for the production of quality data. The size of samples depends on the total amount of food needed for analyses. The number of samples needed depends on the variability of the samples' composition. Apart from the number of samples collected, quality of data depends on the number of samples prepared for analysis and of samples analyzed, the number of analytical determination, the number representing the best value and the variability [BURLINGAME, 2004; GREENFIELD and SOUTHGATE, 2003].

Representativeness and completeness are important but sometimes misleading expressions. High quality data may derive from non-representative sampling, when considering different criteria [BURLINGAME, 2004].

Food composition data is used in many fields of work, for example, clinical practice, research, public health and education as well as food industry [WILLIAMSON, 2006]. Due to these uses the concept of representativeness has to be adjusted, considering, for example, contaminant data as well even though not being representative of the food in principle. Furthermore it is necessary to realize that nutrient data on specific cultivars is useful in many cases [BURLINGAME, 2004].

The ideal high quality food composition database, in terms of completeness, would consist of data on all foods and all food components, feasible for every user group [GREENFIELD and SOUTHGATE, 2003].

There are two strategies trying to deal with this dilemma:

- Develop priorities for the selection of those food items that should be included in the database and accept moderate data quality. This also means agreeing with missing foods and values when there is no analytical data available.

- Accepting different data types (such as borrowed, imputed, analyzed). This would mean no missing foods or values for basic foods or components [BURLINGAME, 2004].

Some user groups may consider completeness as a quality criterion. As long as the quality of each value is recorded, a database can be considered as a high quality database concerning its completeness. This means that a database can be high in quality even though some data is not of the highest quality level [BURLINGAME, 2004].

This also makes clear that quality of food composition data always depends on appropriate and complete documentation. Unambiguous documentation at every stage from sampling to the aggregation of final values is a basic determinant for the quality of a food composition database [BURLINGAME, 2004; GREENFIELD and SOUTHGATE, 2003].

Process

Process and product and/or service are closely connected to each other and one cannot exist without the other. A process is an activity (or a group of activities) taking a company's resources to produce certain results. A process is sometimes described as an input, adding value to this input and offering an output to the customer [HARRINGTON, 1991].

Processes can be very simple actions but in many cases they are consisting of many different sub processes. Those sub processes on the other hand are made up of simple activities.
An example for a process would be the writing of a letter. Sub processes would be in this case the writing of the address, the salutation and so on. The tapping of the key would be the activity [RAINER, 1997].

When looking at these descriptions of a process, it is clear that nearly everything we do is a process.
In the working environment processes can be classified as follows:

- A Production process is every process connected to the product, up to the packaging.
- Business processes are all processes supporting the production process [HARRINGTON, 1991].

A company, therefore, is a complex system of processes [RAINER, 1997]. It is of great importance to realize that not only production processes but also business processes need rigorous regulations and standardization for the production of high quality products [HARRINGTON, 1991].

A clearly defined and managed process involves the following advantages:

- Clearly defined responsibilities
- Clearly defined process scope
- Documented procedures, tasks and required instruction or training
- Control and measurement take place at the point at which activities are taking place
- Better customer orientation
- The Development potential can be better estimated
  [HARRINGTON, 1991]

Standardization

Standardization is a basic requirement for the improvement of a process. It means that there is a predetermined way of doing an activity. All employees have to follow these instructions in any case. Standardization is normally achieved by using procedures [HARRINGTON, 1991].

Procedures

Procedures should be available for most activities performed in a company and consider the following aspects:

- Who is responsible and where are the limits of authority?
- Emergency situations should be covered
- Procedures need to be based on accurate analysis and experience
- They have to be unambiguous and plain
- Each document has to be clearly explained concerning its purpose and use
- Training requirements have to be defined
- Procedures can be complemented by flowcharts
- Every employee has to be trained in using the procedures
- Procedures have to be updated and checked at frequent intervals [HARRINGTON, 1991]

Standard Operating Procedures

SOPs are essential resources in quality management, supporting the production of high quality products [EPA, 2007]. Different types of SOPs are possible, like for example technical SOPs, Laboratory SOPs or Administrative SOPs. SOPs are needed for work steps that are related to product quality or decisions concerning the quality of the product [LAPITAJS and WESTENBRINK, 2008].

In some cases SOPs are used for staff training, because they offer detailed guidance through work processes and highlight critical points [EPA, 2007].

When developing a SOP, some important things have to be considered:

- A Standard Operating Procedure should always be written by a person who is in the know of the work process to be described. Only then the writer can evaluate which information is essential.

- It can be useful to write a SOP in collaboration with other people to bring in different perspectives and knowledge [LAPITAJS and WESTENBRINK, 2008].

- SOPs should always be easy to read, unambiguous and complete in describing the particular process. Writing style and complexity should be adjusted to the experience and the knowledge of the user.
  Words like "should, may, could,…" have to be avoided. Precise instructions leaving no diversity in interpretation are essential [EPA, 2007; LAPITAJS and WESTENBRINK, 2008].

- SOPs have to be reviewed by people who are familiar with the described process [EPA, 2007].

- A consistent and well structured format should be used for all SOPs of a company. The most important information should be easily detectable [LAPITAJS and WESTENBRINK, 2008].

SOPs developed in the course of the EuroFIR-project

EuroFIR is a European Network of Excellence linking Food composition databases to achieve effective management, reproducibility and modernization and is therefore supporting European food and health research.
EuroFIR objectives are:

- Strengthening scientific and technological competency concerning food composition databases in Europe.
- Providing new information on missing data for nutrients and bioactive substances for all food groups.
- Sharing methods and facilities and spread competences through cross-border training.
- Communicating with users and stakeholders to develop high quality and seminal food databank systems.
- Encouraging European food and nutrition industry, with the goal of evidence-based health-related production of foods [EUROFIR NOE, 2008].

One of the main goals of the EuroFIR network is to bring more clarity and uniformity into the compilation process to enhance comparability among different food composition databases. For this purpose standardization and quality management are necessary tools [CASTANHEIRA et al., 2009].
The EuroFIR project started its work for the harmonization and standardization of European food composition databases in 2005. Results of a questionnaire conducted in 2005 among EuroFIR compilers showed the necessity of quality control tools, quality management systems or standard operating procedures especially for the compilation process [WESTENBRINK et al. 2009].

EuroFIR used the Hazard Analysis Critical Control Points (HACCP) approach as the basis for the identification of points at which errors can creep in and control has to be applied [CASTANHEIRA et al., 2009; WESTENBRINK et al., 2009].
The HACCP system is very useful for the application of quality because it describes a process very well. ISO standards were used, apart from the HACCP approach, as a basis for the implementation of quality standards [WESTENBRINK et al., 2009].

HACCP

The Hazard analysis critical control point system started out as a possibility to guarantee 100% save foods for crewed spaceflights in 1959. It was developed by the Pillsbury company in Minneapolis together with the National Aeronautics and Space Administration and the US Army Laboratories in Natick. The HACCP concept was first presented to the expert public in 1971. In 1985 HACCP was recommended for general use in the food industry by the National Academy of Science. The 3 basic principles of HACCP left too much room for interpretation and were therefore revised many times until the actual version of 1997, consisting of 7 principles [FELLNER and RIEDL, 2009].
The 7 principles of Codex-Alimentarius for the implementation of HACCP are: (Original text – Codex 1997)

- Conduct a hazard analysis
- Determine the Critical Control Points (CCPs)
- Establish critical limit(s)
- Establish a system to monitor control of the CCP
- Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control
- Establish procedures for verification to confirm that the HACCP system is working effectively

- Establish documentation concerning all procedures and records appropriate to these principles and their application
  [FELLNER and RIEDL, 2009]

HAZARD ANALYSIS comes in the beginning of the HACCP approach. Some questions have to be asked, based on the final product: Which hazards, concerning the composition or production, are related to the product? How possible is the existence of this hazard? How much damage can be done by the hazard?
When these questions have been answered it is possible to move on to the CRITICAL CONTROL POINTS (CCPs). CCPs clarify at which points in the production process the already identified hazards can be mastered [FELLNER and RIEDL, 2009]. These points are the last opportunity to correct a hazard or reduce it to an acceptable level [WESTENBRINK et al., 2009].

HACCP shows, that hazard control is only possible by causal avoiding of the hazard itself. Therefore it is necessary to apply the HACCP system to the whole production process [FELLNER and RIEDL, 2009].

The basis of the HACCP approach is detailed knowledge of the process. EuroFIR compilers were involved in the description of the compilation process. Two independent descriptions of the process were used as a basis and assembled into one generic process, with the aid of basic literature on food composition. This process was described by a provisional flowchart.
According to the HACCP approach hazards had to be identified and critical control points determined in a next step.
Each Critical Control Point then was complemented by the according Standard Operating Procedure. The provisional flowchart, the hazards, CCPs and SOPs were then reviewed and discussed by compilers at the EuroFIR compiler network meeting in 2007. These documents were revised and finally favored by the EuroFIR compiler network [WESTENBRINK et al., 2009].

Final result is a generic flowchart consisting of 22 steps. 11 Critical Control Points could be identified based on detected hazards. To apply control at these points it was necessary to prepare the corresponding SOPs [WESTENBRINK et al., 2009]. These SOPs are applicable to every food composition database of the EuroFIR network [CASTANHEIRA et al., 2009].

For the implementation of the EuroFIR SOPs for the compilation process it may be necessary to make some adjustments, due to the fact that additional hazards may emerge or that some of the already identified hazards are not applicable. Compilers have to decide if the existing CCPs correspond to the CCPs of the particular compilation process [WESTENBRINK et al., 2009].

Generic hazards that can appear at each point of the compilation process are: deficient knowledge and the absence of standardized procedures or documented criteria. These hazards can be prevented or reduced by:

- Sufficient training of compilers
- Standardized procedures (SOPs) and tools
- Inclusion of users and experts for advice or assistance
- Improved data validation due to comparison between compilers
- The existence of adequate Food composition database management systems (FDBMs) equipment [WESTENBRINK et al., 2009]

Appearance of EuroFIR SOPs

Each EuroFIR SOP for the compilation process consists of a front page showing the number and topic of the present SOP as well as a short table of contents and the documentation, who prepared and reviewed the document in hand.
EuroFIR Standard Operating procedures are divided into different chapters. Each SOP covers the following topics:

- Scope
  Highlights who is addressed to by the present SOP.

- Objective
  Describes what the SOP is about and gives a short introduction of the topic.

- Definitions
  Defines technical terms and abbreviations that have been used in the SOP to avoid misinterpretation.

- Responsibilities
  This chapter is important to clarify who is in charge of which task (described in the section Procedure). No names are specified in this section because the SOPs are used by different members of the EuroFIR compiler network. This section specifies the responsibilities of the compiler, the project leader or head of department and the EuroFIR organization.

- Procedure
  Describes the tasks to be carried out in detail. This section is divided into subchapters to increase comprehensibility and clarity. This chapter also details corrective measures, needed material and technical requirements and the necessary qualifications and training of compilers.

- Remarks
  Gives a short explanation of how the instructions of the SOP have to be followed.

- References
  Lists all literary sources used in the present SOP.

[BORGEJORDET, 2008; PORTO, 2009; PORUBSKÁ et al., 2008; ROE and REYKDAL, 2008; WESTENBRINK and LAPITAJS, 2009; WESTENBRINK 2009]

Material and Methods

The first step in the development of Standard Operating Procedures is to determine which steps of a procedure should be regulated. Since this work is focused on the development of Standard Operating Procedures for the use of a food composition database in the field of nutrition surveys it was essential to identify the persons involved in this process in the beginning.

Identification of persons involved

Due to the fact that Standard Operating Procedures should always highlight the responsibilities of each person involved, the first step in developing the present SOPs was to identify and classify all people involved.
Those people primarily involved in data entry and the connected work steps are:

- **Data typist**
  those people actually entering data derived from protocols into the database.

- **Director of studies**
  responsible for the particular study and in most cases the first contact person for data typists.

- **Compiler**
  those people including (or excluding) foods and food components in the Food Composition Database.

Furthermore there are two other functions marginally involved in the process of data entry:

- **Head of department / Project leader**
  is the top decision maker and therefore important in the planning and implementation of a study.

- **User**
  is the person finally working with data enclosed in the database and with data from protocols. In the present case the user is mostly the Department of Nutritional Sciences of the University of Vienna itself.

Identification of Critical Control Points

The second step in the development of the present Standard Operating Procedures was the elaboration of areas where data entry, compilers and directors of study need regulations, concerning their work with the database and nut.s nutritional software [DATO DENKWERKZEUGE, 2010].

The applied method to assure the quality and uniformity of data is inspired by the Hazard Analysis Critical Control Points (HACCP) approach. HACCP is the most common precautionary system used to assure food safety in the field of food processing and production. The basic concept of the HACCP approach can also be implemented in other areas [WESTENBRINK et al., 2009].

Corresponding to the HACCP principles it was necessary to detect possible hazards along the entire process in the beginning. Therefore, it was essential to become aware of the working process and to describe it in detail. This was necessary for the identification and analyses of those parts of the process that could affect quality [BFR, 2005].
In the case under consideration the SOPs deal with only one step of the working process – the entry of protocol data into a Food Composition Database using nut.s nutritional software [DATO DENKWERKZEUGE, 2010]. This work step is divided into many different sub processes.

The next step was to determine Critical Control Points (CCPs). A CCP is a point at which control can be implemented and is necessary to avoid or eliminate a hazard or to reduce it to a tolerable level [NATIONAL ADVISORY COMMITTEE ON MICROBIOLOGICAL CRITERIA FOR FOODS, 1997].
The following schedule shows the identified hazards and CCPs for which SOPs have been developed.

Hazards and CCPs

- Ambiguous foods or recipes in a protocol
    - Hazard: Entry of different foods or recipes by different data typists leads to biased results
        - CCP: Identification of standards
        - CCP: Documentation of standards
            - Documentation form
            - Database
        - CCP: Defining new standards whilst data entry

- Indistinct portion size in a protocol
    - Hazard: Entry of different portion sizes by different data typists leads to biased results
        - CCP: Identification of portion sizes
        - CCP: Documentation of portion sizes
            - Documentation form
        - CCP: Defining new portion sizes during data entry

- Problem report
    - Hazard: Data typists not knowing what has to be documented on the problem report or when the report has to be passed to the director of studies
        - CCP: Specification of handling of the problem report

- Standby time due to decision-making / Temporary solution
    - Hazard: Working process is stopped
        - CCP: Defining temporary solutions
            - Documentation of temporary solution
        - CCP: Final solution

Development of Standard Operating Procedures

A Standard Operating Procedure structures and regulates the work proceeded on a Critical Control Point. Its objective is to avoid or eliminate hazards and it is therefore a measurement of quality assurance [WESTENBRINK et al., 2009].
After having clarified which work steps need regulation, Standard Operating Procedures were developed for each Critical Control Point.
The regulated work steps were illustrated as flowcharts for better understanding.

Demonstration of operational procedures as flowcharts

Operational procedures can be displayed as flowcharts. This is an understandable and demonstrative method of illustrating working processes and sub processes as well as the connected points of decision. Flowcharts have the advantage that they can easily be understood by professionals as well as laymen.

Explanation of flowchart-symbols

Flowchart-symbols have different meanings. Each symbol stands for a different step in an operational procedure.
Generally there are symbols for:

- Process / Operation
- Data
- Connection between symbols
- Display assistance [RAINER, 1997]

Symbols relevant for this thesis will be described in the following.

The process symbol

The process symbol is a rectangular symbol in the middle of a flowchart.

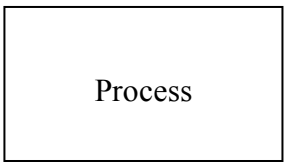


Figure 1: The process symbol

A process means a modification or transformation caused by a human being, the activity of a machine or a combination of both [RAINER, 1997].
The process symbol can display different activities:

- Compilation of data
- Transaction of data
- Insertion of machinery or other tools [BOHL, 1975]

Flow lines / Arrows

Arrows serve as connection between symbols, illustrate the order of operations and define the direction of the workflow [BOHL, 1975].

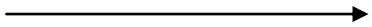


Figure 2: Arrow demonstrating the direction of workflow

If the direction is always from the left to the right or from the top to the bottom, it is possible to abdicate the arrowheads. To avoid misunderstanding it is recommended to always display the arrowheads [HARRINGTON, 1991].

Point of decision

The diamond symbol appears whenever a decision has to be made. Usually there are different alternative decisions illustrated by the corresponding number of continuative branches of the flowchart [RAINER, 1997].

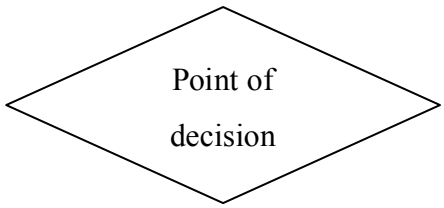


Figure 3: Symbol for a point of decision

The decision is typically formulated as question (for example: Is there a standard entry?). Possible answers are written next to the continuative process flow ("Yes" or "No") [RAINER, 1997].

Illustration of documents

This symbol is used whenever a document is used during the working process.

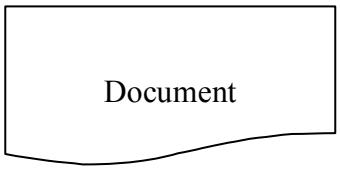


Figure 4: Symbol for the illustration of documents

The junction symbol

The junction symbol is used to display a connection from or to another part of the flowchart [BOHL, 1975]. Whenever an arrow points at this symbol, the process is continued elsewhere. When the arrow points away, this indicates the continuation of a process.

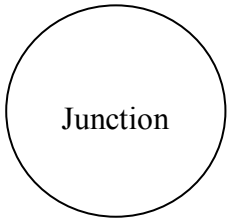


Figure 5: Junction symbol

The limiting symbol

This symbol indicates the beginning or ending of a workflow. The words “Start” and “Stop” are frequently written in this symbol [RAINER, 1997]. It is also possible to directly enter the work step or problem that initiates the CCP.

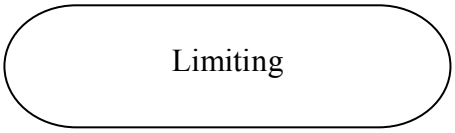


Figure 6: Limiting symbol

Development of examples

A Standard Operating Procedure is a very complex document and requires a high degree of concentration from its reader. To advance comprehensibility, it was decided to insert several examples. These examples demonstrate the practical application of the rather theoretical SOPs.

All examples are displayed in grey colored boxes.

Development of documents

Developing instructions for the use of a Food Composition Database in the field of Nutrition surveys not only meant generating the SOPs but also the corresponding documents. The necessity of developing particular documents arose during the preparation of the SOPs.

The following documents were generated together with the SOPs:

- Documentation form 1 (“Documentation of standards”)
- Documentation form 2 (“Documentation of defined portion sizes”)
- The problem report

Revision of SOPs and completion

After the completion of the first draft of SOPs, including documents and flowcharts, these were tested for comprehensibility and practicability by laymen and experts. Therefore it was necessary to develop an example study and a corresponding example protocol.

Development of example study

To guarantee that those problems the SOPs are dealing with, would really appear during testing, it was decided to develop an example including all these problems.
The example study includes:

- The first draft of SOPs including examples and flowcharts
- An example protocol
- Documentation form 1 ("Documentation of standards"), including example standards
- Documentation form 2 ("Documentation of defined portion sizes"), including example portion sizes
- A corresponding notepad entry
- A feedback form
- Problem reports for each test person
- Instructions on how to use the SOPs

The instructions, the example protocol, the feedback form as well as documentation form 1 and 2 are displayed in the following:

Annex

Instructions

First of all, I would like to thank you for reading and testing my Standard Operating Procedures (SOPs)!

- I developed a short example protocol to test the practicability of the present SOPs, which I would ask you to enter, using nut.s nutritional software.
- Please log in to the computer as user "diplomi5" with the password: diplom
- You will find the SOPs, documentation forms, the problem report, the example protocol and the feedback form under:_____.
- The notepad (Merkzettel) is a function you will need. Please contact Mag. Verena Nowak for installing the notepad file. (PCs that are already equipped with the notepad: F + H)
- The Flowcharts mentioned in the SOPs are saved as extra files.
- In the present example you will act as a data typist, whereas I am the director of studies.
- Please read the SOPs carefully and comment inconsistencies or ambiguities in the feedback form!
- Of course it is possible to give your feedback in German language..
- Enter the present example protocol using the necessary documentation forms and document appearing problems in the feedback form.
- Please save the entered protocol under your name (create a new person with your name).
- Please save the completed problem report and feedback form under your name and send them back to me via email: _____
- Finally you have to export your protocol to the server.
- If it is not possible to connect to the server save the protocol locally and send it to me via email.

Example Protocol

Name and subject of study	Protocol number
Example Study	EX0001
	Date
	19. 05. 2010

Meal	Amount	Food/Drink
BREAKFAST	2 Scheiben	Vollkornbrot
	2 TL	Butter
	2 TL	Konfitüre Marille/Aprikose
	250 ml	Tee
	2 TL	Zucker
SNACK	1 Glas	Wasser
	1 Stück	Banane
LUNCH	1 Stk (mittelgroß)	Kalbskotelett gedünstet
	60 g	Nudeln (gekocht)
	50 g	Gemüse
	1 Stück	Rosinenkuchen aus Rührmasse
	1 Glas	Fruchtsaft
SNACK	1 Stück	Apfel
	1 Tasse	Kaffee mit Milch
	1 TL	Zucker
DINNER	2 Scheiben	Toast
	100g	Mozarella
	50g	Tomaten
	2 Gläser	Wasser
	1 Becher	Fruchtjoghurt
SNACK	½ Glas	Milch

Feedback form

Name:	Date:

Please document each ambiguity, inconsistency or problem that occurs while reading and testing the Standard Operating Procedures! Please, be as precise as possible and document page numbers or chapter names when possible!

Have you been working with nut.s nutritional software before?_____

Documentation form 1 "Documentation of standards"

Name and subject of study Example Study		
Director of study _____ Title	Ingrid Name	Fürhacker Surname
Type of documentation within database ☐ Synonym ➔ _____ ☒ Notepad "Merkzettel"➔ Name of notepad: Ingrid Fürhacker		
Documentation completed Date 19.05.2010	Temporary Solution Entering a placeholder	

Basic or compound standard found in protocol or recipe	Food or recipe to be used as standard	BLS code of food or recipe to be used as standard
Vollkornbrot	Vollkornbrot – Weizen/Roggenvollkornbrot	B161011
Butter	Butter	Q610000
Tee	Tee (Getränk)	N600100
Zucker	Zucker weiß	S111000
Wasser	Trinkwasser	N110000
Nudeln	Teigwaren eifrei gegart	E420022
Saft	Obst Fruchtsaft	F000611
Kaffee	Kaffee (Getränk)	N410100
Kaffee mit Milch	Kaffee mit Milch (Getränk)	N410200
Toastbrot	Weißbrot-Toastbrot	B304000
Milch/Vollmilch	Kuhmilch	M110000

Documentation form 2 "Documentation of defined portion sizes"

Name and subject of study Example study		
Director of study ——— Title	Ingrid Name	Fürhacker Surname
Documentation completed Date 19. 05. 2010		Temporary Solution: Solution for indistinct portion sizes

Portion size documented in a protocol	Food or recipe	Weight or amount	Unit (g/ml)
1 Scheibe	Brot	50	g
1 TL	Butter	5	g
1 TL	Marmelade/Konfitüre	10	g
1 Tasse	Tee/Kaffee/Kakao...	250	ml
1 TL	Zucker	4	g
1 Glas	Wasser/Saft	250	ml
1 Stück	Banane	125	g
1 Stück	Fleisch klein	55	g
1 Stück	Fleisch mittel	110	g
1 Stück	Apfel	125	g
1 Becher	Joghurt	250	g

Testing of SOPs

Each test person was provided with the necessary documents and asked to complete the given exercise independently. After having completed the exercise the test persons had to report their experiences, appeared problems or misunderstandings in the feedback form.
Feedback forms and problem reports were then returned for evaluation.

Revision and completion of SOPs

The completed feedback forms and problem reports were evaluated with regard to

- Comprehensibility of SOPs
- Applicability of SOPs
- Occurred problems during the completion of the example study
- Misunderstandings in the implementation of the SOPs

Problematic sections of the SOPs were then revised and complemented.

Results

The aim of this thesis was the development of Standard Operating Procedures for the Use of a food composition database in the field of nutrition surveys.

A first draft of SOPs was developed and tested for comprehensibility and clearness by experts and laymen. Test persons had to complete an example including the errors that may occur during working with a FCDB. The testing phase showed that some adjustments and improvements had to be made.
Although each test person reported, that he/she had no problems understanding the instructions in the SOPs, one person could not detect all the errors included in the example study. It has therefore been decided to describe several chapters more clearly.
The testing phase showed that the SOPs needed more detailed information on what has to be documented. Some of the test persons had problems in understanding which information has to be documented in the problem report and therefore reported needless information.
Although the present SOPs can be applied by experts and laymen, it is useful to give inexperienced data typists a short introduction into general database work. The results from the testing showed that at least some experience is necessary to work with these SOPs correctly.

The SOPs were then revised based on the information gained during the testing phase. Examples were elaborated to increase comprehensibility and documents, as well as flowcharts were adjusted to resolve ambiguities.

The elaborated, reviewed and finalized SOPs are the result of this thesis and are displayed in the following.

Table of contents (SOPs)

General Introduction to SOPs

The present Standard Operating Procedures (SOPs) have been developed to facilitate the work with a Food Composition Database (FCDB) in the field of nutrition surveys. The paper is based on the database BLS 2.3.1 and nut.s science (nutritional software) [DATO DENKWERKZEUGE, 2010].

It is important to mention that the SOPs at hand cannot compensate for a basic instruction into data entry. General knowledge of how to enter data derived from nutrition surveys into a database is a precondition.

Based on a general knowledge of data entry, these SOPs can be applied for autonomous working. Therefore it is essential to read the SOPs, including flowcharts, attentively and, if necessary, repeatedly until the document is entirely understood. Particular chapters can be read over and over again whenever necessary.

When reading the present SOPs properly, the reader will notice that particular explanations recur several times. This is necessary due to the fact that the individual chapters have to be independently comprehensible.

Recommendations

- To guarantee the actuality of data included in a database, it is necessary to guarantee periodic maintenance. Before starting to work with a new database or software program it is suggestive to determine a staff member responsible for database maintenance as well as the time lag between database services.

- Where many different people are working with the same database or program it is more confident to equip people with different rights of access, according to their work with the database or program. Therefore it is recommended to use different passwords or access codes. This measure prevents modifications in the database by mistake and guarantees traceability of procedures.

Definitions

Project leader / head of department

The project leader or head of department is the highest ranking person in a team responsible for the collection of nutrition data.

Compiler

The compiler is responsible for inclusion and/or exclusion of relevant foods and food components, as well as additional information, in the Food Composition Data Base. The compilers work provides the basis for every working process necessitating the FCDB.

Director of studies

Each director of studies is responsible for at least one study, accomplished for or at the department of nutritional sciences. The director of studies can be represented by a staff member, a student carrying out his thesis or a graduate working on his dissertation.

Data entry

Data entry is usually carried out by students or staff members. Data entry includes entry of protocols collected during the course of a study as well as the insertion of recipes if necessary.
A person responsible for data entry will be called data typist in the following.

User

The user is a person or organisation working with data enclosed in the database. In the present case users are directors of studies as well as individuals involved in data entry.

Study

In the present case a study describes scientific research, in terms of thesis, dissertations or scientific surveys carried out for or at the department of nutritional sciences. Any such study is supervised by a director of studies.

Protocol

A protocol is a document containing information on what a subject has been eating in a fixed period and provides the basic information in every nutrition survey. It gives detail on the type and magnitude of the foods consumed. It is irrelevant if the food consumption data has been collected in a prospective or retrospective way.

List of abbreviations

BLS

Bundeslebensmittelschlüssel

FCDB

Food Composition Database

SOP

Standard Operating Procedure

Regulation of standards

Objective

In the course of a study it may be necessary to define certain standards, to assure homogeneity of data and to simplify data entry. The required standards may vary from study to study. (see: Example 1 and 2)

Therefore standards have to be designed separately for each study.

Example 1: Regulation of Standards

In a given protocol, the test person has recorded that he/she has been eating 100g of bread, without any further information on the type of bread.

Study A:

It has been decided to use "Graubrote / Brown breads" (BLS Code B200000) as standard for bread.

Study B:

It has been decided to use "Roggen/Weizen-Mischbrot mit Hefe / Brown bread made of rye and wheat with yeast" (BLS Code B880111) as standard for bread.

Example 2: Regulation of standards

In a given protocol, the test person has recorded that he/she has been drinking 250ml of cocoa for breakfast. There is no further information on the fat content of the milk, the brand or sort of cocoa or the mixing ratio of milk and cocoa powder.

Study A:

It has been decided to use "Kuhmilch / Cow´s milk" (BLS Code M110000) together with "Kakaopulver / cocoa powder" (BLS Code S710000) in a weight ratio of 10:1 as standard for cocoa.

Study B:

It has been decided to use "Milcherzeugnis mit Kakao/Schokolade / Milk product with cocoa/chocolate" (BLS Code M206011) as standard for cocoa.

Responsibilities

Data typist

- Has to follow the instructions of the director of studies
- Needs basic knowledge of data entry to work with these SOPs properly
- Has to follow the instructions in this SOP
- Has to enter appearing problems and ambiguities on the problem report, according to the instructions of this SOP
- Has to make sure that his/her entries are clear and unambiguous
- Has to check documentation forms and the "Synonym"- or Notepad function exactly, to avoid nonessential entries on the problem report
- Has to pass the problem report on to the director of studies as agreed, though by the end of the day at the latest
- Has to follow the instructions of the director of studies concerning the chosen temporary solution

Director of studies

- Has to follow the instructions of this SOP
- Makes sure that the data typist has the basic knowledge of data entry
- Ensures that the data typist has the necessary competences and information to follow the instructions in this SOP
- Makes sure that problems documented in the problem report are solved as soon as possible
- Informs data typists as soon as documentation forms have been updated
- Has to inform data typists about the temporary solution he/she wants to be used

Description of work

Identification of relevant standards

During the initial stage of a study, though before data entry at the latest, the director of studies has to define the basic standards, which may occur in every nutrition survey. (see: Example 3) Furthermore he/she has to make clear which foods and/or recipes are of great importance for the particular study (compound standards) (see: Example 4).

ATTENTION: It is not possible to define a standard for each food that may possibly occur during data entry. Basic standards, as well as compound standards, are meant as simplification-tools. Both, basic and compound standards only cover those foods that appear frequently in a particular study and often lead to misunderstanding.

Example 3: Basic Standards

Examples for Basic standards

- Bread
- Coffee
- Tea
- Milk
- Cheese
- Ham
- Nuts
- Salad
- …..

Example 4: Compound Standards

Examples for compound standards

Compound standards are foods or recipes that may occur in a study more frequently, because of the study's subject.

E.g.: Study subject is consumption of dairy products in Austria.

Compound standards in this case could be:

- Yoghurt
- Yoghurt with fruits
- Long-life milk
- Vanilla milk
- …

Usually it is possible to find similar foods in the database for those that have no defined standard. If there is no similar or comparable food in the database, this fact must as well be reported in the problem report (see: chapter "The problem report"). In this case the entry is skipped or a placeholder is entered and the chosen temporary solution also has to be reported in the problem report (see: chapter "Temporary solutions").

ATTENTION: Do not report every single food that cannot be found in the same wording in the database as in the protocol. Sometimes research is necessary to find the way a similar food is described in the database.

Documentation of standards

Settled standards have to be completely documented in documentation form 1 ("Documentation of standards") before data entry.

Documentation should always contain the following points:

- Name and subject of the study
- Name of director of studies
- Date of completion
- Temporary solution
- Common name of basic and/or compound standard
- Name of food or recipe to be used as standard
- BLS code of food or recipe to be used as standard
- Type of Documentation within the database

Documentation has to be accessible for every person involved in the study. Therefore it is recommended to distribute documentation forms via network.

Type of Documentation within the database

To simplify localisation of standards during data entry, nut.s science software provides two different methods [DATO DENKWERKZEUGE, 2010]. Both ways are described in the following. Due to reasons of simplicity, it is recommended to use the notepad (Merkzettel) method. Within one study, the chosen documentation system has to be maintained.

The chosen documentation method has to be quoted on documentation form 1 ("Documentation of standards").

Synonym function

Nut.s provides a feature called "Synonym" [DATO DENKWERKZEUGE, 2010]. Every entry in the database (foods and recipes) can be complemented by descriptions, words or abbreviations that simplify finding and specifying particular entries. (see: Example 5)

Example 5: „Synonym" function

There is no BLS entry for the typically Austrian roll, called "Semmel". In the nut.s system, "Semmel" has been attached as a synonym to the german expression "Brötchen / bun" (BLS Code B501000). If the word Semmel is now entered in the search function of BLS, the corresponding food can easily be found.

For defining standards, this feature can easily be used. Therefore a word like "standard" or an abbreviation like "st" can be entered in the column "Synonym". It is recommended to use the same word or abbreviation for every standard within one study. The chosen word or abbreviation has to be documented in documentation form 1 ("Documentation of standards").

The disadvantage of this method is that the used word or abbreviation has to be deleted for every food or recipe that has been supplied with an entry in the column "Synonym", after data entry is completed. This measure is necessary, because any entry in the column "Synonym" is visible for every person using nut.s nutritional software [DATO DENKWERKZEUGE, 2010] and future studies may be influenced and obstructed by former entries.

Therefore it is advisable to use the notepad or "Merkzettel" method as described below.

Notepad (Merkzettel) (recommended method)

Nut.s nutritional software offers the feature “Merkzettel”, which is called notepad in the following [DATO DENKWERKZEUGE, 2010].

Notepad offers the possibility to integrate all standards necessary for a study into one file.

The name of the notepad has to contain the name or code of the study as well as the word “standards”.

Example 6: Name of notepad (Merkzettel)

OESESkid_08 standards

It is not urgent to delete the notepad after data entry, because every study can have its own notepad. Furthermore, the findings from one study can be used for another one.

Defining new standards whilst data entry

The following steps are displayed as flow charts in flowchart 1 for the definition of new standards whilst data entry.

Numbers in rectangular brackets are linked with the according steps in the flow chart.

Steps [1-7] of the flowchart for the definition of new standards whilst data entry are carried out by data entry.

Possibly it may become necessary to define further standards whilst data entry. This may be the case when an ambiguous food or recipe, which has not yet been supplied with a standard entry, is detected during data entry. [1]

Example 7: Defining new standards whilst data entry

> In a given protocol, the test person has recorded that he/she has been eating 23g of cheese, without any further information on the type or fat content of the cheese.
> There is no defined standard for cheese in the notepad or the column "Synonym", accompanying the particular study [2]. Furthermore there is no entry in documentation form 1 ("Documentation of standards") [3].

If a standard entry can be detected in step [2] or [3], data entry can be continued using the appropriate standard→ [4].

If there is no appropriate standard in the notepad or the column "Synonym" [2] but in documentation form 1 [3], the director of studies should be informed about the missing entry. This fact has to be documented in the problem report [5].

Document in problem report: Document the standard entry found in documentation form 1, including basic or compound standard, full name of the food or recipe used as standard and BLS Code.

If there is no standard entry found in the notepad or as synonym and no entry in documentation form 1, this has to be documented in the problem report [6].

Document in problem report: The report has to contain the ambiguous entry of a food or recipe in the protocol. Furthermore it is necessary to enter the code number of the protocol (or the numbers of each protocol if the same entry is found in different protocols) and to describe the problem itself.

Example 8: Defining new standards whilst data entry - problem report

Protocol number	Description of the problem	Decision
dairy102	Protocol contains the food "cheese" without any further description There is no standard entry for "cheese" in the notepad. There is no standard entry for "cheese" in documentation form 1.	

This is the point where data typists have to be provided with a temporary solution. The temporary solution is described in the chapter "Temporary solutions" and is documented in documentation form 1 ("Documentation of standards").

The problem report has to be passed on to the director of studies [7]. This has to be done by the end of the day at the latest. Before data entry the director of studies should decide whether he/she wants the data typists to pass the problem report on to him/her whenever a problem appears or if he/she wants to receive the report at the end of the day.

Steps [8-12] of the flowchart for the definition of new standards whilst data entry are carried out by the director of studies.

After having received the information on the missing standard entry [8] the director of studies has to decide which food or recipe should be used as standard [9]. It is of great importance to go ahead with this step as soon as possible. To avoid stagnation of workflow, data typists have to be provided with a temporary solution in the meantime. The importance of the temporary solution is pointed out in the chapter “Temporary solutions”.

The director of studies is responsible for entering the new standard in documentation form 1 (“Documentation of standards”) [10] as well as in the notepad or the column “Synonym” [11], depending on the chosen method.
Furthermore it is important to inform data typists about the existence of a new standard as soon as possible [12]. This information can easily be passed on via email.

Regulation of portion sizes

Objective

Protocols completed during the execution of a study can contain indistinct information on the portion size consumed (Of course this is not the case when using weighted food records).

Ambiguous or undefined declaration of portion size may lead to different entries by different data typists, and therefore leads to incorrect results.

The sources used for the definition of portion sizes may vary from study to study. It is therefore necessary to specify which sources are to be used as standards for a particular study.

Example 9: Indistinct portion sizes

- A protocol contains the entry „1 slice of white bread“ without any further description of the size or thickness of the slice.
- A protocol contains the entry “1 cup of tea” without any further description of the cups size or filling capacity.
- A protocol contains the entry “1 plate of cooked noodles” without any further description of the size or charging of the plate.

Responsibilities

Data typist

- Has to follow the instructions of the director of studies
- Has to follow the instructions in this SOP
- Has to enter appearing problems and ambiguities on the problem report, according to the instructions of this SOP
- Has to make sure that his/her entries are clear and unambiguous
- Has to check documentation forms exactly, to avoid nonessential entries on the problem report
- Has to pass the problem report on to the director of studies as agreed, though by the end of the day at the latest
- Has to follow the instructions of the director of studies concerning the chosen temporary solution

Director of studies

- Has to follow the instructions of this SOP
- Ensures that the data typist has the necessary competences and information to follow the instruction in this SOP
- Makes sure that problems documented in the problem report are solved as soon as possible
- Informs data typists as soon as documentation forms have been updated
- Has to inform data typists about the temporary solution he/she wants to be used

Description of work

Identification of relevant portion sizes

During the initial stage of a study, though before data entry at the latest, the director of studies has to define the basic portion sizes, which may occur in every nutrition survey. Furthermore he/she has to make clear which portion sizes are of great importance for the particular study.

Example 10: Definition of portion sizes

Example for different portion sizes that need to be defined:

- A slice
- A plate
- A spoon
- A cup
- A glass
- A can
- A pot
- A piece
- ….

It is necessary to define not only the size of a particular portion, but also to pull together the portion size with a specific food.

Example 11: Portion sizes and specific foods

- For example, a slice of bread does not necessarily always have the same size or weight. An average slice of wholegrain bread and an average slice of white bread usually do not have the same weight and size.
- Soup in a soup plate, for example, does not always have the same weight. An average plate of creamy soup (potage) and watery soup do not have the same weight.

Documentation of defined portion sizes

Settled portion sizes have to be completely documented in documentation form 2 ("Documentation of defined portion sizes") before data entry.

Documentation should always contain the following points:

- Name and subject of the study
- Name of director of studies
- Date of completion
- Temporary solution
- Common name of portion size and the corresponding food or food group
- Weight or amount that has to be used as standard
- The unit of the defined portion size – "g" or "ml"

Documentation has to be accessible for every person involved in the study. Therefore it is recommended to distribute documentation forms via network.

Defining new portion sizes during data entry

Due to the fact that a portion size has not been defined and documented before the beginning of data entry, it may be necessary to define new portion sizes during data entry.

The following steps are displayed as flow charts in flowchart 2 for the definition of portion sizes whilst data entry.

Numbers in rectangular brackets are linked with the according steps in the flow chart.

Steps [1-5] of the flowchart for the definition of portion sizes whilst data entry are carried out by data typists.

Example 12: Defining new portion sizes whilst data entry

- A protocol contains the entry „2 pieces of milk chocolate". There is no standard entry for a piece of chocolate in documentation form 2 ("Documentation of defined portion sizes"). [1]
- Another protocol contains the entry "1 spoon of honey". There is no standard entry for a spoon of honey in the documentation form 2 ("Documentation of defined portion sizes"). [1]

Whenever the data typist does not know which portion size to enter, due to an indistinct description, it is necessary to check documentation form 2 ("Documentation of defined portion sizes") accurately. [2]

If the appropriate entry is found in documentation form 2 ("Documentation of defined portion sizes") [3], data entry has to be continued immediately, entering the corresponding portion size.

If there is no appropriate entry in documentation form 2 ("Documentation of defined portion sizes"), the data typist has to document the missing portion size on the problem report [4].Therefore it is necessary to indicate the expression for the portion size as well as the food, used in the protocol. It may be important to include other foods and portion sizes documented in the protocol, to clarify which portion size is needed.

Example 13: Documentation of indistinct portion sizes in problem report

A protocol contains the entry "Butter", without any further description of the portion size. The next entry in the protocol is "one slice of dark bread (50g)". In this case it is necessary to document "butter" as well as "one slice of dark bread (50g)", because it can be presumed that bread and butter have been eaten together.

This is the point where data typists have to be provided with a temporary solution. The temporary solution is described in the chapter “Temporary solutions” and is documented in Documentation form 2 (“Documentation of defined portion sizes”).

The problem report has to be passed on to the director of studies [5]. This has to be done by the end of the day at the latest. Before data entry the director of studies should decide whether he/she wants the data typists to pass the problem report on to him/her whenever a problem appears or if he/she wants to receive the report at the end of the day.

Steps [6-9] of the flowchart for the definition of portion sizes whilst data entry are carried out by the director of studies.
After having received the information on the missing portion size entry [6] the director of studies has to decide which source should be used to define the new standard portion [7]. It is of great importance to go ahead with this step as soon as possible.

To avoid stagnation of workflow data typists have to be provided with a temporary solution in the meantime. The importance of the temporary solution is pointed out in the chapter “Temporary solutions”.

The director of studies is responsible for entering the newly defined portion size in documentation form 2 (“Documentation of defined portion sizes”) [8].
Furthermore it is important to inform data typists about the existence of a new entry as soon as possible [9]. This information can easily be passed on via email.

The problem report

Objective

The problem report is a document necessary for the documentation of problems appearing during data entry. It is a tool that simplifies the communication between data typists and the director of a study.

During data entry numerous problems may appear.

Example 14: Problems during data entry

- Ambiguous foods or recipes without any further description appearing in a protocol. There is no appropriate standard entry.
- A standard entry is found in documentation form 1 ("Documentation of Standards") but is missing in the notepad or the column "Synonym".
- A food or recipe in a protocol is described clearly, but there is no suitable entry in the database.
- A protocol contains an indistinct portion size

Responsibilities

Data typist

- Has to follow the instructions of the director of studies concerning the use of the problem report precisely
- Has to make sure that he/she understands the basic rules of data entry to avoid misleading or unnecessary entries in the problem report.
- Has to report every problem appearing during data entry that cannot be solved by him/herself using the present SOPs
- Has to report every problem when he/she is told to by the instructions in the present SOPs
- Has to make sure that his/her entries are clear and unambiguous
- Has to pass the problem report on to the director of studies as agreed, though by the end of the day at the latest.

Director of studies

- Has to follow the instruction in this SOP
- Has to make sure that the data typist knows the basic rules of data entry
- Makes sure, that data typists have the necessary information on the importance of the problem report
- Ensures that data typists receive appropriate training to use the problem report correctly
- Has to inform data typists how and when he/she wants to be informed about the appearance of a problem
- Has to solve every problem documented in the problem report as soon as possible
- Has to provide a temporary solution to the data typist so that he/she is able to continue data entry

Description of work

The problem report always has to contain the following points:

- Name of data typist
- Date
- Name and subject of the study
- Name of director of studies
- The number or code of the concerned protocol
- A clear and unambiguous description of the problem
- A note, that the corresponding SOP has been followed
- The decision of the data typist according to the instruction he/she has been given by the director of studies or by an SOP

Ambiguous food or recipe without corresponding standard entry

The procedure that is carried out when an ambiguous food or recipe is not clearly specified in a protocol and an appropriate standard entry is missing, is described step by step in the chapter "Regulation of standards" and illustrated in flowchart 1 ("Flowchart for the definition of new standards whilst data entry").

Document in problem report: Enter the ambiguous food or recipe in the problem report and specify the occurred problem. Document the protocol number as well. Specify the food or recipe that has been added as temporary solution, including BLS Code and denomination.

ATTENTION: Basic and compound standards are only necessary for those foods or recipe that occur frequently in protocols and need further declaration to avoid misleading entries. It is not necessary to define a standard for each food or recipe that does not literally appear in the database.

Standard entry is missing in notepad or "Synonym"

The detailed procedure is described in the chapter "Regulation of standards" and demonstrated in flowchart 1 ("Flowchart for the definition of new standards whilst data entry").

Document in problem report: Document the standard entry found in documentation form 1 ("Documentation of standards"), including basic or compound standard, full name of the food or recipe used as standard and BLS Code.

No suitable entry in the database

Usually it is possible to find a corresponding or similar entry in the database for each food or recipe that has no standard entry (see: chapter "Regulation of standards"). The data typist has to do some research, if necessary, to find an appropriate entry in the database.

In some cases there will be no comparable food or recipe in the database or the available entry is not similar enough.

Example 15: No suitable entry in the database

A protocol contains the entry „Stifado" without any further description. The data typist has found out that "Stifado" is a greek stew with beef, tomatoes and onions.

There is no corresponding food or recipe in the database.

- The data typist has two options:
  - Skipping this food / recipe and making a corresponding note in the problem report
  - Finding a "placeholder" – for example a vegetable stew, onions and beef as separate entries. This decision has to be recorded in the problem report

The data typist has to decide which option he wants to choose. Whenever possible a "placeholder" should be added rather than skipping the entry. Whatever decision is made, a corresponding note in the problem report is essential.

Document in problem report: Document the food or recipe in the problem report literally. Specify the protocol number and the chosen method, including BLS Code and denomination of the selected food or recipe.

ATTENTION:. Do not report every single food or recipe that does not literally appear in the database.

Example 16: Similar food with other denomination

A protocol contains the entry: „Banana“
It is not necessary to report that the data typist has chosen “Banane frisch / Banana fresh” (BLS Code F503111) although the entry in the database has another name than the entry in the protocol.

Indistinct portion size

The procedure that has to be implemented when a protocol contains an indistinct portion size is described in the chapter “Regulation of portion sizes” and illustrated in flowchart 2 (“Flowchart for the definition of portion sizes whilst data entry”).

Document in problem report: Document missing portion sizes including the related food or recipe and the portion size that has been added as temporary solution. Enter the protocol number as well.

Example 17: Problem report

1. A protocol (code: dairy079) contains milk with a fat content of 1%. There is no corresponding or similar food in the database.
2. Another protocol corresponding to the same study (code: dairy031) contains the entry "Yoghurt" without any further description. There is no standard entry as a synonym, in the notepad or documentation form 1.
3. A protocol (code: dairy114) contains the entry "Cheese" without any further description. There is a standard entry in documentation form 1, but not in the notepad or as a synonym.

Problem report

Name of data typist Franziska Name	Hummer Surname	**Date** 14. 3. 2009
Name and subject of study Consumption of dairy products in Austria		
Director of study Mag. Title	Marianne Name	Feuer Surname

Protocol number	**Description of the problem**	**Decision**
Dairy079	Milk containing 1% fat no corresponding entry in database	Entry skipped – no similar food found
Dairy031	Yoghurt no description No standard entry found in notepad and documentation form 1	Placeholder entered M140000 Joghurt Oberbegriff
Dairy114	Cheese Standard entry present in documentation form 1, but missing in notepad (or the column "Synonym").	M400000 Schnittkäse According to existing entry in documentation form 1

Temporary Solutions

Objective

In many cases it will be necessary to provide data typists with temporary solutions to guarantee a fluent workflow. Whenever a problem appears, that leads to an interruption of data entry, the problem has to be documented in the problem report, as described in the chapter “The problem report”.

After having passed the problem report to the director of studies, he/she will decide how the problem can be solved. In some cases this decision may take some time and data entry cannot be continued without the availability of an interim solution.

Example 18: Circumstances that require a temporary solution

- A protocol contains ambiguous foods or recipes without any further description. There is no appropriate standard entry. This fact has been documented in the problem report. The problem report has been forwarded to the director of studies. The director of studies has to decide which food or recipe should be used as standard. Until he/she has come to a decision, data typists need a temporary solution.
- A food or recipe in a protocol is described clearly, but there is no suitable entry in the database. This problem has been documented in the problem report. The problem report has been forwarded to the director of studies. The director of studies has to decide if it is necessary to enter a new food or recipe in the database. Until he/she has made a decision, data typists need a temporary solution. Especially when the entry of a new food or recipe in the database is required, it is necessary to provide data typists with a temporary solution, due to the fact that it can take long time to achieve data on new foods or recipes.
- A protocol contains an indistinct description of the portion size consumed. This problem has been documented in the problem report. The problem report has been passed on to the director of studies. The director of studies has to decide which portion size should be used as a standard portion size. Until he/she has come to a solution, data typists need a temporary solution.

Responsibilities

Data typist

- Has to document every standard, portion size, food or recipe that is needed for data entry, in the problem report
- Has to pass the problem report on to the director of studies as agreed, though by the end of the day at the latest.
- Has to follow the instructions of the director of studies concerning the chosen temporary solution (documented in documentation form 1 ("Documentation of standards") and documentation form 2 ("Documentation of defined portion sizes").
- Has to do research (for example on the internet) to find the appropriate temporary solution (especially if comparable foods or recipes are the chosen method)
- Has to document the food or recipe used as temporary solution on the problem report, in the column "Decision"
- Has to correct the entry, when the director of studies has come to a final solution

Director of studies

- Has to choose a type of temporary solution
- Has to inform data typists about the chosen type of temporary solution before they start working (documented in documentation form 1 ("Documentation of standards") and documentation form 2 ("Documentation of defined portion sizes")).
- Has to document the chosen method of temporary solution in the documentation form for the definition of standards (documentation form 1) as well as in the documentation form for portion sizes (documentation form 2).
- Has to inform data typists when he/she has come to a final decision which food or recipe should be entered
- Has to inform data typists which food or recipe should be used as standard
- Has to inform data typists which portion size should be used as standard
- Has to inform the compiler when a new food or recipe has to be entered in the FCDB

Compiler

- Has to enter a new food or recipe in the FCDB as soon as possible

Description of work

The steps described below are displayed as flow charts (Flowchart 3 “Entering new foods or recipes in the FCDB”, Flowchart 4 “Entering new standards in the FCDB” and Flowchart 5 “Defining new portion sizes”).
Numbers in rectangular brackets are linked with to the according step in the flow chart.

Flowchart 3: “Entering new foods or recipes in the FCDB”

When the director of studies is informed about the need of a new food or recipe in the problem report [1], he she has to decide [2] if it is really necessary to enter a new food/recipe or if an existing entry should be used instead. If it is necessary to enter a new food or recipe in the database [4], the director of studies has to inform the compiler about this need. In the case of a decision against entering a new food or recipe, the director of studies has to decide, which entry should be used instead [5]. Data typists need to be informed about this decision straight away [6].
In both cases it is necessary, that data typists know exactly what to do in the meantime [3], so that data entry can be continued immediately. The temporary solution is documented in documentation form 1 (“Documentation of standards”).

Flowchart 4: "Entering new standards in the FCDB"

Steps [1-6] of the flowchart for entering new standards correspond to steps [8-12] of flowchart 1 ("Flowchart for the definition of new standards whilst data entry").

After having received the information on the missing standard entry [1] the director of studies has to decide which food or recipe should be used as standard [2].It is of great importance to go ahead with this step as soon as possible. The director of studies is responsible for entering the new standard in documentation form 1 ("Documentation of standards") [4] as well as in the notepad or the column "Synonym" [5], depending on the chosen method.

Furthermore it is important to inform data typists about the existence of a new standard as soon as possible [6]. This information can easily be passed on via email.

Data typists need to know which food or recipe should be entered while waiting for the new standard entry. Therefore it is important to provide them with a temporary solution [3]. The temporary solution is documented in documentation form 1 ("Documentation of standards").

Flowchart 5: "Defining new portion sizes whilst data entry

Steps [1-5] of the flowchart for defining new portion sizes correspond to steps [6-9] of flowchart 2 for the Definition of new portion sizes whilst data entry.

When the director of studies is informed of an indistinct portion size [1], he/she has to decide which portion size should be used as standard [2]. In the meantime he/she has to provide data typists with a temporary solution [3]. The temporary solution is documented in documentation form 2 ("Documentation of defined portion sizes").

After having decided which portion size should be used, the director of studies has to document his decision on the documentation form 2 ("Documentation of defined portion sizes") [4]. Finally he/she has to inform data typists about the existence of a new portion size [5].

Defining temporary solutions

The following section corresponds to step [3] of flowchart 3 “Entering new foods or recipes in the FCDB”, flowchart 4 “Entering new standards in the FCDB” and flowchart 5 “Defining new portion sizes”.

There are different types of temporary solutions. The possible solutions are described in the following. The chosen method has to be documented in the corresponding documentation form. It is possible to choose different solutions for portion sizes and standards.
Regardless which type of temporary solution is used, data typists always have to document the interim solution in the problem report.

ATTENTION: Not every temporary solution is suitable for every problem! Indistinct portion sizes and missing standards may need different solutions!

Skipping a food or recipe

It is possible to omit a food or recipe that has been documented in a protocol. This means that the corresponding food or recipe is simply not entered in the database while data entry.
In this case the data typist has to make a note in the problem report in the column “Decision”. This note should be short and unambiguous.

Example 19: Skipping a food or recipe

A protocol contains the entry: “Chocolate-banana yoghurt, 5% fat”

Protocol number	Description of the problem	Decision
oeses_kid023	Chocolate-banana yoghurt with 5% fat; no corresponding entry in the database	Entry skipped

This type of temporary solution can also be used if a food or recipe is not clearly described in the protocol and there is no standard entry or if the portion size is unclear.

Example 20: Skipping a food or recipe

Example:
A protocol contains the entry "Yoghurt" without any further description. There is no corresponding standard entry in documentation form 1 ("Documentation of Standards"), the column "Synonym" or the notepad (depending on the chosen type of documentation)

Protocol number	Description of the problem	Decision
Dairy_112	Yoghurt; no description no standard entry found	Entry skipped

Solution for indistinct portion sizes

ATTENTION: This method is not suitable for missing standard entries!

This temporary solution can be used whenever a portion size is not clearly defined.
Nut.s nutritional software offers the possibility to enter an exact declaration of weight as well as a portion, which is a predetermined weight for every food or recipe [DATO DENKWERKZEUGE, 2010]. This standard weight can be used as temporary solution, and if necessary, as final solution as well.
The data typist has to make a note in the problem report in the column "Decision".

Example 21: Temporary solution for indistinct portion sizes

A protocol contains the indistinct portion size "one plate of noodles". There is no standard portion size for one plate of cooked pasta.

Protocol number	Description of the problem	Decision
oeses_kid123	One plate of noodles No further description of the portion size	One portion entered

Entering a comparable food or recipe

In this case a food or recipe, that is similar to the original entry in the protocol, is entered in the meantime.

The data typist has to find an entry in the database that can be compared to the food or recipe in the protocol. Here the focus can be on different ingredients, depending on the study goal.

ATTENTION: This method is not suitable for indistinct portion sizes!

Example 22: Entering a comparable food or recipe

If the study goal is to collect data on the fat intake of a population, it is useful to concentrate on a comparable food or recipe with a nearly similar fat content.

Protocol number	Description of the problem	Decision
Fat_404	Birnenstrudel; not found in the database; no standard entry	Comparable recipe: Wiener Apfelstrudel BLS Code: D540111

Whenever a comparable food or recipe is used as temporary solution, the director of studies can decide to turn the temporary into the final solution. Therefore it is necessary to find the food or recipe that is the closest to the original protocol entry.
It is not recommended to use this type of temporary solution when a new standard entry is needed.

The data typist has to make a note on the problem report in the column "Decision". The note should contain the chosen food or recipe with a short explanation.

Entering a "placeholder"

The placeholder can be used as temporary solution or alternative to a comparable food or recipe, if there is no entry in the FCDB that can be compared to the entry in the protocol.
The placeholder can also be used as temporary solution if there is no corresponding standard entry to an ambiguous food or recipe.

ATTENTION: This method is not suitable for indistinct portion sizes!

The placeholder is always the next higher generic term of the food group where the protocol entry belongs to.

Entering a placeholder is the method of choice when the data typist cannot find an entry corresponding or similar to the food or recipe in the protocol.

Example 23: Entering a placeholder

- A protocol contains the entry: “Bread containing tomatoes”. There is no entry of a bread with tomatoes in the database. Due to some research the data typist found out, that Bread containing tomatoes is always a white bread. He/she decides to enter the next higher generic term “White breads” (Weißbrote; BLS Code: B300000)
- A protocol contains the ambiguous entry: “Bread” without any further description. There is no standard entry in documentation form 1 (“Documentation of Standards”), the notepad or the column “Synonym” (depending on the chosen type of documentation).

Protocol number	Description of the problem	Decision
Bread_238	Bread with tomatoes; no corresponding entry found in database	White breads (Weißbrote) entered BLS Code: B300000
Bread_123	Contains “Bread” without any further description; no standard entry found in notepad and documentation form 1	“Graubrote” entered BLS Code B200000

Whenever a placeholder is used as temporary solution, the director of studies can decide to turn this temporary into the final solution. Therefore it is necessary to find the generic term that is the closest to the original entry in the protocol.

The data typist has to make a note on the problem report in the column “Decision”. The note should contain the chosen generic term and the BLS code.

Entering the final solution

The final solution is the food, recipe or portion size that is entered in the database instead of the temporary solution. Unlike the temporary solution, the final solution is meant to remain permanently. The director of studies has to inform data typists about the existence of a final solution immediately.

The final solution may be:

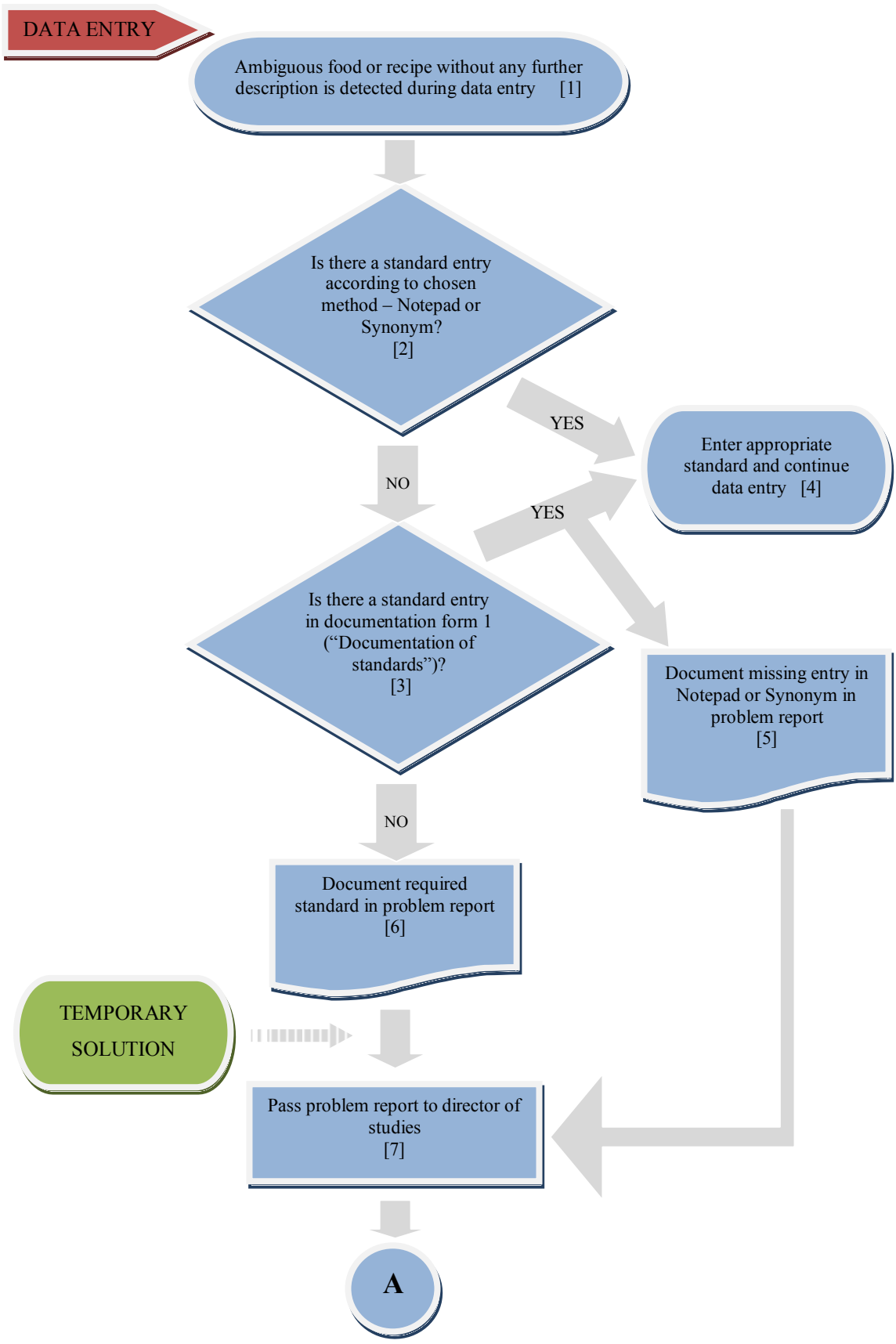
- A new food or recipe has been entered to the database
- The temporary solution is used as final solution (exception: skipping a food or recipe)
- Another food or recipe than the one used as temporary solution has been chosen as final solution
- A new standard has been defined and entered in documentation form 1 ("Documentation of standards") and the column "Synonym" or the notepad (depending on the chosen type of documentation).
- A newly defined portion size has been entered in documentation form 2 ("Documentation of defined portion sizes")

It is essential that all data typists are informed about the final decisions made by the director of studies. The director of studies has to instruct one of the data typists to correct the temporary solution if necessary (or correct the temporary entry himself).
The selected data typist (or the director of studies) has to replace the temporary solution with the final solution. He/She has to document this correctional measure within the corresponding entry in the problem report (see: Example 24).

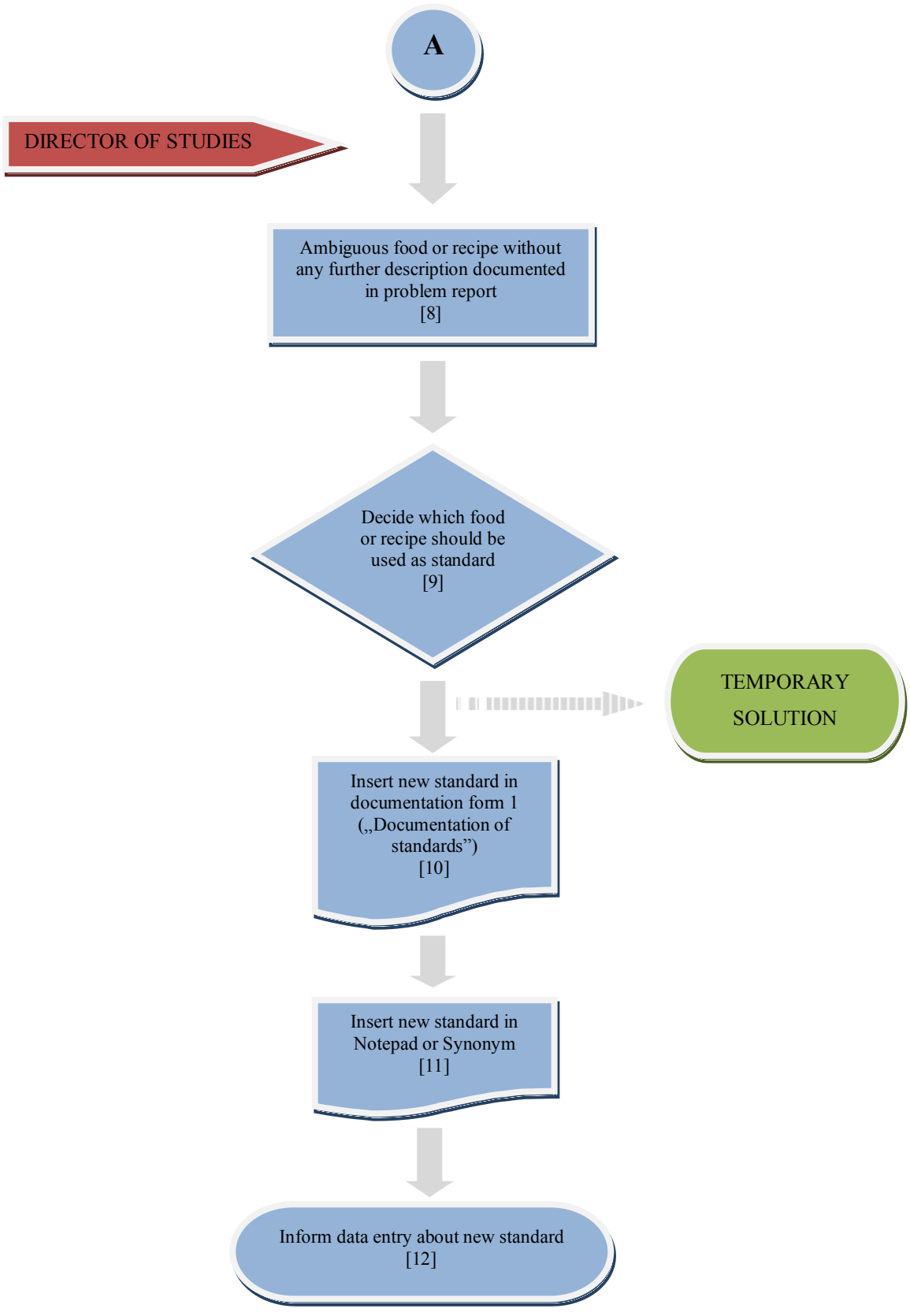
Example 24: Entering the final solution

Protocol number	Description of the problem	Decision
Bread_238	Bread containing tomatoes; no corresponding entry found in database	White breads / Weißbrote entered BLS Code: B300000 Replaced by new food: Tomato bread BLS…….
Bread_123	Contains "Bread" without any further description; no standard entry found in notepad and documentation form 1	Brown breads / Graubrote entered BLS Code: B200000 Replaced by new standard: Brown breads made of rye and wheat / Roggen/Weizen Mischbrot BLS Code: B880111

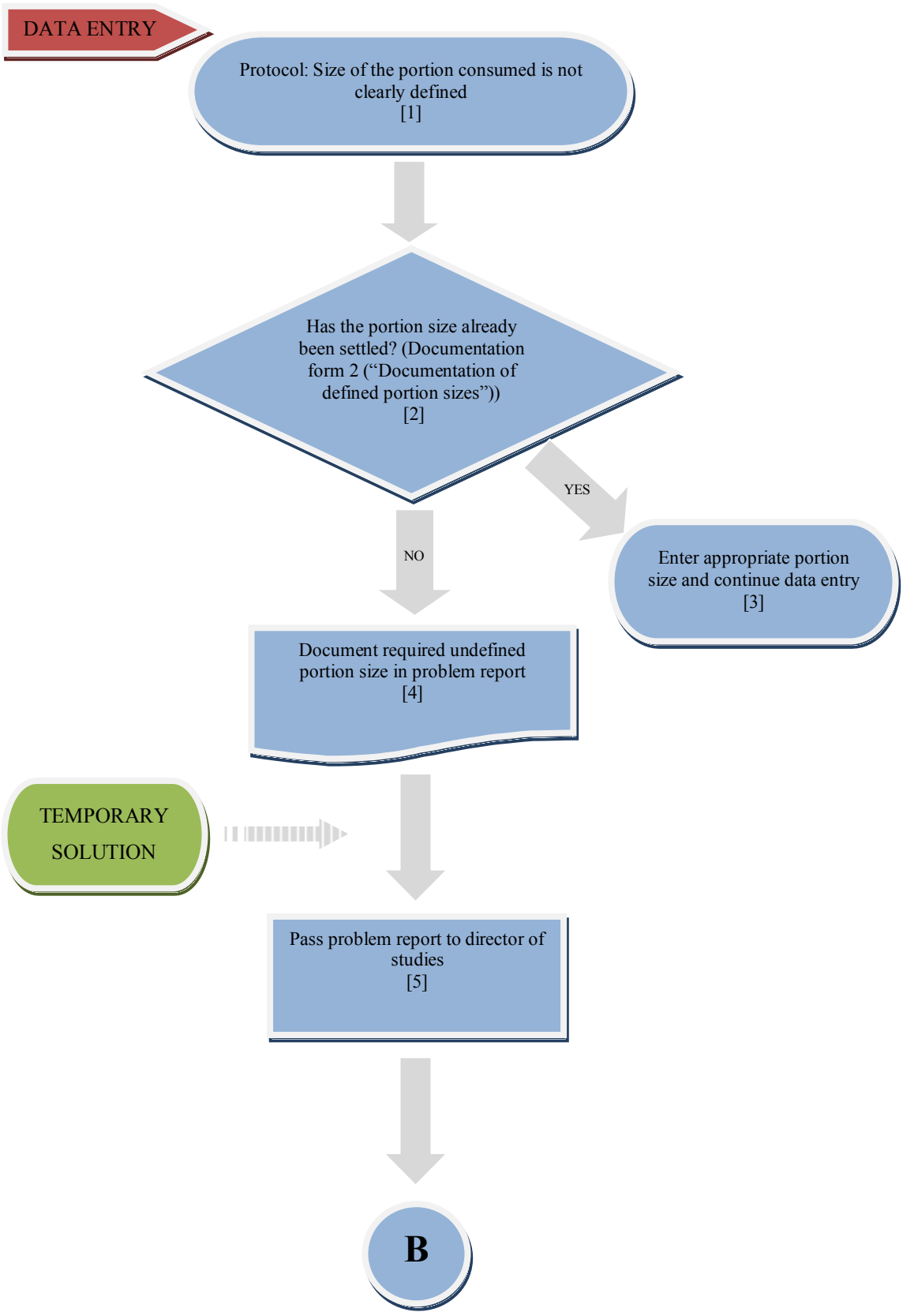
Flowchart 1 for the definition of standards whilst data entry



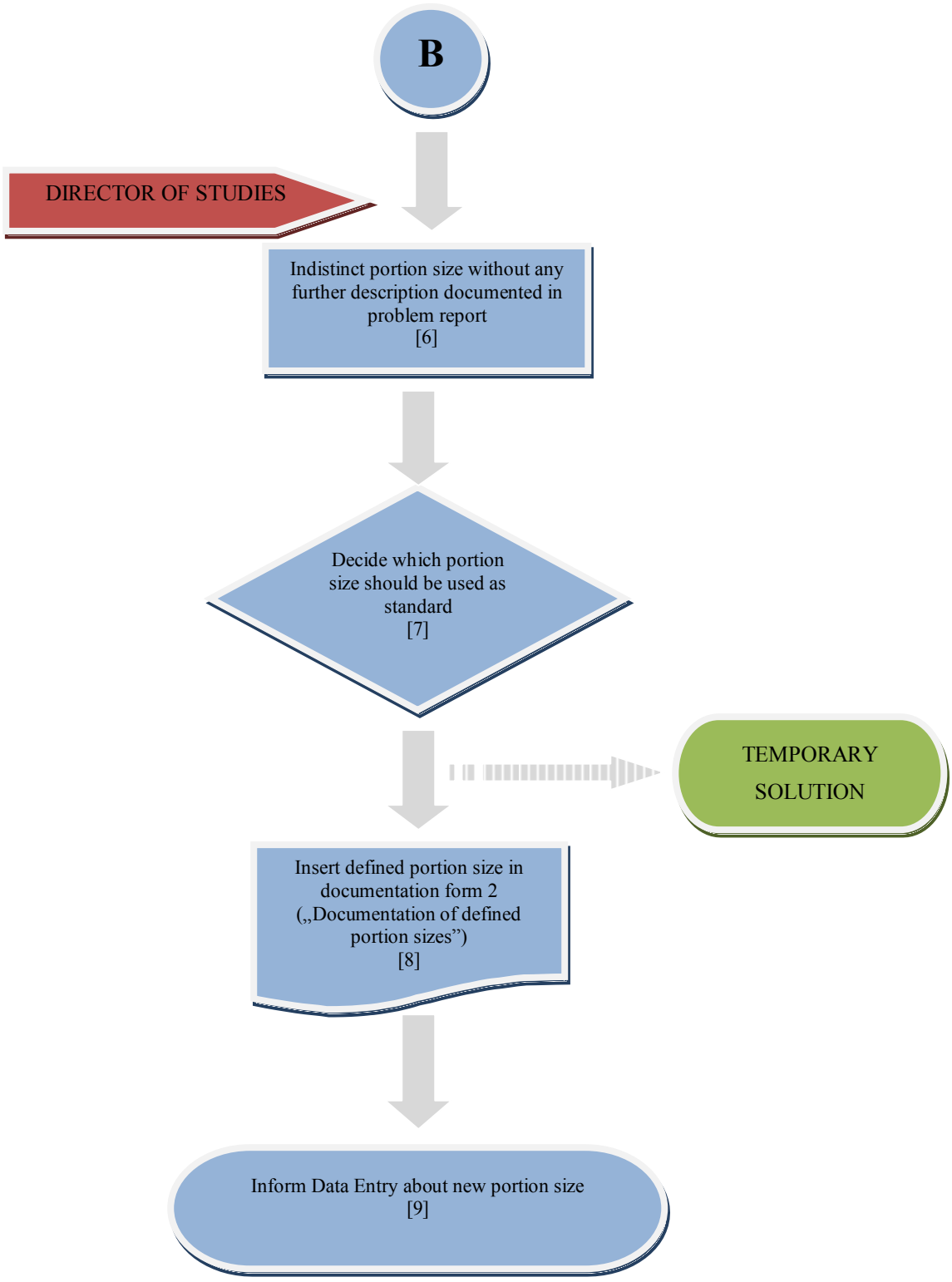
Flowchart 1 for the definition of standards whilst data entry



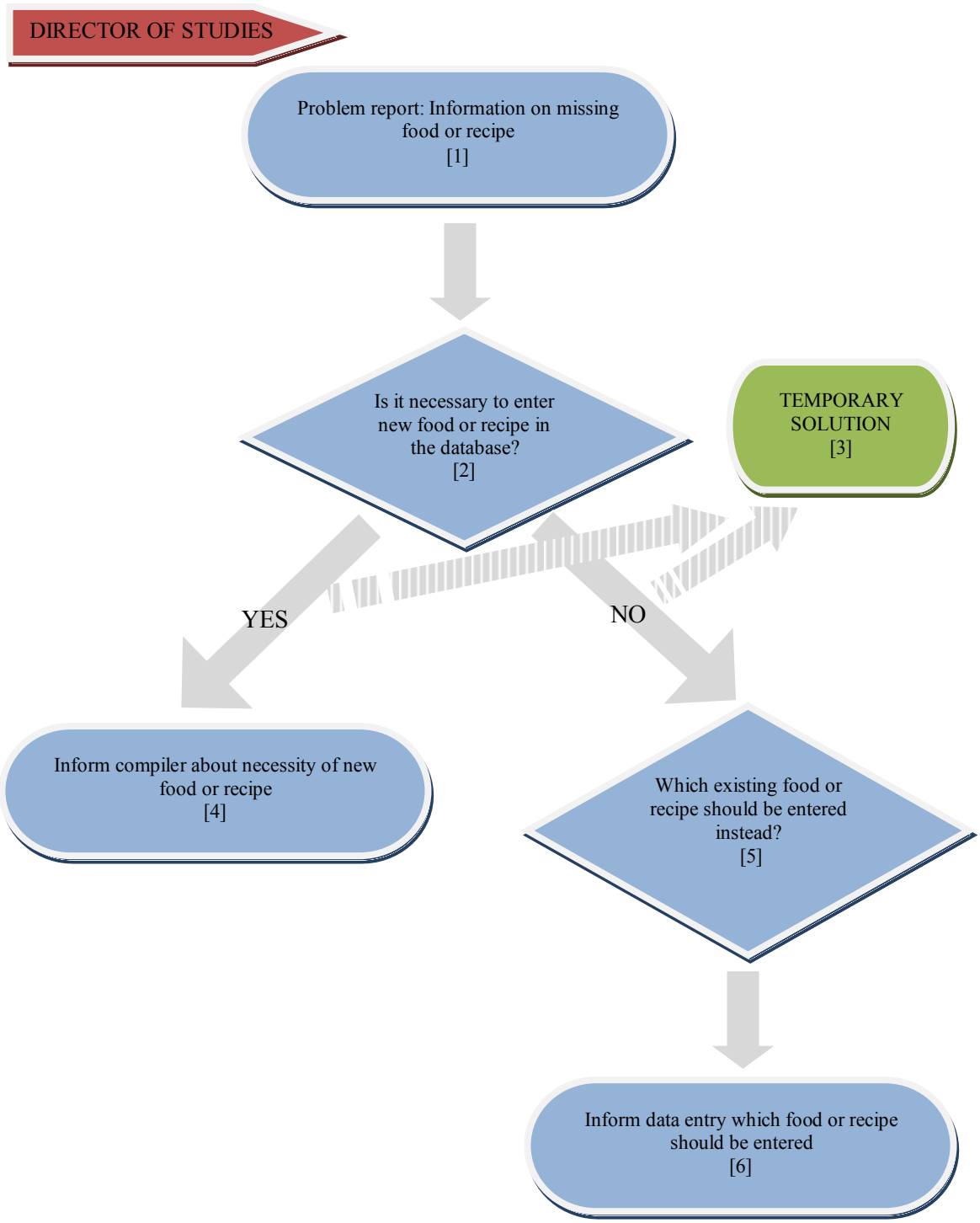
Flowchart 2 for the definition of portion sizes whilst data entry



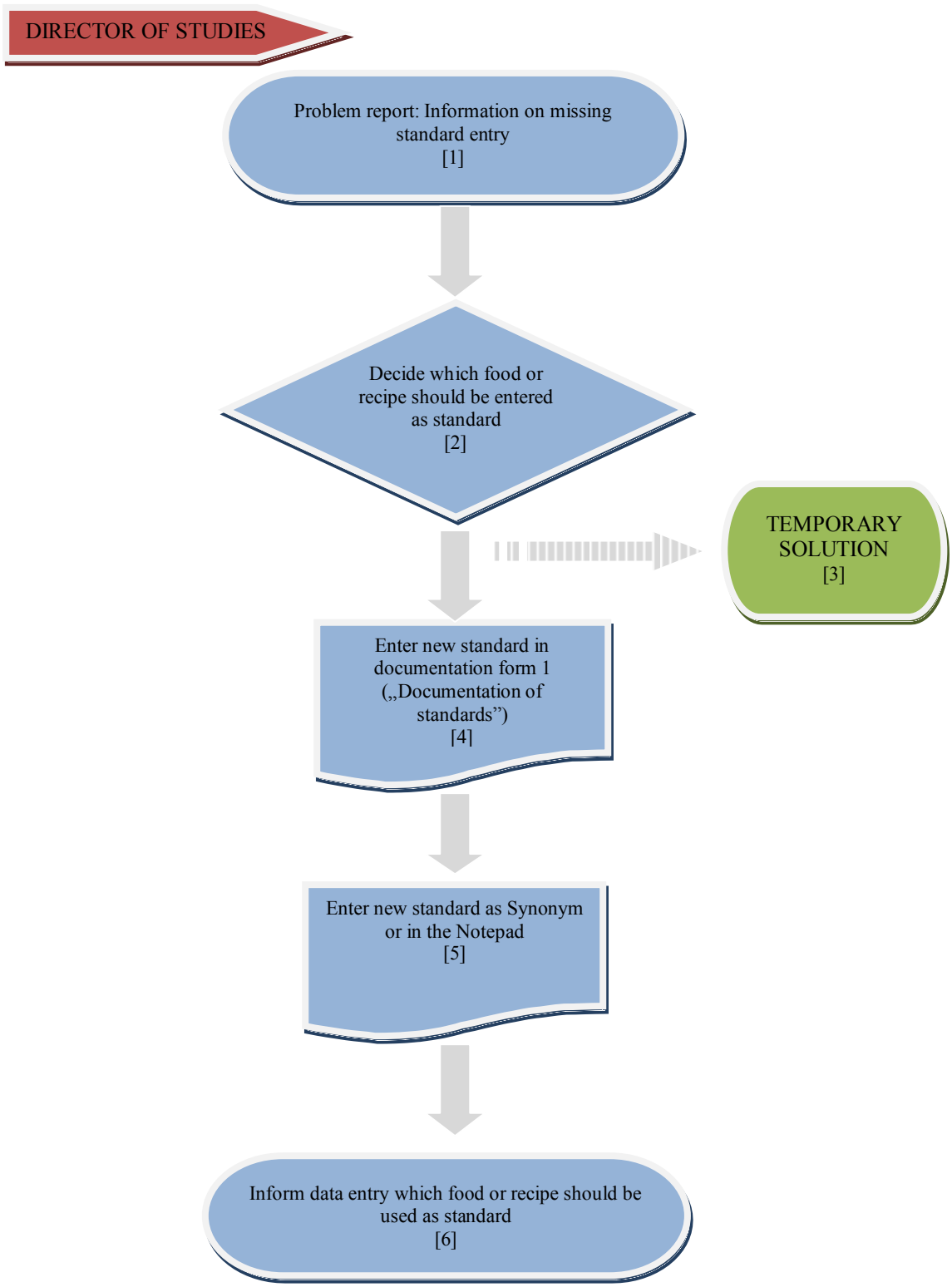
Flowchart 2 for the definition of portion sizes whilst data entry



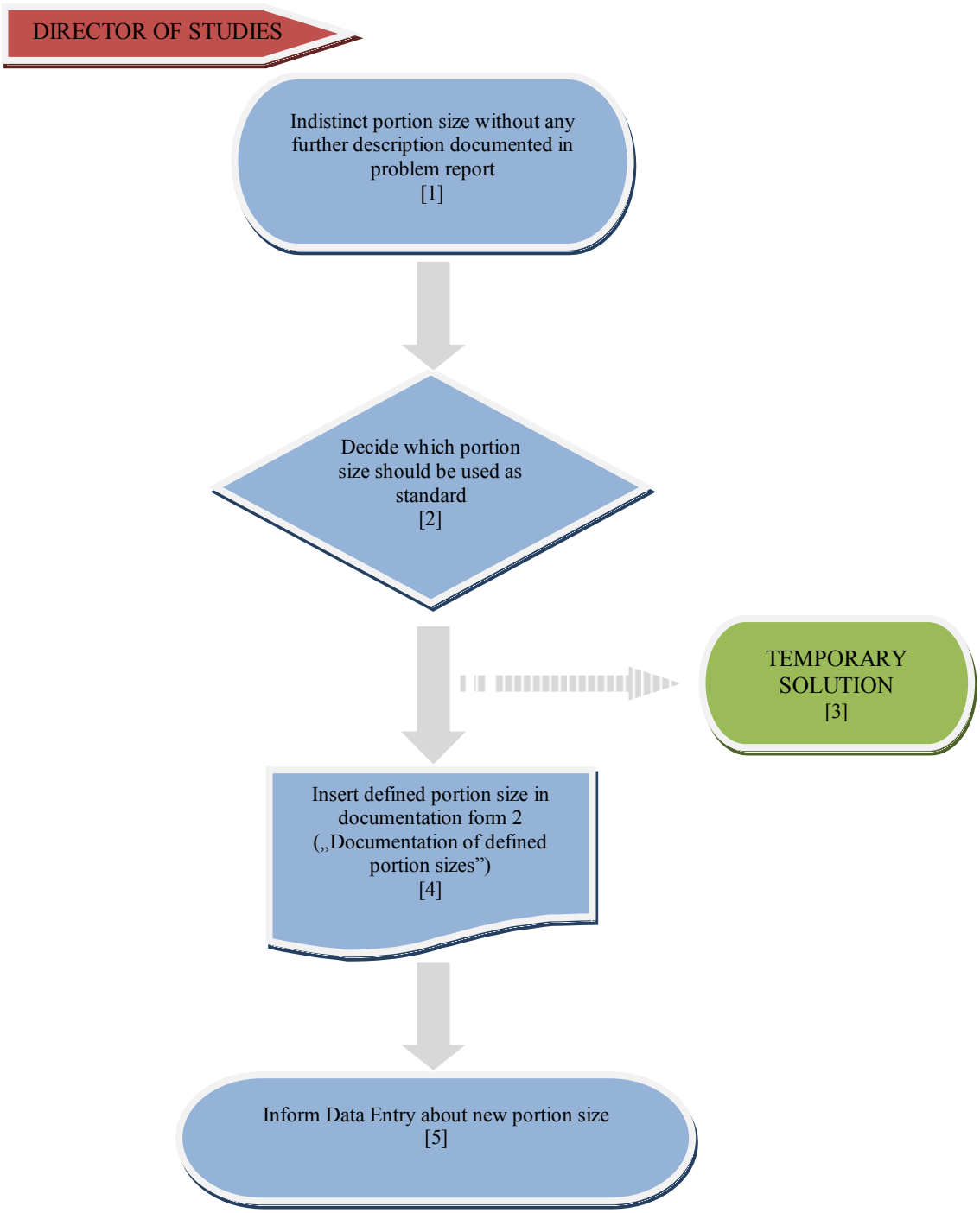
Flowchart 3: Entering new foods or recipes in the FCDB



Flowchart 4 for entering new standards in the FCDB



Flowchart 5: Defining new portion sizes



Documentation form 1: "Documentation of standards"

Name and subject of study _____		
Director of study _____ Title	_____ Name	_____ Surname
Type of documentation within database ☐ Synonym ➔ _____ ☐ Notepad "Merkzettel"➔ name of notepad: _____		
Documentation completed Date _____	Temporary Solution _____	

Basic or compound standard found in protocol or recipe	Food or recipe to be used as standard	BLS code of food or recipe to be used as standard

Documentation form 2: "Documentation of defined portion sizes"

Name and subject of study _____		
Director of study _____ Title	_____ Name	_____ Surname
Documentation completed Date _____		Temporary Solution _____

Portion size documented in a protocol	Food or recipe	Weight or amount	Unit (g/ml)

Problem report

Name of data typist _____ Name	 _____ Surname	Date _____
Name and subject of study _____		
Director of study _____ Title	 _____ Name	 _____ Surname

Protocol number	Description of the problem	Decision

Discussion

It is a fact that limited knowledge of the compilation process is an important hazard source and that appropriate training of compilers can reduce this risk [WESTENBRINK et al., 2009].
Letting volunteers test the first draft of SOPs, including flowcharts and documents, by working through an example study, showed that basic knowledge of data entry in the field of nutrition surveys is essential. Data entry as well is a major source of errors when working with a Food Composition Database. The SOPs at hand have been designed to regulate those processes that are most defective and the testing phase showed that they can only guide the work of a person when he/she has at least basic knowledge of what is important in data entry.

Therefore the SOPs were extended with more basic explanations and the addition that basic knowledge of data entry is a precondition to work with the SOPs properly.
A basic knowledge of how food composition data are being generated [GREENFIELD and SOUTHGATE, 2003] and applied is an asset for every person involved in working with a FCDB. Face-to-face training or workshops are preferable but should be supplemented by basic literature (e.g. Greenfield and Southgate, 2003) [WESTENBRINK et al., 2009].

Complete documentation is one of the most important requirements for effective working, especially in the work with a FCDB. From the sampling to the work with data included in the database, documentation should always be clearly kept in mind [GREENFIELD and SOUTHGATE, 2003].
Therefore it was important to develop all the necessary documents together with the SOPs and to describe the way they are used exactly. This measure and the repeated mentioning of the importance of documentation guarantee traceable results.
Documentation needs to be available at a later date to ensure high quality results when working with these data [WESTENBRINK et al., 2009].

A SOP is a document that needs to be precise and unambiguous. Complex or insufficient explanations are misleading and distracting [EPA, 2007]. Ambiguities can only be detected through practical application and testing by experts and laymen.

Testing the SOPs was a good measure of detecting missing or misleading explanations. The changes made in this connection are explained in the following:

The results of the example study were unequal. Although each of the 3 test persons indicated that they did not have problems in understanding the SOPs, the results of one person showed a different outcome. The chapter dealing with the standardization of portion sizes was understood correctly by all the testers. One person unfortunately could not detect the other errors included in the example study.

Two of three test persons could complete the example, but documented additional and therefore nonessential information in the problem report. To avoid unnecessary entries in the problem report, the SOPs were revised and complemented with more exact explanations on what needs to be documented. In addition to more detailed explanations, examples were developed to point out what needs to be documented in the problem report and what needs further research before documentation.

Another fact that needed further explanation was that an entry missing in the notepad or as synonym, although existing in documentation form 1 (“Documentation of standards”), needed to be reported in the problem report. None of the test persons did deal with this problem properly. By inspection of the first draft of SOPs it was discovered that this problem has been mentioned, but it has not been clearly described how to deal with it. Therefore this point has been elaborated and described more clearly to avoid misunderstanding.

All in all the development of Standard Operating Procedures is a time-consuming process and requires detailed knowledge of the process that needs to be described. It is recommended that SOPs should only be written by members of staff who are very much in the know of the described process [EPA, 2007].

SOPs should contain enough information to guide even those people who have not dealt with the described process before [EPA, 2007]. Therefore, a basic requirement to design SOPs is to tailor the document to the target group.
By analyzing the former situation, the work steps of staff involved and the work process itself, it was possible to detect potential sources of errors and find a way to avoid them.

A small lack of clarity can lead to misapplication and therefore false results. Hence it is necessary to use distinct, unambiguous and precise descriptions. Flowcharts and examples were included in the SOPs to improve the comprehensibility of descriptions.
Flowcharts, for example, are a good measure of depicting a process. Flow diagrams should demonstrate all the necessary steps in a process in an understandable and clear way [NATIONAL ADVISORY COMMITTEE ON MICROBIOLOGICAL CRITERIA FOR FOODS, 1997].

Conclusion

The development of Standard Operating Procedures for the work with a FCDB in the field of nutrition surveys is a major step towards the standardization of work processes at the Department of Nutritional Sciences of the University of Vienna.

Each person's workflow using the database has been analyzed and optimized, based on the HACCP concept. Since each person has other interests and duties, while working with the FCDB, it was necessary to determine different areas of authority and responsibility. Work areas were divided into: Project leader, compiler, director of studies, data entry and users.

This is the first step into optimized working, because misunderstandings and disputes can easily be reduced by pointing out the tasks of each area of authority.

Communication between different work areas has to be fluent, unambiguous and uncomplicated but not disruptive or dispensable. Clearly regulated work processes and simplifying documents help to improve and administer communication. If everybody is aware of what he/she has to do, unnecessary communication will be avoided.

Standardization of working with a FCDB can improve internal work processes and their efficiency. Complaints, human errors and redundant work steps are reduced by the availability of SOPs. Nevertheless, all these positive aspects of the existing SOPs are worthless if people are not reading the instructions precisely or do not apply them as required.

Finding a way to describe the necessary work steps as unambiguous and clear as possible was a challenge. Although the elaboration of SOPs is a complicated and demanding task, this work is worthwhile. The existence of SOPs influences work and working atmosphere in a positive way.

Elaborated Standard Operating Procedures are a good method to reduce misconceptions and false results to a minimum, when applied accurately.

The present SOPs provide a basis for effective working and high quality results, still it may become necessary to adapt or complement the existing documents in a while. If this is the case, a staff member should be chosen to be in charge of the streamlining of the SOPs. All adjustments made should be clearly documented and tested by other members of staff.

Abstract

The goal of the present thesis was the development of Standard Operating Procedures (SOPs), to restructure and simplify the work with a Food Composition Database (FCDB) at the Department of Nutritional Sciences of the University of Vienna. Information on the origin of food composition data was collected and the general structure of SOPs was analyzed. The SOPs, developed in the course of the EuroFIR-project, have been used as the basis for the development of the present SOPs.

In the beginning it was necessary to identify those people who are involved in working with a FCDB.

The HACCP-concept built the basis of the development of the SOPs, and therefore it was important to detect possible hazards and critical control points (CCPs). The present SOPs have been elaborated for these points. Examples and flowcharts were then worked out to explain certain steps more precisely. Documents, necessary for the work with a FCDB, have been integrated into the SOPs and their application was described clearly.

An example study was then developed to test the SOPs for comprehensibility and applicability. The example was then worked through by experts and laymen, using the SOPs. Problems and ambiguities have been documented by the test persons. The first draft of SOPs was then revised and refined, based on the information from the testing phase. Flowcharts and examples have been reworked and corrected, if necessary.

The final version of SOPs is dealing with the following points:

- Regulation of standards
- Regulation of portion sizes
- The problem report
- Temporary solutions

The elaborated SOPs are the result of the present thesis and shall be applied for the work with a FCDB in the field of nutrition surveys at the Department of Nutritional Sciences of the University of Vienna.

Zusammenfassung

Ziel der vorliegenden Diplomarbeit war die Entwicklung von Standard Operating Procedures (SOPs), die die Arbeit mit Nährwertdatenbanken am Institut für Ernährungswissenschaften der Universität Wien, strukturieren und somit vereinfachen sollen. Zu diesem Zweck wurden Informationen über die Herkunft, der in Nährwertdatenbanken enthaltenen Daten, eingeholt und der prinzipielle Aufbau von SOPs analysiert. Als Basis für die Entwicklung der vorliegenden SOPs wurden die im Rahmen des EuroFIR Projektes entstandenen SOPs herangezogen.

Bevor mit der eigentlichen Entwicklung der SOPs begonnen werden konnte, musste überlegt werden, welche Personen in die Arbeit mit einer Nährwertdatenbank tatsächlich involviert sind. Da das HACCP-Konzept für die Ausarbeitung von Betriebsanweisungen als Anleitung dienen kann, wurden in einem nächsten Schritt alle möglichen Gefahrenquellen und die kritischen Kontrollpunkte (CCPs) identifiziert. Für diese Punkte wurden die vorliegenden SOPs entwickelt. Um die einzelnen Abläufe verständlicher darzustellen, wurden Beispiele und flowcharts ausgearbeitet. Die für die Arbeit mit Nährwertdatenbanken benötigten Dokumente wurden ebenfalls in die SOPs integriert und deren Verwendung ausreichend erklärt.

Um die SOPs auf Verständlichkeit und Anwendbarkeit zu überprüfen, wurde eine Beispielstudie entwickelt. Dieses Beispiel wurde von Experten und Laien unter Zuhilfenahme der SOPs durchgearbeitet. Die dabei aufgetretenen Probleme und Missverständnisse wurden von den Testpersonen dokumentiert. Diese Informationen dienten als Basis für die Überarbeitung und Weiterentwicklung des ersten Entwurfs der SOPs. Auch die flowcharts und Beispiele wurden überarbeitet und gegebenenfalls korrigiert.

Die SOPs behandeln die folgenden Punkte:

- Festlegung von Standards
- Festlegung von Portionsgrößen
- Problem report
- Vorübergehende Lösungen

Die ausgearbeiteten SOPs bilden das Ergebnis der vorliegenden Diplomarbeit und sollen künftig für die Arbeit mit Nährwertdatenbanken (im Zusammenhang mit Ernährungserhebungen) am Institut für Ernährungswissenschaften der Universität Wien eingesetzt werden.

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