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JOINT GUIDANCE OF EFSA, FAO AND WHO

Towards a harmonised Total Diet Study approach: a guidance document[1]

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ABSTRACT

A Total Diet Study (TDS) can be a complementary approach to traditional monitoring and surveillance programs, which instead of focusing on compliance is designed to provide a solid basis for calculating population dietary exposure and assessing potential impact on public health. A TDS includes the selection of foods based on food consumption data to represent a large portion of a typical diet, their preparation to food as consumed and the subsequent pooling of related foods before analysis. There is already a wealth of international TDS data available, but to better enable comparisons it is important that methods are harmonised to the extent possible. The Working Group of experts provides a definition of the TDS approach highlighting its inherent value; it gives guidance for a harmonised methodology starting from the TDS planning to the collection of analytical results, exposure assessment calculation and communication of TDS results; and it proposes a general approach to facilitate the use of TDS information at international level. A TDS can be used for screening purposes or as a more refined exposure assessment tool. It provides background concentration and exposure levels of chemical substances in a range of representative foods prepared for consumption, while monitoring and surveillance programs can better capture highly contaminated individual food items. Their complementarities would allow the identification of the relative importance of individual sources of chemical substances from the whole diet. In conclusion, a TDS is considered to be a good complement to existing food monitoring or surveillance programs to estimate population dietary exposure to beneficial and harmful chemical substances across the entire diet. Harmonising the TDS methodology will enhance the value of these programs by improving the comparability at international level.

KEY WORDS

Total Diet Study, Dietary Exposure, Contaminants, Nutrients, Harmonisation

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SUMMARY

There is a need to improve the efficiency and accuracy of dietary exposure assessments for chemical substances and to harmonise the collection of the data that are necessary to conduct such assessments. Data derived from the food control systems are often not suitable for calculating population dietary exposure because the sampling is targeted, the samples analysed may not be representative of the food as consumed, and the analytical method may use a too high limit of detection or quantification (LOD or LOQ).

A TDS can be a complementary public health tool to determine population dietary exposure to both beneficial and harmful chemical substances across the entire diet by analysing main foods prepared as consumed and pooled into representative food groups. Steps characterising a TDS include the selection of foods based on food consumption data to represent as best as possible a typical diet, their preparation to food as consumed and the subsequent pooling of related foods before analysis.

There is already a wealth of international TDS data available that have served as important resources for monitoring exposure to beneficial and harmful chemical substances in food. To better enable comparisons of TDSs results between different surveys, it is important that methods used are harmonised to the best extent possible.

At the beginning of 2010, a Working Group (WG) of experts on TDS was formed aiming at reviewing the state of the art on TDSs worldwide with a particular emphasis on activities in Europe and at developing a guidance document for a harmonised approach of TDS.

The result of the work of the WG is provided in the current document. This guidance describes the TDS concept and highlights its inherent value; it gives principles on TDS methodology from the TDS planning to the collection of analytical results, exposure assessment and communication of TDS results with the overall objective of proposing a general approach to facilitate the use of the TDS information either internationally or at European level.

There are two distinct approaches: TDS for screening or TDS for refined dietary exposure assessment. A TDS is sometimes used for screening purposes, analysing a limited number of broadly pooled food samples. This might be useful as a starting point towards setting future priorities for more detailed collections of data on beneficial and harmful substances in food. Such screening will generate an overview at fairly low cost for a limited number of food groups. Countries that already have established monitoring or surveillance programs can use the TDS approach as a more refined dietary exposure assessment tool, which includes analysis of a greater number of less pooled samples often separately covering different seasons and regions.

Using pooled samples of individual food items means that the analytical data generated represent averages of concentration data. Therefore, TDS results are best suited for calculating chronic exposure to food chemical substances and may allow the analysis of trends where the sample size is sufficiently representative. The TDS approach will provide background contamination levels in the general food supply suitable for estimating population dietary exposure, while monitoring and surveillance activities can capture more highly contaminated individual food items. Their complementarities allow the identification of the relative importance of individual sources of beneficial and harmful chemical substances through coverage of the whole diet.

It can be concluded that a TDS can be an excellent complement to existing food monitoring and surveillance activities or it can also be a stand-alone screening tool as a starting point for further analyses. Harmonising the TDS methodology will enhance the value of these programs by improving the comparability at international level.

TABLE OF CONTENTS

BACKGROUND AS PROVIDED IN REQUEST

The European Food Safety Authority (EFSA), the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO), directly or through Expert Committees or Advisory Groups, work to ensure a high level of consumer protection by providing scientific advice on potential risks in the food chain. In order to perform risk assessments, the availability of reliable and detailed occurrence data for chemicals in food are essential.

At the European level EFSA typically carries out much of its risk assessment work at the request of the European Commission, European Parliament and EU Member States (MSs), as well as initiating its own scientific activities. Normally, this implies the collection of available occurrence data of specific compounds, through calls for data initiated by EFSA or by the European Commission. Such occurrence data often derive from targeted monitoring or surveillance programs. Since these programs aim at monitoring problematic areas or special food groups, the occurrence data collected for certain contaminants do not always reflect the situation for the whole diet. Attempts to calculate population dietary exposure using monitoring or surveillance data might thus produce potentially misleading overly-conservative results.

There is a need to improve the efficiency and accuracy of dietary exposure assessments for chemical substances and to harmonise data collections. This is at least partly addressed through the introduction of a number of international and national standards with detailed specifications on sampling and analytical protocols for official food controls. Despite such actions, data deriving from the official control system are often not suitable for calculating population dietary exposure because the sampling is targeted, the samples analysed may not be representative of the food as consumed and the analytical method may use a too high limit of detection or quantification (LOD or LOQ). Some incongruence in the reporting of analytes can also be observed. For example, specificity and quantification limits of analytical methods used are not always provided when reporting results following data collection. This can limit the usefulness of such data for dietary exposure assessments.

An alternative to relying on data from food control systems is the use of the Total Diet Study (TDS) approach. A TDS involves selecting a list of foods as consumed representing the overall diet of the population while including specific foods containing the chemical substances under review. The foods are sampled in predefined areas according to a sampling plan, prepared as consumed and pooled before being analysed for an agreed range of chemical substances. The analytical results are then combined with food consumption data and the dietary exposure for the population is estimated.

TDSs are conducted among many countries in the world for addressing specific concerns related to food safety. However, developing international guidelines for TDS would allow the harmonisation of the methodology and, therefore, of dietary exposure assessments for international purposes.

At European level, one of the main benefits of a pan-European TDS for EFSA will be the definition of baseline results for a range of chemicals that can be compared to information on the compound under study in specific products, collected within more detailed targeted surveys, TDSs will generate important information for assessing dietary exposure to harmful and beneficial chemicals in food from the overall diet and a pan-European TDSs could help in planning future targeted occurrence monitoring and surveillance programs for specific compounds and in tracking the impact of the regulations over time.

EFSA intends to facilitate this harmonisation process by creating a Working Group aiming at developing possible guidelines for the TDS.

During the 2nd meeting of the 'Expert Group on Chemical Occurrence Data' (2009), the TDS issue was presented and discussed. The experts participating at the meeting supported the creation of a Working Group coordinated by EFSA aimed at reviewing the initiative and guiding Member States in the implementation and development of TDSs.

TERMS OF REFERENCE AS PROVIDED IN REQUEST

It is proposed to form a Working Group to develop guidance for a harmonised approach to collect chemical contaminant information through the use of a TDS framework. The overall objective of the review should be to propose a general approach for performing a TDS to facilitate the use of the information either internationally or at a European level.

The guidance should deal with the following list of issues:

- basic instructions for the implementation of a TDS in case the approach has not been used previously;
- establishment of a harmonised list of foods (with respective food preparation instructions) to be based, if available, on representative food consumption surveys data of the population's diet, and representative sampling plans developed accordingly;
- developing a proposal for the range of substances to include in the testing scheme annually or on an ad hoc basis for special needs;
- defining, where possible, the preparation, storage and analytical requirements (e.g. limit of detection and limit of quantification of the analytical methods) for the harmful and beneficial chemical substances of interest, to be implemented and reported in a TDS;
- developing a standardised procedure and format for reporting of analytical results;
- exploring a data structure for a common database storing the information from countries willing to participate in a collaborative approach.

PREAMBLE

It is recognised worldwide that the availability of reliable and detailed occurrence data for chemicals in food are essential in order to perform risk assessments. International organisations like the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) have been supporting the Total Diet Study (TDS) approach since the 1970s and have provided general guidelines. Nevertheless, there has so far been no attempt towards agreement of a generally harmonised TDS approach.

During the 2nd meeting of the 'EFSA Expert Group for Chemical Occurrence Data' in 2009, the European Member State representatives expressed their interest in considering the TDS approach for collecting chemical contaminant information and supported an EFSA initiative to form a Working Group (WG) aimed at developing a possible harmonised guidance to carry out TDSs.

At the beginning of 2010, a Working Group of experts on TDS was formed and coordinated by EFSA. Participants from European Member States, FAO and WHO covered the needs for expertise and knowledge on TDS at European and international level. The work of the WG included two major steps:

1. As a first step, in order to avoid unnecessary costs, the WG investigated the feasibility of initiating such coordinated efforts across multiple countries and reviewed possible cost savings in the potential pooling of available resources.

After the first WG meeting, a feasibility statement on the potential harmonisation of the TDS approach was agreed and published (DCM TDS working group, online). All members of the WG agreed that a guidance document is the first requirement for harmonising TDSs and, although not guaranteed, a guidance document could also help competent national authorities in national fund raising for implementation purposes.

2. After ascertaining the feasibility of the project and taking into account the positive conclusion, the activities of the WG focused on preparing a review of the state of the art on TDSs worldwide with a particular emphasis on activities in Europe and on developing a guidance document for a harmonised TDS approach.

To support the compilation of a comprehensive overview of TDSs carried out worldwide, the WG conducted a survey among both European countries that were known to have experience with TDS methodology and also those that had never conducted a TDS, to map their readiness to undertake a TDS in the future. Data on TDSs conducted outside Europe were collected with the help of WHO and FAO experts. The results of the two surveys are described in the separate joint EFSA/FAO/WHO report on 'State of the art on Total Diet Studies based on the replies to the EFSA/FAO/WHO questionnaire on national total diet study approaches' (EFSA/FAO/WHO, 2011), which should be considered as an integral part of the current guidance document.

The present document is intended for competent authorities and institutes aiming at initiating a TDS. It provides general principles for international harmonisation of the TDS approach. However, because of inherent differences between countries in consumption habits and food supply, as well as the availability of analytical and other resources, more detailed methodological aspects must be developed at a regional or national level. The guidance document is structured in three sections providing an introduction to the TDS concept and highlighting its value (Section A: Value of the Total Diet Study Approach), giving principles of TDS methodology from the TDS planning to the collection of analytical results (Section B: TDS Methodology), and detailing exposure assessment calculation and communication of TDS results (Section C: Exposure Assessment and Communication of Results).

Addressing the Terms of Reference

The WG reviewed the terms of reference and decided to address them by grouping the topics into four different areas covering:

- an outline of the overall principles that should be applied when designing and implementing a TDS;
- a detailed guidance on food collection, food sampling and food analysis procedures in view of a harmonised approach to collect and analyse data on harmful and beneficial chemical substances in food through the use of a TDS approach;
- a guidance for producing a harmonised exposure assessment using the TDS approach;
- a recommendation of a standard sample description format to facilitate data exchange.

The document does not provide a list of chemical substances to be analysed or a list of foods (with respective food preparation instructions) to be sampled in a TDS but rather a set of criteria for their development was proposed. Additionally, it recommends the use of existing formats for data interchange and to extend them to include TDS meta-data.

SECTION A: VALUE OF THE TOTAL DIET STUDY APPROACH

1 Introduction

1.1 Definition of the Total Diet Study concept

A Total Diet Study (TDS) consists of selecting, collecting and analysing commonly consumed food purchased at retail level, processing the food as for consumption, pooling the prepared food items into representative food groups, homogenising the pooled samples and analysing them for harmful and/or beneficial chemical substances. TDSs are designed to cover the whole diet and to measure the amount of each chemical substance of interest ingested by the population living in a country over their lifetime, using low-level, average, and high-level consumption data as appropriate for the substances being assessed (chronic dietary exposure). Exposure through drinking water and water used in cooking should be included in the TDS assessment. The chronic dietary exposure calculations assist in determining whether specific food chemical substances pose a risk to health.

Pooling is an essential step in the TDS process and it consists of creating a unique food sample for analysis by combining various individual food items either of the same type (individual food approach; e.g. one fruit sample made of different varieties of apples) or by mixing several different foods from the same food group (mixed food approach; e.g. one fruit sample made of different types of fruits like apple, pear, banana…) (see Chapter 7.2).

Essentials principles of a TDS:

1. Representative of the whole diet
2. Pooling of foods
3. Food analysed as consumed

Studies deviating in some detail from these essentials principles are described in the chapter 3.1 on 'Deviations from TDS'.

1.2 Historical aspects of food control systems

An assessment of the presence and levels of beneficial or harmful chemical substances in the diet is important for nutrition and food safety. Beneficial chemical substances include e.g. macro- and micronutrients. Potentially harmful chemical substances include e.g. pesticide or veterinary drug residues, heavy metals, environmental or process contaminants, naturally occurring toxins, but can also include micronutrients, that can be present in food at levels that might adversely affect the health of consumers.

Early historical documents indicate that regulators have been concerned with protecting consumers from dishonest practices in the sale of food. In ancient Athens, beer and wine were inspected for purity and soundness, and the Romans had a well-organised food control system to protect consumers from fraud or malicious practices. In Europe during the Middle Ages, individual countries passed laws concerning the quality and safety of eggs, sausages, cheese, beer, wine and bread. Law enforcement officers, among many other tasks, inspected foods for compliance using simple tools as part of an official food control system. With the development of food chemistry, there has been a rapid development from simple checking of purity and adulteration to sophisticated tests for the presence of

a range of chemical substances in food at increasingly lower levels. Today, effective food control systems are considered essential to protect the health and safety of consumers.

The selection of priorities for chemical, microbiological and physical laboratory analysis is part of the official food control system and it follows general scientific principles for protecting the public from potential hazards in the food supply. Nevertheless, individual societies may perceive the selection of these priorities differently in accordance with their own political, economic or cultural practices and traditions (FAO/WHO, 2005). Currently this responsibility has been delegated to food safety risk managers who are advised by risk assessors.

Food control systems are also critical in enabling countries to assure the safety and quality of their food entering international trade and to ensure that imported food conforms to national and international requirements. The global environment for food trade places considerable obligations on both importing and exporting countries to strengthen their food control systems and to implement and enforce risk-based food control strategies. The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) of the World Trade Organisation (WTO) requires that health and safety specifications related to food be based on scientific risk assessments. For trade disputes and benchmark for health and safety requirements, the SPS Agreement refers to the standards, guidelines and other recommendations of the Food and Agriculture Organisation of the United Nations (FAO)/World Health Organisation (WHO) Codex Alimentarius Commission. Equally, the European food safety legislation specifies that, in order to achieve the general objective of a high level of protection of human health and life, food law shall be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure. Risk assessment shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner.

Beside risk assessment for harmful substances in food, the need for the evaluation of the risk for potential adverse effects that might occur with an inadequate or excess intake of certain nutrients and related substances has also been highlighted. Several international working groups have provided guidance for the risk assessment of intake of nutrients and related substances (FAO/WHO, 2009; Renwick et al., 2003 and 2004; FAO/WHO, 2006a).

Official food control systems cannot cope alone with assuring food safety without the active collaboration of the industry. For some time, a common foundation for building an industry food safety management system based on Hazard Analysis and Critical Control Point (HACCP) methodology has been recommended. The principles of HACCP are traceable to the Codex Alimentarius Commission and it is now widely accepted as an essential tool for managing food safety, especially when combined with an auditable management system (FAO/WHO, 2006b). However, formal food safety risk assessment in an overall public health setting is most often still the sole responsibility of government organisations.

1.3 The need for representative data

Food safety risk assessments take account of both toxicological information and estimates of dietary exposure of the population to the chemical substances in order to evaluate benefits and risks for public health. To estimate exposure, it is essential to analyse the food we eat for the presence and levels of contaminants and of other chemical substances, like nutrients, then relate the occurrence levels to the amounts of the respective food consumed. Some monitoring or surveillance data focus on individual chemical substances in raw commodities and may not provide a direct link to the dietary exposure assessment of the population. An example is the prescribed testing of grains for the presence of mycotoxins. The grains are further processed and milled to flour and the flour is used as an ingredient in e.g. making bread or producing pasta. In the absence of analytical data of food as consumed, it is a challenge to estimate the level of mycotoxins in such processed foods on the basis of the contamination in raw commodity. Thus, dietary exposure could potentially be incorrectly estimated if based on levels that are detected in raw commodities following targeted food monitoring or

surveillance activities. The TDS approach provides a suitable way for countering the uncertainty associated with such processing factors.

1.4 Role of official food monitoring or surveillance and TDS

In an international context, the Codex Alimentarius Commission generates guidance and standards for the management of food safety and consumer protection. Countries have responded accordingly by introducing food legislation and Codex based standards and by establishing or strengthening food safety agencies to monitor compliance with such regulations.

In the European context, general principles of food law as defined in the Regulation (EC) No 178/2002[5] (known as the 'General Food Law Regulation') specify that EU Member States shall maintain a system of official controls and other activities as appropriate to the circumstances, including food and feed safety surveillance and other monitoring activities covering all stages of production, processing and distribution. The emphasis of the official control is on regulatory compliance of individual food items and food production systems. Analytical methods used for enforcing regulatory compliance only require sufficient precision to meet the prescribed maximum limits set in the legislation. In practice, detection/quantification limits (LODs and LOQs) of the analytical methods used in regulatory monitoring are typically five to ten times lower than the Maximum Residue Limit (MRL) or Maximum Level (ML) to ensure this confidence. The LODs or LOQs might not be sufficiently sensitive for detecting background levels of chemicals in food, thus, be unable to calculate meaningful exposures, since many substances are present in food at much lower levels than the regulatory ones. Consequently, the use of such data also for risk assessment purposes can introduce a high level of uncertainty. In addition, in monitoring and surveillance programs foods that have a higher probability to exceed maximum limits are often overrepresented, so the data are unlikely to be representative of the food supply in general.

On the other hand, results from TDSs are not appropriate for compliance checking of the adherence to prescribed legal limits, since a TDS includes food as consumed, as well as pooling of samples and not individual product testing, as it would be required in order to check adherence to legal limits. For these reasons countries should ideally conduct food control monitoring as well as TDSs.

2 Purpose of using the TDS approach

The estimation of the actual dietary exposure to harmful and beneficial chemical substances is a prerequisite for risk assessment. Both traditional food monitoring or surveillance systems and the TDSs explore the presence and levels of food chemical substances and, when combined with consumption data, they enable exposure assessments to be carried out.

One of the key aspects about TDSs is that the resulting dietary exposure is usually the most accurate and reliable estimate of chronic dietary exposure. This is because many of the conservative assumptions contained in other types of dietary exposure assessment are absent. A TDS most accurately represents the levels of the compounds in the edible portion of the food at the point of consumption and takes account of losses during processing, food preparation and storage.

5 Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1-24.

A TDS might be an important approach used to complement existing food monitoring or surveillance systems in quantifying the presence of harmful or beneficial substances in food and for estimating total dietary exposure. A TDS differs from other chemical monitoring or surveillance programs in that:

- it always focuses on chemical substances across the total diet;
- the food is processed as consumed by the population; thus, it considers the impact of food preparation and cooking on the chemical substance under investigation, providing a more realistic estimate of exposure;
- it is only the edible portion of the food that is analysed;
- it assesses background dietary population exposure for public health purposes of regulated and non regulated chemical substances, rather than evaluating their levels in the food against regulatory end-points.

A TDS is mainly useful to assess contamination that may be widely distributed across the entire food supply and that may be present at very low levels, such as heavy metals or dioxin or to identify potentially contaminated food groups. The TDS approach can be used:

- as a screening tool to identify foods or food groups in need of detailed monitoring or surveillance;
- as a risk management tool to develop priorities for possible public intervention and to provide advice to indicate whether or not there is a need to take protective action to defend public health;
- as an evaluation tool to identify possible trends in dietary exposure to chemical substances in the general population and in specific population groups and to assess the effectiveness of previous risk management decisions;
- to serve as a cost-effective complement to other related food safety activities;
- to support and communicate the evaluation of the chemical safety of the food supply as part of the risk assessment process.

2.1 Screening vs. refined TDS approaches

The TDS can be used as a screening tool and for a refined dietary exposure assessment (WHO, 1999 and 2002). Used for screening, it can provide information about total dietary exposure for a population as a whole, which is then compared to some toxicological standard to determine whether it presents a potential health hazard. TDS used as screening tool does not provide information about specific foods that contribute significantly to the exposure nor it provides information about exposure for specific subpopulations. A refined dietary exposure assessment provides much more detailed information about foods that contribute significantly to dietary exposure, which requires analysis of composites of individual foods (e.g., oranges) or less aggregated food categories (e.g., citrus fruits and juices). These assessments also generally provide exposure assessments of specific subgroups of the population.

a) When used as a **screening tool**, a TDS can be based on a limited number of food samples to represent the whole diet (e.g. pooling of food items into 20 to 30 different food group samples). This means that the TDS food list should be established for broad food categories rather than for individual food items. The choice of chemical substances to be analysed should be based on substances widely distributed across the diet and at relatively homogeneous levels of occurrence (e.g. heavy metals). When levels of occurrence are expected to vary in different food categories, the samples should not be pooled together (e.g. cadmium in kidney vs. cadmium in meat) as this may limit the validity of the assessments.

In theory, a screening could even be based on a single pooled food sample reflecting all products of a typical diet in the relevant proportions according to the respective amounts consumed. Such a sample could be analysed for a range of beneficial or hazardous compounds and thus set priorities for future analysis. However, such an approach is discouraged because it would be difficult to ensure complete sample homogeneity, most analytical methods would not be able to detect compounds at the necessary level, and it would not be possible to address differences in dietary exposure in sub-groups of the population with different eating patterns. In most situations, a minimum of 20-30 food groups is recommended for TDS screening purposes.

Use of the TDS as a screening tool does not allow identification of major contributors to overall exposure at individual food or food group level beyond the broad pooling used. If screening work indicates high exposures, further evaluation should be performed to identify its source. This may involve another TDS, or if food samples that went into the pooled samples were retained, these could be analysed further.

b) When used as a tool for **refined dietary exposure assessment,** a TDS is based on grouping of foods at a much more refined level when pooling in order to more clearly identify those specific foods contributing to dietary exposure (e.g. pooling of food items into 200 to 300 different food group samples). Because the TDS results are based on food as consumed, the resulting dietary exposure should be more representative than the one based on traditional monitoring and surveillance data. The approach would also allow the estimation of accurate levels of exposure of specific foods (e.g. from biscuits) in a specific group of consumers (e.g. children below 15 years). The number of food items in each sample depends on the expected variability. In general, for doing a refined assessment a TDS would have to include more samples that are less pooled as well as detailed national food consumption data for specific population subgroup estimations. A refined TDS is more likely to detect chemical substances that are less widely present across the diet, as compared to a TDS for screening purposes. Still, even a refined TDS is unlikely to detect a local or sporadic contamination because of its more generalised nature, but coverage could be expanded if required.

TDSs have been used as screening tools in countries where the monitoring or surveillance systems are not yet fully implemented (e.g. Cameroon, Gimou et al, 2008, EFSA/FAO/WHO, 2011). TDSs have also been used as a complement in countries with a monitoring or surveillance system (e.g. France, UK, EFSA/FAO/WHO, 2011) to better assess the dietary exposure of the population.

There are, however, some cases where the TDS approach is unsuitable:

- to calculate exposure for populations with dietary habits not differentiated by the TDS food list;
- to provide a comprehensive view of the full distribution of a chemical substance in the food supply;
- to calculate high dietary exposure levels specifically arising from high contamination or to estimate acute dietary exposure, given that pooled samples provide only mean concentration values;
- to estimate the adherence of individual samples to prescribed legal limits;
- or when contamination occurs rarely, locally, inhomogeneously or limited in time.

2.2 TDS for assessing nutrient intake

The growing interest in the relationship between nutrition and health and the awareness of the protective effect that adequate dietary habits can have on the development of a number of diseases, reinforces the need for better knowledge of the nutritional quality/composition of foods in the total diet. A common approach so far has been to use food composition tables with general estimates of the influence of food preparation coupled with food consumption information to calculate nutrients intake. Since a TDS involves food as consumed, it can be used to complement and validate the prior approach.

The TDS approach is currently used in several countries to estimate the intake of nutrients, especially minerals, which are then compared to recommended dietary allowances (RDA)(van Dokkum, 1988; van Dokkum and de Vos, 1989 ; Ockhuizen et al., 1991; Lowik et al. 1994; Pennington and Schoen, 1996; Turrini and Lombardi-Boccia, 2002; Lombardi-Boccia et al., 2003). As with assessing hazardous chemical substances, a TDS can also be used as a screening tool or for refined assessments for nutrient intake adequacy or for nutrient intake excess with comparison of intakes against the Upper Limits (ULs) (FSZANZ, 2008)

2.3 Support for TDS approach

TDSs have been carried out in different countries since the 1960s. In 1968, the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) endorsed the TDS concept for pesticide residues (WHO, 1968a and 1968b) and TDS approaches have been promoted since 1978 through the WHO/FAO Global Environment Monitoring System - Food Contamination Monitoring and Assessment Programme, commonly referred to as GEMS/Food and now being coordinated by WHO (WHO, 1981). WHO and FAO promoted and supported TDSs to assess several contaminants in the diet and many countries endorsed the TDS approach. GEMS/Food and FAO have actively collaborated with counterpart national agencies to sponsor a series of TDS workshops and training courses to promote and support TDSs internationally and to provide a forum in which countries that had conducted such studies could share their experiences and expertise. As of 2010, international workshops combined with training courses have been held in Kansas City, USA (1999), Brisbane, Australia (2002), Paris, France (2004) and Beijing, China (2006), and separate regional training courses in Brno and Prague, Czech Republic (2000), Buenos Aires, Argentina (2002), Cairo, Egypt (2007), Jakarta, Indonesia (2007) and Hong Kong (2008). Altogether, ten training courses have been held over the past 10 years, where 250 individuals from 60 countries have been given appropriate training.

In 2008, EFSA completed a strategic review of existing data collection systems and future data collection needs to support its activities. For the first time, an explicit need was raised for a TDS approach for collecting baseline and trend information on the presence and level of beneficial or harmful chemical substances in the food supply. In 2010, EFSA appointed a Working Group, including participants from FAO and WHO, to review how to best address the data needs identified and to develop harmonised guidelines to support the further implementation of TDS data collections in support of dietary exposure calculations.

3 Worldwide approaches to TDS

As of early 2011 some 30 countries, including 5 in Europe, have carried out a TDS. In most countries the TDS has been funded through government agencies which provide some assurance that it can be carried out on a regular basis. WHO and/or FAO fund some TDS projects in developing countries; in these cases a TDS is a one time study, unless further government funding is allocated to make it a regular event. Many countries start with a smaller number of food samples and increase the number over time as its national importance was recognised and more funds were made available; while other countries have kept the same number of food samples over time. Those who carry out a TDS as a screening tool include fewer food samples to be analysed, usually 10 to 30 food groupings to represent

overall dietary exposure (Moy, in press), but sometimes repeat sampling to get results also for different regions. Examples are China or the United Kingdom. Those who use a TDS as a refined exposure assessment tool include up to 300 different food groupings, often sampled in different regions and seasons and analysed separately. Many countries used household budget survey data to identify the food to be sampled, while others used individual food consumption data. Coverage of some 80-95 % of food in the diet is often targeted for inclusion in the TDS food list, selected using different criteria: e.g. food consumed at > 1 g/day per person or > 10 g/day per person or consumed by >5 % or at least 10 % of consumers. The chemical substances investigated range from heavy metals (FSA, 2009) to radionuclides (Anderson and Cunningham, 2005). For some developing countries the analysis were outsourced to laboratories in Europe. In other cases, laboratories in their own country were used, often reference and/or accredited laboratories. Whatever laboratory was selected, strict QC/QA and detection/quantification limit (LOD/LOQ) requirements were imposed. Most countries report exposure only for the general population, while others differentiate according to age, sex and ethnic group.

More information on TDS methodologies and implementation aspects as applied in different countries can be found in a separate document (EFSA/FAO/WHO, 2011). This document summarises the information gathered through a specifically designed questionnaire prepared by the EFSA/FAO/WHO working group on TDS addressed to European countries. Additionally, data derived from published sources on TDSs conducted in Africa, Asia, America and Oceania was included.

3.1 Deviations from a typical TDS approach

It has been noted that occasionally a study is described as a TDS but does not cover the total diet, focusing instead only on particular food groups known to be major contributors to exposure for the considered chemical substances. For example in the study of Bakker et al (Bakker et al., 2008), where the dietary intake of polybrominated diphenyl ethers in the Dutch population was being investigated, only food groups suspected of being affected by the contamination were included in the study. Such studies are better classified as TDS-like investigations. Other studies used occurrence data analysed for other purposes or did not analyse foods as consumed. Such investigations are not TDS per se according to the definition provided above.

Summary of the section on value of TDS

A TDS is a cost-effective tool that has been used in about 30 countries since the 1960s. It allows relatively accurate estimates of population dietary exposure to beneficial or harmful chemical substances to be made. There are three principles that define a TDS: (1) includes food samples representing the whole diet (2) which are pooled (3) and analysed after preparation as consumed. A TDS used as a screening tool investigates if there are potential risks to the general population and it is normally done by analysing only a small number of highly pooled food samples. On the other hand, a TDS used as a refined exposure assessment tool, includes analyses of many more, yet less pooled food samples, often covering different regions and/or seasons separately. In this case, the exposure can be estimated for different population groups and individual foods can be identified that contribute in a major way to the dietary exposure.

SECTION B: TDS METHODOLGY

4 Overall principles

In general, a TDS is a large-scale study that needs careful organisation and planning in order to provide high quality data in a timely manner. The planning normally includes the following points that will be elaborated further down in the text:

- allocation of human and financial resources;
- selection of the chemical substances to be investigated;
- establishment of the TDS food list and details about the levels of pooling needed;
- establishment of a sampling plan, including descriptions of the collection of food samples, their standardised culinary treatment, and sample transport conditions;
- requirements for the chemical analyses;
- details of the exposure assessment methodology;
- ways of publishing and communicating results to stakeholders.

A TDS, starting from the planning and ending with publication of the results, may take about three years in total, with the overall time dependant on its size, scope and design (see Figure 1). It might be wise to include a contingency plan to allow extra time in anticipation of potential problems that require further validation of TDS results. A planning period of six months is often necessary, depending on administrative procedures, availability of specific data (e.g. food consumption data) and other information (e.g. market share of brand names or varieties, pesticides used in country, and theoretical maximum dietary exposure) and legal requirements to tender for components (several months).

The length of the sampling period depends on the sampling plan: collection of samples in different regions and/or seasons will lengthen the sampling period (see Chapter 8). The time needed for chemical analyses depends very much on the linking between sampling, sample preparation and the laboratory operation. Often, sample analyses can start soon after the sampling starts, but if batching is required for analytical efficiency it might lengthen the time.

It is important to allocate sufficient time for the final steps covering exposure assessment, risk characterisation and communication of results, which then can be used by risk managers to take appropriate measures.

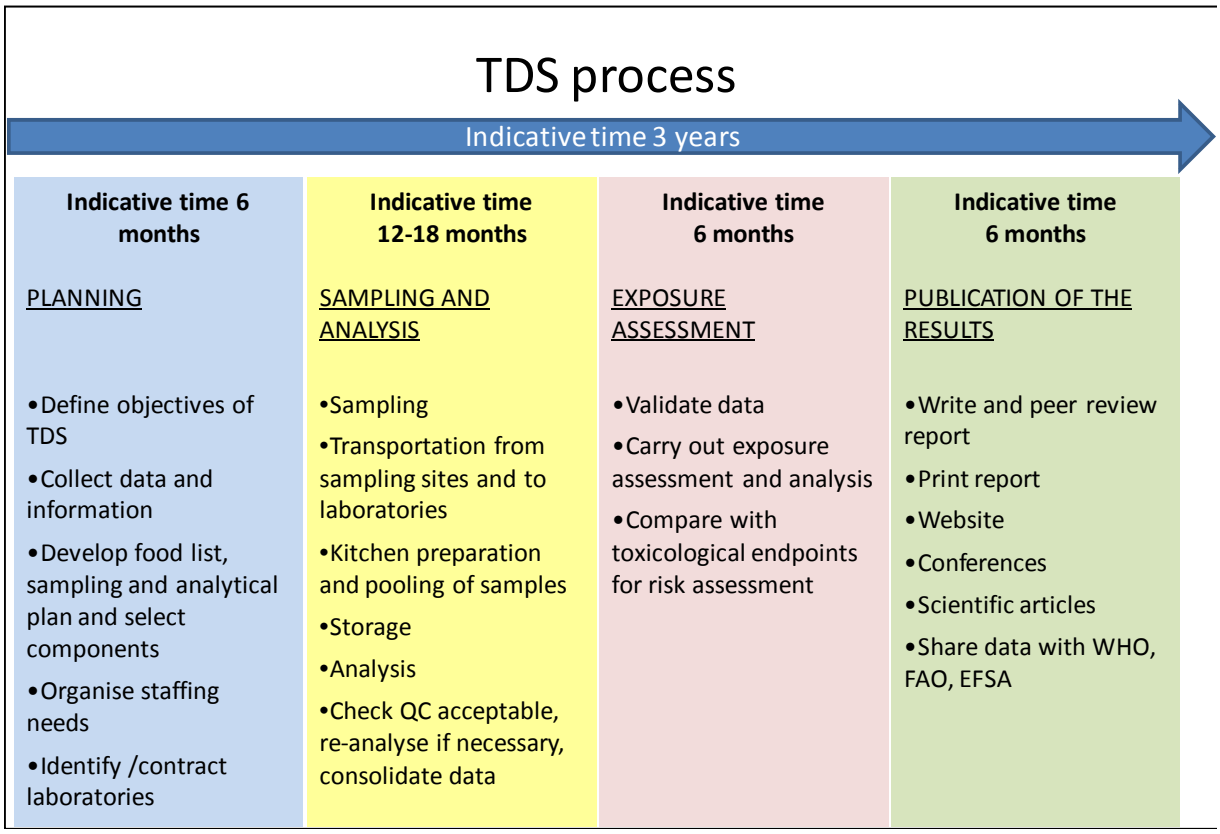

Figure 1: Steps and timelines of the TDS process (time is a rough indication).

5 Coordination and financial aspects of TDS

As part of the responsibilities of government to oversee adherence to general food safety principles and assuring that chemical substances are not present in foods at unsafe levels, they often provide the funding for and coordination of TDS activities. General stakeholder needs should be addressed in the objectives and planning of a TDS, therefore TDS stakeholders should be comprehensively identified (risk assessors, risk managers, laboratory scientists, etc.) and consulted already at the planning stage. Budget structure and cost distribution play important roles in the funding of the different parts of a TDS project (Table 1). Beside the budget for the actual TDS, the cost of a pilot study should also be considered in order to verify the quality of all the procedures and activities.

Table 1: Proportion of approximate budget allocation in the TDS process.

Approximate budget needs	Budget %
Staff for planning and management • coordinator • assistant (if needed) • experts, e.g. Steering committee **Tasks**: coordination, chemical substances and food lists, sampling, procedures manual, analytical methods and/or analytical laboratory tenders, management, conduct of TDS, validation of analytical results, exposure assessment, report writing, publication	10-20 %
Sampling and transport • staff training • the cost of the shopping contractor/staff • the cost of foodstuff • the packaging/labelling (sample traceability) • transport to sample preparation site • sample storage	10-15 %
Kitchen preparation and pooling • sample receipt and registering into spreadsheet/database, photo of packaging if needed • culinary preparation of samples (e.g. peeling, cooking, etc.) • the homogenisation and pooling of food samples, preparation of analytical batches, packaging, labelling before analytical processing • technical equipment, sample containers • staff training • (pilot study)	5-10 %
Storage and transport of samples • buy freezers and/or deep freezers • electricity • staff to handle stored samples • cost of transportation to laboratory	5 %
Chemical analysis Depends on • chemical substance(-s) to be analysed • laboratory and staff training (if needed) • number of food samples • Quality Assurance/Quality Control (QA/QC) and LOD/LOQ requirements	50 %
Exposure assessment • depends on choice of statistical treatment and software needed • staff time	5 %
Publication and dissemination of results • report • web • conferences • scientific articles • data sharing between EFSA-FAO-WHO	5 %

The cost of the food collection includes all operations from the food purchase to the preliminary preparation of food samples for the analyses. The kitchen preparation usually requires some additional investment for special technical equipment, for training of involved staff and for the pilot study. The cost for the analyses usually represents the largest part of cost for a TDS (about 50 %), but strongly depends on the analyses planned, i.e. the chemical substances and the number of samples to be analysed. Laboratories can be selected by invitation to tender and selection criteria should include both the compliance with analytical method requirements and cost for the analyses. For chemical substances that are commonly analysed with standardised and well-known methods and carried out by a large number of laboratories, numerous laboratories may be eligible, which might lower the costs.

Summary of the coordination and financial aspects of TDS

A TDS needs to be carefully planned and funding of the different elements needs to be accurately costed and secured before the start of the project to be able to achieve the objectives of the TDS. In order to produce useful and high-quality results, overall TDS coordination is very important, as is stakeholder consultation at an early stage in the planning process.

6 Selection of chemical substances

The wide variety and extremely large number of beneficial and harmful chemical substances potentially present in our diet demands the setting of priorities for chemical analysis in TDSs. The process of priority setting is of extreme importance and should be undertaken by risk managers in close consultation with risk assessors and with the involvement of all key stakeholders.

Most chemical substances in food might be grouped into one of the following areas:

- natural components considered beneficial or essential (e.g. micronutrients such as vitamins, iron, iodine, and selenium);
- chemical substances intentionally added to foods (e.g. preservatives and colours);
- chemical residues of substances being deliberately applied at other points in the food production chain (e.g. pesticides and veterinary drug residues);
- contaminants from the environment (e.g. heavy metals, polychlorinated biphenyls (PCBs) and dioxins);
- naturally occurring contaminants (e.g. mycotoxins and alkaloids);
- contaminants formed during food processing (e.g. polyaromatic hydrocarbons (PAHs), furans and acrylamide);
- contaminants transferred from food packaging or food contact materials (e.g. phthalates and bisphenol A);

The decision on the chemical substances to be analysed in a TDS may influence the food selection, pooling and sampling process. This decision should consider the following minimum criteria:

a. Use of health data

Health statistics and epidemiological studies, linking disease outcomes with particular chemical substances, could be used to support the selection of relevant chemical substances. Nutritionally

important chemical substances in the diet also need to be considered because their deficiency or excess can also cause significant health problems.

b. Chemical substances that are recognised as potential health risk to the population

Chemical substances selected as priorities under this criterion are those for which the evaluation of toxicological information and exposure data indicate a potential public health risk. The risk assessment may have been carried out by an individual country or an international body, e.g., Joint FAO/WHO Expert Committee on Food Additives (JECFA), Joint FAO/WHO Meetings on Pesticide Residues (JMPR) or the EFSA. The TDS can include certain chemical substances to verify the effectiveness of risk management measures to provide information on dietary exposure trends, or to support risk communication with stakeholders.

c. Chemical substances for which their presence and level in food are uncertain

A TDS used as a screening tool can support a first assessment of total dietary exposure to chemical substances that have been recently identified as potential risk to public health. There might also be chemical substances of interest with inconclusive results from dietary exposure calculations. This can be due to an overestimation by using regulatory limits for concentrations, because of high differences in upper- and lower-bound estimates (see glossary) or due to targeted sampling. Also for substances where data are available only for raw agricultural commodities (RAC) a TDS could complement existing results by covering samples analysed as consumed.

d. Budgetary issues

The budget will influence the level of pooling necessary, so with limited budgets it may be important to prioritise selection of substances that will be present at detectable levels also after the dilution caused by the pooling process. Further, availability and costs of appropriate analytical methods can be important criteria for the selection of substances to be analysed.

e. Political or socio-economic reasons

The public perception of chemical substances in the diet could influence the selection process as well whether or not this is due to scientific, political or socio-economic reasons. Stakeholder inputs should be used to assist in prioritising such substances.

Summary on the selection of chemical substances

In summary, the selection of priority chemical substances to be studied in a TDS should be based not only on available scientific information concerning risk, but may also reflect socio-economic issues. The technical feasibility of undertaking the analyses and ability to include the desired chemical priorities within budgetary constraints may also be key factors. Ultimately, priorities set through an open and transparent communication process will serve to make the TDS more useful and valuable for all stakeholders.

7 Establishing the TDS food list and level of pooling

Given that in a TDS foods are analysed as consumed, the aim of this section is to describe the process of identifying foods to be included in a TDS and then how to collect, prepare and pool them before analysis. The goal should be to represent the diet of average and possibly high level consumers in the

study population. The selected and prepared foods, pooled for analysis are called the TDS food list. The TDS food list is normally constructed in several steps. Initially the most representative foods are selected according to food consumption patterns, followed by decisions on preparation/cooking methods to employ and where and when foods are to be sampled. The final step involves decisions about which prepared foods to combine for each pooled sample before analysis.

The food list is a central part of the TDS design and takes into account the range of chemical substances to be analysed. The composition of the food list will also be determined by the objective(s) of the study, the allocated funds and available food consumption data. The range of foods to include in the food list should be decided in close consultation between all key partners involved in the survey, including the analysts and exposure assessors. The extent of actual diet coverage contributes significantly to the precision of the dietary exposure assessment for the selected chemical substances.

The TDS food list is constructed using food consumption data from which the most consumed foods are selected covering the main contributors to exposure to the chemical substances under consideration. The construction of the TDS food list is based on the available food consumption data, and depending on their coverage of age classes or specific population groups, the TDS can be designed to flexibly address different groups of the population (e.g. children or vegetarians). If food consumption information is available at an individual level, includes a detailed food description and is expressed 'as consumed', it can be used without further modifications after cleaning and validation. If, on the other hand, the information is expressed 'as purchased' and on household level, it needs to be transformed to 'as consumed' per individual (see Chapter 7.1). Ideally, food consumption data should be representative of the dietary habits at national level and the more accurate and precise these food consumption data are the better the estimate of dietary exposure from the TDS will be.

The food list should describe how the foods should be prepared and cooked to reflect as much as possible customary approaches. Examples include cooked foods (e.g. grilled steak without bone; vegetable soup; boiled rice), processed foods (e.g. cornflakes, bread, biscuits) or foods eaten raw (e.g. banana without peel). The food list should also include beverages (e.g. brewed coffee, black tea in liquid form, whole milk, beer and wine) and drinking water. The latter is often forgotten because drinking water is not always included in food consumption or supply data, especially tap water, but it can be a significant source of chemical substances in the diet. The water for cooking and for drinking has, therefore, to be considered carefully for the TDS. When sodium or chloride are part of the TDS analytes, care must be taken to include salt in cooking. The addition of salt and contents of iodine in the salt have to be documented in detail to allow the calculation of alternative scenarios. Further consideration concerning the type of water and inclusion of salt in the cooking process are described in Chapter 8.3.1 on kitchen preparation.

Finally, foods prepared as consumed are pooled into predetermined combinations of food items prior to analysis. The degree of pooling is driven by the purpose of the survey and funding available. It should consider the need to keep food groups separated, avoid combining foods with very different levels of the chemical substances to be analysed, with amounts of the respective food item in the pooled sample proportional to its approximate share in the typical diet.

The following parts of this chapter describe in more details the processes of food selection and pooling, respectively, while chapter 7 covers food sampling and sample preparation.

The three steps in establishing a TDS food list:

1. Identification and selection of representative food items from food consumption data.
2. Review of customary food preparation/cooking processes in common use and selection of food and process combinations to apply.
3. Determination of pooling level of foods, i.e. which prepared food items to combine before analysis

7.1 Criteria for food selection for the TDS food list

Foods are initially selected to cover a large proportion of the diet after aggregation of the consumption data of food and beverages to a reasonable level (grouping similar foods and beverages reported in a food consumption survey). The feasible level of aggregation is determined by the chemical substances under study and the overall purpose of the TDS with factors like species or varieties, fat content in case of fat-soluble substances or the range of household preparation methods used to be considered. The individual foods and beverages would be selected after listing them in descending order by weight consumed. Foods included in the TDS food list should cover at least 90 % of the food intake and as close as possible to the whole diet. This is followed by the addition of special foods considered particularly important for the calculation of exposure (e.g. foods that have especially high levels of a substance or that may be consumed by certain sub-populations such as infants and children).

Most countries have at least some food consumption data for adults, but less often for children and infants. Ideally, food consumption data[6] should be collected at the individual level (e.g. 24-h-recalls, food diary/records, food frequency questionnaires (FFQ), dietary history method). If such data are not available, household data, e.g. household budget surveys (HBS), preferably expressed in adult equivalent[7] (not per head) would suffice. HBS data are less useful as they include foods 'as purchased' and will have to be transformed to foods 'as consumed' (through prices, and edible and yield factors, e.g. see EFSA, 2009). No age-sex differentiation can be achieved, although regional and seasonal differences can be determined. HBS data exclude foods consumed outside the household (which could be a significant amount of food in some countries) and every consumed food is treated as if it was consumed by all members of the household (which might not be the case, e.g. beer or infant formula).

The least preferred choice is food supply data (e.g. FAOSTAT, EUROSTAT or GEMS/Food cluster diets), which are based on agricultural production information. These do not allow any differentiation of food consumption patterns by age-sex, region or season, and also need to be transformed to 'as consumed' (e.g. by applying edible portion and yield factors).

[6] For details about advantages and disadvantages of each consumption survey methods, refer to EFSA guidance for EU Menu survey (EFSA, 2009); General principles for the collection of national food consumption data in the view of a pan-European dietary survey, http://www.efsa.europa.eu/fr/scdocs/doc/1435.pdf) and to IPCS book (FAO/WHO, 2009).

[7] Data expressed in adult equivalent have been adapted to the energy intake of persons in the household according to their age and sex

As not all food consumption surveys include the necessary descriptive information about the foods (e.g. brand names, packaging, origin, or household preparation methods), if relevant, the missing information will have to be assembled through other means. For example, for food consumption data 'as purchased' representative (or standard) preparation and cooking methods need to be selected, e.g. through other studies or focus groups; and where necessary market shares should be obtained through trade statistics. These assumptions need to be documented.

Sometimes, additional care is taken to include all important foods in each food group (e.g. specific fish species, within the fish group, that are likely to contain high levels of certain contaminants for which MLs exist) or those foods eaten in great amounts by consumers (e.g. fish which is consumed by 15 % of the population with an average portion of 200 g while the average portion of the population is 2 g).

If many different population groups are to be considered (e.g. different age and gender groups, ethnic groups or special groups such as vegetarians), more foods need to be analysed individually (because their consumption is different among the population groups), as compared to one population group, e.g. general population, per capita, per adult equivalent. In a second step, additional foods may be included for specific reasons, either foods that could be significant sources of specific contaminants or nutrients, e.g., liver and dried foods (dried fish) for heavy metals, fortified foods and supplements for nutrients, sauces, herbs and spices, or foods that are important for specific population groups or regions (e.g. infant formulae). These two steps will assure that the main contributors to exposure for the chemical substances under investigation (contaminants and/or nutrients) are included; otherwise the TDS might underestimate the exposure.

Once the foods are selected, a decision has to be made for each food to determine if it is an international (see Chapter 7.3), national or regional/local food. National foods are considered to have a similar distribution for the levels of chemicals throughout the country (e.g. brand name foods produced in a central factory), while regional foods may have different levels depending on the region and/or season (e.g. fruits and vegetables, tap water etc.). Handling of national and regional foods is covered in more detail in Chapter 8 under sampling plan.

When dishes are reported in the food consumption surveys, a decision has to be taken either to analyse the final composite food (i.e. the dish) or the constituent ingredients. In the latter case the amounts for the respective recipe ingredient should be added to the corresponding food (e.g. the weight of the pasta from lasagne is added to the food consumption of pasta). Some countries analyse the dish while others, especially when recipes represent a big part of the diet, break them into their ingredients and analyse only single foods (no dishes). Arguments for analysing only single foods and ingredients are: that it is more cost-effective, that dilution effects are minimised, and that this approach provides information on which foods in the dish contribute to the overall exposure. In addition, it is more difficult from an analytical point of view to analyse dishes than single foods. Arguments for analysing dishes are: that some chemical substances might be produced, increased or decreased during the recipe preparation, or that industrially produced recipes might include specific ingredients (e.g. industrial margarine, additives and flavouring agents). Therefore, a decision on whether to analyse dishes or their ingredients needs to be made at an early stage in the planning process.

7.2 Pooling of samples

The issue of pooling is crucial in establishing a TDS food list as pooling influences both the accuracy and the cost of a TDS. Pooling consists of creating a unique food sample for analysis by combining various individual food items. This can either be done through an **individual food approach** (different forms of the same food such as different varieties, seasons, regions or brands or the food prepared with different cooking methods merged into one food sample), or a **mixed food approach** (several

different foods from the same food group merged into one food sample such as a fruit sample comprising of 10 different types of fruits e.g. apple, pear, banana…).

The main advantage of pooling with the mixed food approach, which is mainly used in the TDS for screening purposes, is that a smaller number of food samples are needed to represent the major foods consumed by the population, which is therefore more cost-effective.

Pooling with the individual food approach allows for a more robust estimation of the mean level of concentration, assuming that there is little variation in the concentration levels of beneficial or hazardous chemical substances between the different food items in the sample. In the 2nd French TDS, 15 individual food items were included in a pooled food sample, which provided a 95 % confidence interval of +/-15 % of the mean assuming a standard deviation in the range of 30 % of the mean and a normal distribution (Sirot et al., 2009). In the Catalonian TDS, 24 individual samples were combined per pooled sample (Martí-Cid et al., 2008).

The main disadvantage of pooling is the dilution effect (or a smoothing effect), i.e. when a highly contaminated food item is combined with several less contaminated foods, the pooled samples will have little or no measurable contamination. If foods are pooled to a high degree, the level of the contaminant in the food sample might be so highly diluted that the level of the whole food sample becomes negligible and/or drop below measurable levels. Even if a contamination is detected it would be impossible to define mitigation measures as it is not possible to determine which food(s) in the pooled sample contributed to the contamination, unless sub-samples of the primary foods were retained in storage and analysed individually. The smoothing effect is similarly applicable for nutrient analyses. Additionally, extensive pooling limits the ability to calculate dietary exposure of different population groups with different consumption patterns for the foods comprising the pooled sample, since it will not be possible to distinguish between different consumption behaviour of its components.

As pooling has to be done for the purposes of a TDS, the degree of pooling needs to be determined according to the following considerations:

- Foods should only be pooled within a food group and never across food groups, e.g. do not pool meat and dairy products (except for dishes).
- Pooling should be done according to the relative amounts of the respective food consumed according to the food consumption data, while sometimes taking additional criteria into account such as different regions or seasons as outlined in the sampling plan. Therefore, clear indications should be given on the proportion of every food item and its form in a pooled food sample.
- It is not recommended to pool samples where variability of the contamination is expected to be high, either among foods, seasons or regions, especially in the case of TDS used for refined exposure assessment purposes.
- Pooling should be driven by where the chemical substances are expected to occur (sub-food groups, seasons, market places…) and by the potential need to capture the variability of the chemical substance content.
- Highly consumed foods and foods expected to contain unusually high or low levels of hazardous and beneficial substances should be analysed individually.

If there is a need to consider different cooking methods within one pooled sample, pooling has to be carried out after individual foods have been cooked.

In general, important points not addressed within the sampling plan (see Chapter 8.1) could be considered during pooling. If separate pooled samples are created to represent different seasons but not addressing regional differences, it has to be ensured that the composite for each season is drawn in a representative manner from different regions across the country.

An example of selecting foods and pooling them for different purposes can be found in Table 1 (Appendix A**)**.

7.3 Harmonisation of the TDS food list in an international TDS

Since the TDS food list is intended to reflect the consumption pattern in the population covered, it will be survey specific. However, where there are some commonalities in food consumption patterns between countries there is potential to identify common foods as a starting point for the construction of a partly harmonised international food list. The international TDS food list can only be created after each country has established its national TDS food list, according to the approach described in this document. In addition, agreement could be reached among countries on a basic set of chemical substances that should always be considered for analysis in the respective food. Although a fully harmonised international TDS food list is not envisaged, the use of common principles in the construction of such a list would facilitate international comparisons of dietary exposure assessment results.

There are several prerequisites for such harmonisation attempts to be successful. Participating countries should have a joint mechanism on how to decide on common foods that should be included in each national food list, using common criteria for pooling and sampling. In order to obtain harmonised dietary exposure data, it would be helpful if all countries would have comparable food consumption data. As an example of harmonised collection of food consumption data, EFSA has recently published a guidance for a harmonised approach to collect such information (EFSA, 2009). When individual consumption data are available in all countries, it would be possible to express the data in each country for pre-defined population groups. If some countries would have individual data and other countries HBS data, the common expression for the dietary exposure data would be per person or adult equivalent[8] (and not for different population groups).

It would also be necessary to decide on a common food classification system if the international TDS intends reporting national exposures at food group level or to identify the food groups contributing the most to total exposure. Either an ad hoc food classification system can be developed for this purpose or an existing system can be selected, e.g. FAOSTAT/GEMS/Food, Codex Alimentarius or EuroFIR. The food classification system should fit to other food classification systems if available. In the European context, EFSA is currently developing a modified classification system to specifically address the needs for calculating exposure (EFSA internal mandate M-2009-0135[9]). A draft system called FoodEx 1 has recently been adopted for the Comprehensive European Food Consumption Database and is used in EU Member States for data submissions to the EFSA on chemical substances in food (EFSA, 2011a).

Although it would be desirable to be able to compare occurrence data by food group collected in a TDS framework across countries, this is not considered feasible since the TDS food list is designed on

[8] Data expressed in adult equivalent have been adapted to the energy intake of persons in the household according to their age and sex.

[9] EFSA internal mandate on Development of a Food Classification and Description System for exposure assessment (EFSA-Q-2009-00613, M-2009-0135)

the basis of national consumption data. TDS occurrence data can be compared only when pooled samples are similar, however exposure data are always comparable across countries.

Summary for the TDS food list including pooling

The TDS food list consists of descriptions of pooled samples of ready-to eat foods representative of about 90 % of the population diet as well as special foods considered particularly important for the calculation of exposure. The available food consumption data determine if an exposure assessment of different population groups is feasible. Water consumption needs to be estimated if not reported in the food consumption survey. Foods are always pooled, usually after preparation but before analysis. Pooling should be limited if the purpose of the TDS is to perform a refined exposure assessment. Commonalities in methodology and food selection should be explored when international comparisons are of interest.

8 Food sampling and sample preparation

The main objective of sampling is to collect foods in a way that the exposure estimates represent as best possible the chemical substances in the foods available on the market (WHO, 2007 and 2008a). Each food in the TDS food list has, therefore, to be examined for the factors influencing the level of the chemical substances under consideration in this food. In general, regional and seasonal differences are considered as the main influencing factors. Therefore, they will be explained in detail below. However, other factors can also be important such as variations in fat content (e.g. for dioxins), packing materials used, and differences in varieties, brand name or flavourings. But these factors will not be dealt with in this document.

The sampling details are important as they determine if the samples and the analytical results are representative of the food supply in the whole country, and if the sample volume is sufficient for analysing the different chemical substances and for them to be detected through a TDS approach.

The sampling plan should also specify the weight of the foods to be collected. First, each laboratory has to specify the quantity needed for each analysis, which is usually between 50 and 500 g of fresh weight. Second, the proportion needed of each food in the pooled sample to reflect relative consumption should be calculated. From this information the minimum weight needed of each food can be estimated by considering that only the edible part (removing peel, bones, stones or seeds, etc.) will be analysed and taking account of possible water loss or gain during cooking/preparation. Consideration should also be given to including one or more extra sub-samples to be stored for future testing should this be relevant.

8.1 Sampling plan

Most TDSs cover at least one of the two main aspects of representativeness: seasonality and geographical variation.

The geographical coverage is important because of regional differences in dietary patterns and in the levels of the chemical substances in foods. This issue can be addressed by defining national and regional foods. National foods, including processed foods, are likely to present homogeneous contamination levels in all regions, e.g. the food is produced in one factory by one manufacturer who delivers across the whole country. Regional foods include foods that are expected to differ in levels of the investigated chemical substances due to e.g. environmental factors like levels of substances in soil, local contamination due to waste incineration or mining, regional/local climate, differing species/varieties produced, agricultural practices (fertilisers, pesticides used), or different supply

pattern between regions. Examples of TDSs that include national as well as regional sampling of food are France (Leblanc et al., 2005a and 2005b; Sirot et al., 2009), Catalonia (Martí-Cid et al., 2008), Australia (FSZANZ, 2008) and New Zealand (NZFSA, 2005). Even if no separation is made between national and regional samples, the sampling has to cover geographical differences by taking samples from different representative regions within the area under investigation, as has been done for Italy (Carnovale et al., 2000), UK (Church, 2000) and the U.S.A. (Egan, 2002a, Egan et al., 2002b, Murray et al., 2008).

Apart from regional differences, levels of chemical substances can also vary between urban and rural areas in the same region. Figure 2 illustrates the possible impact on dietary exposure estimates when sampling was only done in urban areas. Depending on the location and heterogeneity of the chemical substance levels, a TDS will over- or underestimate the true exposure of the population. Only when the contamination is uniformly distributed over the entire country, sample bias will be avoided and results correctly estimate actual dietary exposure.

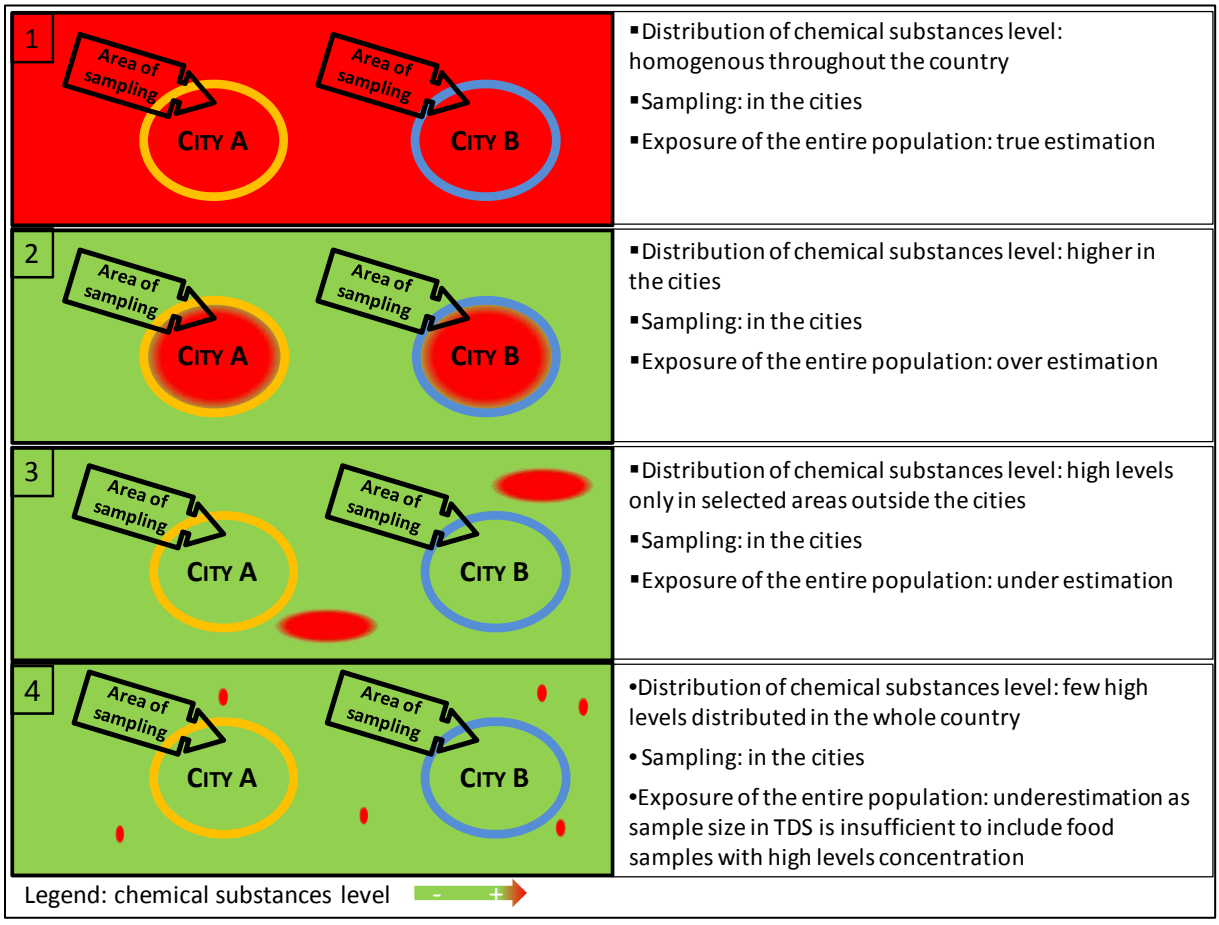

Figure 2: Impact of chemical substance levels and their distribution in relation to sampling in calculating exposure.

The premises where the sample is taken can also have an impact on representativeness of the results. For locally produced unprocessed foods it is important to ensure that discount shops, supermarkets as well as farmers' markets are sampled proportionally to their market share. This can be achieved by using market share data to select the purchase location. Additionally, in some countries market share data will be used to select subsets of food, e.g. according to brands (Sirot et al., 2009; Leblanc, 2006).

Seasonality should be addressed for foods for which the level of specific chemical substances will vary due to climatic conditions (e.g. nitrate in leafy vegetables) or seasonal supply variations (e.g.

fresh fruits that will come from local production during the main season and be imported during the rest of the year). However, it is not always possible for TDS sampling plans to address such differences because consumption of many food items peak during the same period causing a problem with sampling storage and laboratory capacity during a single season.

Seasonal variations can be addressed by planning a number of sampling periods along the year that might vary according to the purpose of the study. In the US, Czech Republic and New Zealand samples were drawn four times a year (Egan, 2002a; Murray et al., 2008; Ruprich and Rehurkova, 2002; NZFSA, 2005) and only two times (each lasting 6 month) in the 2nd French TDS (Sirot et al., 2009). Depending on the purpose of the study seasonal sampling of foods might not be necessary, e.g. in a TDS focusing on food additives (FSZANZ, 2005).

Hence, the main challenge in defining appropriate sampling procedures will be to consider the profiles of different substance classes related to specific food item characteristics, seasonality and geographical coverage. Food collectors need to be aware of how important their work is to the success of the TDS, and that it needs to be carried out strictly according to the sampling plan. Therefore, it is useful to develop and closely follow Standard Operating Procedures (SOPs) for sampling (WHO, 2007).

8.1.1 TDS as a screening tool

When the TDS is used as a screening tool there will only be a limited number of relatively broad food groups in the food list, even though they are often analysed for a large range of chemical substances of interest. It will not be possible to identify seasonal or regional differences in such situations because pooling provides only overall mean values. For the sampling plan to be representative it should include individual food items proportionally sampled in regions and seasons according to consumption profiles to avoid sampling bias, should an impact be expected.

8.1.2 TDS as a tool for refined assessments

On the contrary, when the TDS is used as a tool for a refined dietary exposure assessment it will allow the investigator to take account of seasonal and/or regional differences. For this purpose, samples from at least two seasons and an appropriate number of regions should be taken if seasonal or regional variations are expected. In view of the more detailed nature of the food items in the food list, the sampling plan could also address brand differences, product origin and other factors that might be associated with the contamination.

8.2 Food collection, preparation and transport

After the decision on the chemical substances to be analysed has been made and the food list and sampling plan have been established, it is important to focus on the details of the collection and preparation of food samples for analysis. These two steps are closely linked, thus a team approach would be the most effective way forward (see Figure 3).

To ensure consistency it is recommended that SOPs be used. SOPs should address issues like sample receipt procedures, appropriate documentation, and the setting of priorities for foods to be sent for sample preparation or for analysis. SOPs should provide detailed descriptions for sample preparation (e.g. instructions on how to prepare each food, equipment to be used, acceptable containers, contamination control) and food compositing (WHO, 2002).

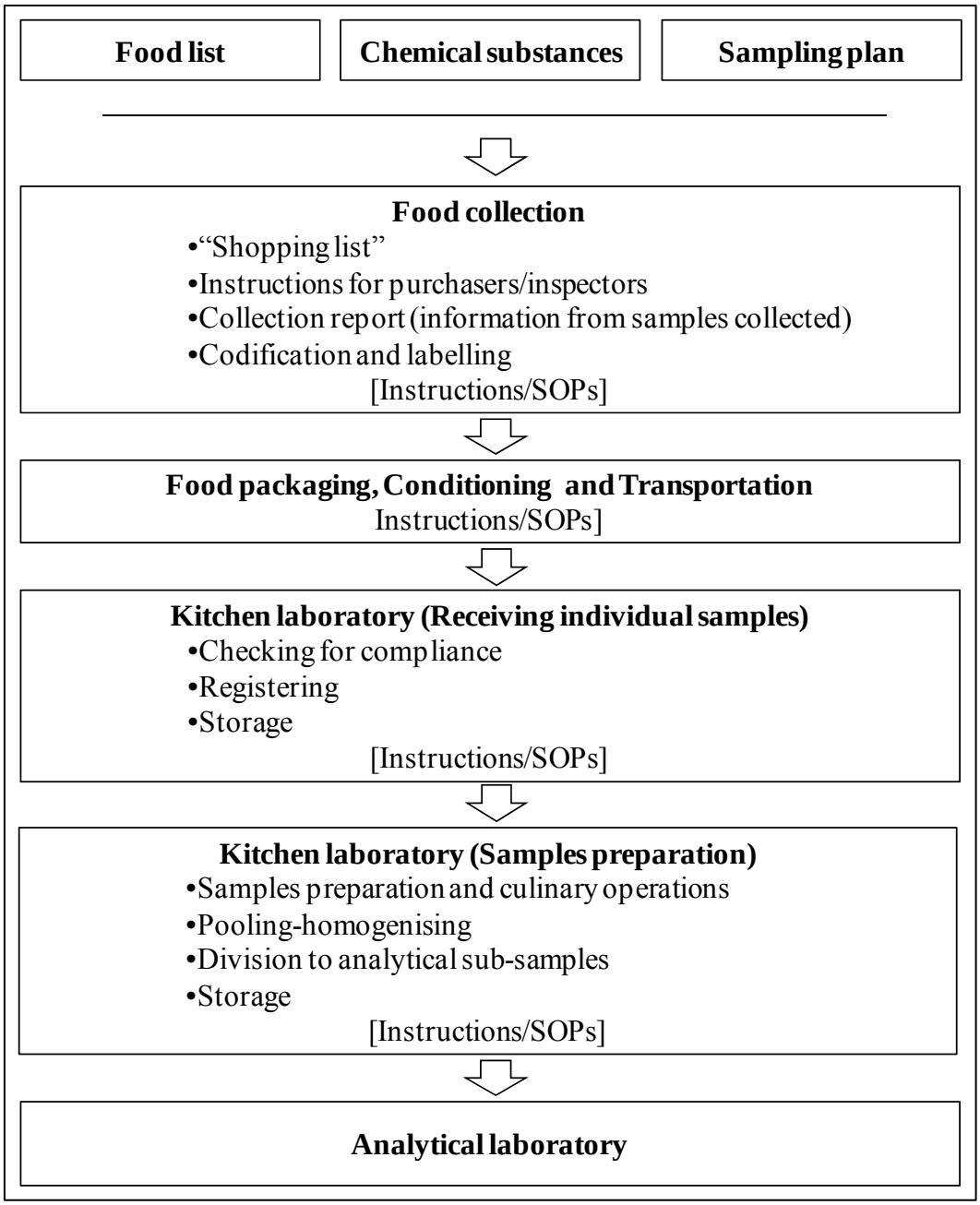

Figure 3: Flow chart of the tasks needed to be carried out for TDS from the food collection to the laboratory analysis.

8.2.1 Food collection

It is recommended that the food collection step (or food shopping) be organised on an individual food basis, considering every food item separately, irrespective of the number of foods defined (e.g., food with or without seasonal variations, or regional and national food) or the number of samples that will be finally pooled. Sample collection can be carried out either by e.g. official inspectors or contractors. Detailed descriptions of every food product to be purchased (type, brand, etc.) and instructions for buying, conditioning and transport should be given to the shoppers.

The design of the protocol for the collection of the foods recorded in the food list should include important practical aspects like time of collection, season, selection of retail market place, and sample size.

It is suggested to draw up a food collection program over a specified period of time (e.g. three months or one year) and for different regions, since collection is carried out over a number of weeks and often in different regions. This is usually the most effective way of managing large volumes of food (WHO, 2002) taking into account factors like kitchen and laboratory capacity.

In the 2nd French TDS, sampling was designed to cover about 20 months of a 3-year period with two seasonal waves of sampling. The Czech TDS has a rolling sampling period of 2 years with every year divided into 4 seasonal parts.

The food collection protocol could include (WHO, 1985; Egan, 2002a; FSA, 2006; Vannoort, 1997; Greenfield and Southgate, 2003):

a) **Instructions for food collection** (to be given to inspectors or purchasers)

- food item, specifying variety or brand (purchaser can also be asked to follow his own decision and indication would be 'any variety' or 'any brand');
- instructions for food codification;
- place of shopping;
- type of retail shop (this information is not needed where a brand is specified);
- number of food samples to collect, including contingency samples where the food is fragile and easily damaged during transport (e.g. eggs);
- sample size (volume or weight); it will be driven by edible portion, chemical substances to be tested, and analytical requirements;
- corrective actions (e.g. what to do if a type or brand is not available in the specified shop or place) and any alternatives applied need to documented.

b) Food logging (Collection Report), codification and labelling

It is recommended that inspectors or purchasers collect useful data on the individual food item when samples are bought. The report document can be named *Collection Report* and it should contain:

- food identification (for traceability purposes a codification system should be adopted so that every food item is kept identified from purchased to kitchen prepared);
- product type, brand and batch number;
- expiry date indicated as "best before" or "use by" date;
- sample size (weight, volume, units);
- sample condition at time of purchase;
- date, location and retail type of purchase;
- packaging type when purchased, e.g. vacuum packed, plastic bag, wrapping paper;
- packaging and conditioning for transport, e.g. cardboard box, isothermal box with coolants;

- costs of the samples.

Any deviations from the sampling instructions should be recorded and every collection report signed by the responsible inspector or purchaser. These documents should be submitted together with the respective samples to the laboratory/kitchen.

Every food item should be labelled with its identification number or code and each label should correspond to a food information report containing the above-mentioned data collected for the respective food product.

8.2.2 Food packaging, conditioning and transport

In a TDS, usually a considerable effort is made to follow normal consumer behaviour. Nevertheless, in most cases, large sample sizes of different foods are collected simultaneously and need to be transported to distant locations. This could potentially affect the stability of food products and the chemical substances of interest jeopardising the reliability of results unless extra care is taken.

Special requirements depend on the type of food and on the specific stability of the chemical substances to be analysed, especially when taking into account potentially harsh climatic conditions in some areas. It is important to keep the time between purchase and delivery to the kitchen or laboratory as short as possible (WHO, 1985). Refrigerated transport is recommended and frozen foods should always be packed and transported to the kitchen by using freezers or isothermal boxes with coolants or dry ice. In some cases, intermediate cooling has been used before transport to the kitchen or laboratory could be organised (FSZANZ, 2008; FDA, 2010).

Cross contamination and other damage during transport should be avoided. Food may be kept in their original packaging only if considered secure enough; if not, samples should be placed into a "clip top" or "whirl-pak bag" for extra protection (Vannoort, 1997).

Close collaboration between staff is essential and it is important to set a time schedule for the relevant steps that need to be followed and co-ordinated, especially if multiple regions are being sampled simultaneously.

8.2.3 Receiving individual samples and acceptance criteria

Before registering the food at the receiving kitchen, any incoming dispatch should be checked for compliance with specific acceptance criteria following a "Food Receipt Check List" as detailed in a SOP. The following criteria could be applied (Vannoort, 1997):

- every individual food item should be accompanied by a collection report and should be the same as indicated in the shopping list;
- the food amount (weight, volume) should be above the minimum required in the purchase instructions;
- the food should be in a reasonable condition (edibility criteria, visual appearance, odour, etc).

Temperature of the food should be controlled on arrival or if considered essential for particular product types a temperature logger could accompany the transport.

Objective measures should be defined to decide if the food items are suitable for the next steps of sample preparation and analysis. Such measures could be defined as "edibility criteria" consisting of sensory parameters specific for each food group and should take account of normal national consumption practices. Below are a few examples of such criteria for certain food groups:

- veal should be red to pale, flesh of medium consistence, without acid smell;
- chicken meat should be pinkish, soft and have a characteristic smell;
- fresh fish should have a closed mouth and eyes with slightly transparent cornea, muscle should be elastic and securely attached to bones, soft and have a characteristic smell;
- fresh fruit and vegetables must have the characteristics indicators for each type when observed at room temperature (colour, smell, taste, appearance etc.);
- nuts are not allowed to smell or taste rancid or be mouldy.

8.2.4 Food sample registration

After checking for compliance food samples should be registered considering the following information:

- reception date in the laboratory;
- identification of sample number from the collection report;
- sensorial test following sensorial criteria: corresponding/not corresponding;
- link with the original sample coding;
- type of sample e.g. yoghurt with vanilla;
- sample weight e.g. 2 X 200g;
- type of sample preparation/cooking, if necessary (e.g. washed, peeled, boiled, grilled);
- type of analysis e.g. pesticides;
- storage e.g. - 4 ^{0}C;
- storage period until sample preparation;
- comments/observation;
- signature of the person responsible for recording and sensorial examination in the laboratory.

8.3 Kitchen preparation

Sample preparation including cooking can be carried out either in a specific total diet kitchen (as in the Czech Republic and Spain) or in an existing kitchen adapted for the purpose (Leblanc et al., 2005a and 2005b; Egan, 2002a). Besides cooking facilities, the kitchen must have specific equipment such as special blenders or homogenisers (adequate to prevent contamination and substance loss, e.g. tinted glassware for light labile vitamins).

The kitchen preparation step prior to chemical analysis is fundamental in mirroring reductions or increases in the levels of chemical substances or the formation of new chemical substances that would occur during household preparation.

It is necessary to understand that a TDS kitchen in reality has a laboratory character and similar quality management requirements are needed in this step of the TDS sample preparation as in the analytical part (Rehurkova, 2002). The kitchen preparation has its own strict rules to ensure standard compliance, i.e. food handling operations should be fully defined, repeatable and documented in SOPs. Instructions should include descriptions of utensils and instrumentation requirements as well as staff training needs and qualifications.

Highly perishable food or food in which unstable chemical substances are targeted should be treated with priority (e.g. dithiocarbamate analysis) or refrigerated and processed within 48h, while for frozen or shelf-stable food the time factor is less important (Vannoort, 1997; FSZANZ, 2008).

Inedible parts (bones, fish skin, shells, seeds, inedible peels, etc.) are always removed before or after cooking depending on the food (Sirot et al., 2009). For some foods, dietary habits are important when defining the edible part, e.g. some fruits (apples) could be eaten either with or without peel.

Dishes and food should be prepared as reported in the food consumption survey or decided for the TDS food list. Additional parameters (e.g. water or salt) should also be considered when preparing food for a TDS. Examples of specific food preparation methods are given below.

Preparation of coffee & teas

Such products are consumed in the form of beverages. The preparation of these drinks leads to the extraction of hydrophilic substances in the presence of hot or boiling water. It is important to mimic the preparation of these drinks in a way that does not lead to the extraction of other chemical substances.

Preparation of powdered food (e.g. infant formulas, instant coffee)

As noted previously for other foods, it is recommended to follow procedures that lead to the release of relevant chemical substances. The alternative is to analyse the powder (e.g. infant formula) and the water separately. For example, in the French TDS very pure water was used to prepare infant milk samples and different water brands were analysed separately to efficiently build different scenarios for the exposure assessment (different milk brands with different water brands).

Preparation of food using water

As the aim of a TDS is to estimate exposure from the entire diet, and not only to certain foods, tap water should be utilised in cooking procedures as recorded in the food consumption survey. This has two advantages in relation to chemical substances. Firstly, the osmotic pressure in cooking water equates to the one used in normal cooking and therefore, no additional leaking will occur from the food into the water which would underestimate the level of the chemical substances in the food. Secondly, the exposure due to water, even though it can vary significantly, is taken into account. In the past, TDS have used distilled or deionised water for cooking (FSA, 2000; Lombardi-Boccia, 2003; Vannoort and Thomson, 2005; Murray et al., 2008) as recommended previously by GEMS/Food (WHO, 2002). Use of distilled or deionised water could significantly underestimate total exposure. It is now recommended to collect tap water from different regions and use a mixture for cooking to simulate mean dietary exposure through water. If this is, however, not possible, the tap water from the laboratory can be used. The water used for cooking but naturally drained before consumption should not be included in the calculation of dietary exposure.

Preparation of food using salt

In the past, many TDSs were performed without salt addition (FSZANZ, 2008; Lombardi-Boccia et al., 2003; Murray et al., 2008; Benkhedda et al., 2009) while others added salt (Sirot et al., 2009). In general, salt should be used in food and recipes preparation in the quantity reported in food consumption surveys or as estimated though other means. The same reasons apply as for water to use

salt (osmotic pressure, minimised loss of chemical compounds into cooking water, intention to capture full exposure).

Preparation of food using kitchen utensils

Use of common kitchen utensils is recommended in order to simulate the same exposure experienced by the population. However, in the past, materials such as stainless steel, Teflon-coated utensils or glass/Pyrex equipment were used (Vannoort and Thomson, 2005; Leblanc et al.,, 2005a and 2005b; Lombardi-Boccia et al., 2003; FSZANZ, 2008), which may underestimate the total dietary exposure to certain migrant chemicals and are, therefore, no longer recommended. Laboratory utensils or equipment like blenders should however not add any additional contamination, as they are not used in the population for normal food preparation.

In summary there are two major options to consider in kitchen preparation:

- *Preferred option*: in order to reflect consumer practices the use of tap water, salt and traditional kitchen utensils is recommended. This way exposure estimates will mirror population dietary habits. In order to evaluate the resulting exposure assessment and to account for all sources of uncertainty, the type of water, the amount and type of salt and the kitchen utensils used should be reported. This is particularly important in case of unexpected analytical results and to assist risk managers in evaluating the exposure estimates.

- *Special option*: in the case of studies on specific substances it could be preferable not to include new sources of uncertainty associated with the use of tap water (during washing and cooking procedures), the use of salt and potential contamination from kitchen utensils (e.g. studies on iron or copper intake from the diet; additional iron intake might derive from the use of utensils). This would give a more precise estimate of the levels in the individual foods but may underestimate total dietary exposure from food as consumed.

8.4 Storage of samples before and after preparation

Different food storage conditions should be set depending on the type of food and the chemical substances to be analysed.

- Perishable fresh food should be kept refrigerated at 2-4ºC until prepared (max. 24-48h), (freezing should be avoided unless there is no other choice in order to reduce freezing and thawing cycles and possible subsequent compositional changes).

- Frozen food should be stored in a freezer (-20ºC), when necessary samples should be thawed in a refrigerator before sample preparation.

- Non-perishable foods (beverages, nuts, canned food) could be stored at room temperature in dry and cool places.

After preparation and pooling, samples are usually stored until delivery to the laboratory. Available data show that in most cases freezing (-20 ºC) is the preferred treatment for such storage (Anderson and Cunningham, 2005; Benkhedda et al., 2009; FSA, 2009; Leblanc et al., 2005a and 2005b; Lombardi-Boccia et al., 2003; Vannoort 1997).

Storage conditions (e.g. time, humidity and temperature) should be set related to the chemical substances to be analysed; some substances may require specific food storage conditions, especially when stored for a long time, e.g. in the case of dithiocarbamates it would be better to store samples at -70 ºC. Freeze drying could be recommended in some circumstances, e.g. when analysing mycotoxins.

Frozen samples should be delivered to the laboratory in a frozen condition. Samples like biscuits, bread, breakfast cereals are exceptions and can be delivered at room temperature.

Improper storage conditions may distort TDS results either by causing chemical substance losses or changes in the final food composition (e.g. loss of water) as is shown in Figure 4.

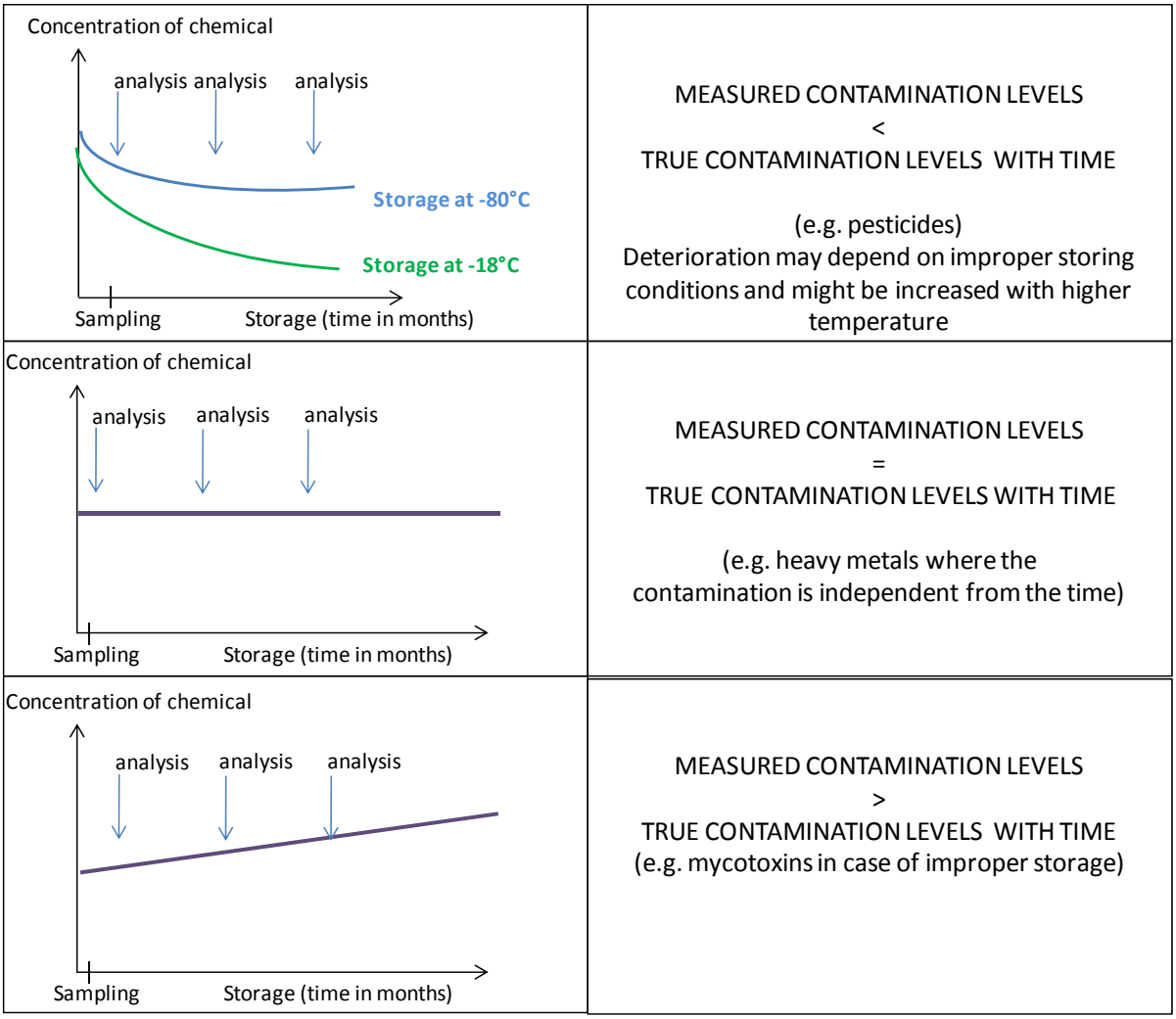

Figure 4: Possible effects on the chemical substance levels in the food matrix due to different storage conditions.

Summary on food sampling and sample preparation

Sampling (e.g. region, season, market share) and sample preparation (e.g. transportation, storage, cooking methods and utensils, which should be as close as possible to the preparation in the population) influence the result of the TDS and care has to be taken to address all factors that could affect the results. SOPs should be developed for each critical step to assure a consistent and rigorous implementation.

9 Chemical analysis

Even though chemical analysis represents the biggest part of the TDS budget the cost of analysis should be a minor issue when selecting an analytical laboratory to carry out a TDS. Most of the emphasis should be placed on the quality of the analytical data produced by the laboratory, because it highly influences the results and robustness of a TDS. Poor laboratory performance may jeopardise TDS results and may be due to an inadequate method, insufficient method performance, inexperienced staff, lack of quality-controlled procedures, and limited experience of the particular food matrix in the analysis of the chemical substances under investigation.

Laboratories should demonstrate the performance of their methods, which have to be fit for the specific purpose of the TDS. Therefore, methods applied in food monitoring and surveillance, when intended to be used in a TDS should be adapted if necessary to take into account its specific requirements (food matrix, chemical substances, LOD/LOQ, etc.).

9.1 Criteria for selecting laboratories for TDS analysis

The TDS laboratory can be equipped for both the laboratory analysis of foods as well as the kitchen preparation, including facilities to convert food samples into analytical samples. No specific quality requirements exist for a TDS laboratory. Therefore any laboratory can be used that can prove their ability to carry out the required chemical analyses in the specific food matrices at the requested LOD/LOQ using a well-implemented quality assurance system covering the whole TDS process (sample extraction, analysis and data interpretation). What is important is that the analytical methods should be capable of quantifying the relevant harmful or beneficial chemical substances at the concentration levels of interest in the respective food matrices.

An important basic requirement for a competent laboratory is to participate in proficiency testing programs. Laboratories carrying out official food control normally do so. Unfortunately, proficiency tests specifically designed for TDS surveys are not available because a TDS includes foods as consumed for which no certified reference material (CRM) is available; therefore the importance of internal performance testing should be emphasised.

In general the highest quality data can be expected from laboratories that are accredited for the chemical substances and food matrices to be analysed in the TDS.

9.2 Laboratory capacity

Finding laboratories experienced in food chemical analysis in the developed world is less difficult than in most developing countries. In theory, there are four different options or combinations of options to identify suitable laboratory capacity, although the use of the fourth option is generally discouraged:

- to use different national laboratories e.g. which have already been involved in monitoring and surveillance activities;
- to nominate a central TDS laboratory to carry out a majority of the analyses of TDS samples;
- to use existing commercial enterprise laboratories;
- to set up a new laboratory.

Whatever option is chosen, the laboratory should provide proof of being able to analyse the chemical substances according to the TDS requirements.

9.2.1 National laboratories

Official national laboratories are typically accredited and are high quality laboratories with established quality-controlled operations. They commonly have state of the art instrumentation and experienced staff to carry out various types of food analysis. Although experience in conducting analysis for TDS would be limited in most laboratories, this issue could be addressed via effective networking with more experienced laboratories in TDS. In the long run, this is probably the low cost model, particularly if a TDS network can be established and a rolling type of TDS is planned for a geographical area.

9.2.2 Central TDS laboratory

Other than the US FDA facility in Kansas, there is currently no nominated central TDS laboratory in any continent. However, the idea of a specialised central TDS laboratory carrying out a majority of the analytical work related to TDS analysis is appealing. It might even be a necessity to establish such a laboratory for particularly demanding and/or expensive sample analyses. This would facilitate the analysis of difficult analytes in complex matrixes, probably lower the cost of the analysis and may produce improved data quality. A good example of this type of arrangement would be dioxin or arsenic speciation analyses. The central laboratory may be one of the laboratories involved in the TDS laboratory network or alternatively an accredited commercial laboratory. Over time, a laboratory network may evolve that have members that are specialised in certain analytical methods providing analytical services to other members of the network.

9.2.3 Commercial enterprises

Commercial laboratories may also provide analytical services applicable to TDS. However, TDS-ready validated analytical methods for all analytes and food matrices planned for the survey may not be available in the commercial enterprises. This fact will put more pressure on the TDS laboratory planning phase because the customer needs to describe in detail the method performance criteria in a tender. Some laboratories may also underestimate the challenge TDS samples may present. Potentially national laboratories/networks may outsource some particular analysis, like dioxin analysis, to a well-established commercial laboratory rather than building their own capacity. On the other hand, commercial laboratories might not be willing to cover the whole spectrum of matrices and analytes necessary at the levels required and lack resources to respond timely. This also highlights the importance of a 'mini' pilot study prior the TDS starting, in order to validate any analytical methods and laboratory to be used. It will also serve to validate procedures associated with sampling and sample preparation.

9.2.4 Establishing a new laboratory

Generally speaking, to establish any analytical laboratory is a challenging task for many reasons. Firstly, the laboratory space has special needs like e.g. air conditioning, extensive ventilation and a highly stable electricity supply. Therefore new laboratories are typically set up in new buildings designed for laboratory use only. Secondly, the instrumentation, chemicals and reference materials needed can be expensive. Thirdly, hiring experienced and qualified personnel to set up quality-controlled laboratory procedures may be difficult. In addition to all these, there is a need for an effective support infrastructure, particularly in relation to information and communication technology practices. Often, there are not always a sufficient demand for analytical work to keep the staff and instrumentation busy enough to run the laboratory cost-effectively.

To set up a brand new laboratory dedicated to chemical analyses of TDS samples is an even more daunting task. From a quality management point of view a new laboratory has no means to prove the quality of the work because of the lack of TDS specific proficiency tests. Therefore, the quality of the

laboratory needs to be proved by using normal procedures e.g. accreditation/validation before it could be considered for analysing TDS samples.

9.3 Worldwide TDS laboratory network

Once the popularity of the TDS approach increases the number of laboratories experienced in TDS activities will grow and the establishment of a TDS related laboratory network could be explored. The goal of a TDS laboratory network would be to strengthen the performance of the laboratories involved and to improve the robustness of the individual analytical methods in the TDS programs. The way in which the laboratory network can help strengthen the quality of the analytical data include:

- proving that the analytical methods used are fit-for-purpose;
- improvements to quality assurance through proficiency testing for TDS purposes;
- implementation of validated analytical methods and SOPs in sample handling;
- training and/or exchange of laboratory staff;
- sharing of in-house and commercially available primary reference materials (RMs) as well as development of CRM for foods as consumed;
- coordination of method development activities to prevent duplicative work.

To ensure comparable TDS data within the TDS laboratory network, unified systems should be in place in order to enable laboratory personnel to attain and demonstrate the accuracy and traceability of the TDS measurements. This would require that the following key elements in the measurement and testing infrastructure be addressed:

- use of only validated methods;
- use of matrix matched CRMs and RMs or fortified/spiked samples;
- participation in proficiency testing if available for TDS methodology.

Within a worldwide TDS laboratory network it may be cost-effective to centralise some particular analytical work to one or more laboratories. This would also help customers not familiar with laboratory work in their tendering process.

9.4 Performance criteria for analytical methods

In validating an analytical method, the laboratory employs systematic quality related testing to ensure that a method produces results that are fit for purpose (Thompson et al., 2002; Eurachem/CITAC, 2003; Eurachem, 1998). General validation parameters for individual analytical methods used in a TDS do not differ from parameters used in e.g. monitoring or surveillance programs. The general validation should include at least the following parameters: selectivity, range of concentrations, linearity, LOD, LOQ, precision, accuracy and recovery (see Glossary). It is important to have definitions for the validation parameters to avoid confusion in data use and communication. It is also important to agree on the minimum requirements for method validation, particularly in the case of non-accredited laboratories.

Laboratories should only use methods that have been characterised as suitable for the matrix and analytes of interest. From the customer's point of view, before being selected a laboratory must provide an adequate documentation describing the performance characteristics of a method and its

suitability for a TDS. Laboratories need to ensure that the method is scientifically sound and that performance characteristics of a method are understood.

European Commission regulations lay down requirements for LOD/LOQ for selected chemical substances as part of the official monitoring and surveillance program. The requirements vary in their specificity in that in some cases maximum fixed performance values are used, while in others relative performance in relation to legislated maximum levels are used. Sometimes no performance criteria are specified. For example:

- In analytical methods for most metals performance criteria indicate that in general LOD should be validated at one tenth of the regulated maximum level (ML) and LOQ at one fifth of the ML (Commission Regulation (EC) 333/2007[9]).
- In analytical methods for 3-MCPD and benzo(a)pyrene fixed values of at least 5 and 0.3 µg/kg, respectively, for LOD and 10 and 0.9 µg/kg, respectively, for LOQ are given (Commission Regulation (EC) 333/2007[9]).
- In analytical methods for dioxins the LOQ for a confirmatory method applied in monitoring should be one fifth of the level of interest (Commission Directive 2002/69/EC[10]).
- Regulatory performance criteria do not exist for pesticides. However, a level of 0,01 mg/kg is regularly used as reference value as it is the LOQ required in the analysis of pesticides from matrices in which pesticide residues are not allowed. This level is also required in proficiency tests for vegetables (TESTQUAL, FAPAS, CRL, etc.).

In contrast to monitoring and surveillance activities, which target compliance with legislated maximum levels, the main purpose of a TDS is to calculate population dietary exposure. Thus, in general, LOD/ LOQ requirements should be lower than regulatory requirements and should be driven by the need to estimate dietary exposure within an acceptable range of uncertainty. This can be achieved by taking into account average food consumption data and some pre-estimate of exposure or toxicological reference value (e.g. Acceptable Daily Intake, ADI). In case that all results are left-censored (below LOD or below LOQ), the resulting upper bound exposure should ideally not be more than a small proportion (e.g. 25%) of the target limit. The target limit being either a toxicological reference value or some pre-estimate of exposure using regulatory maximum levels. How much each food item is contributing to overall exposure/toxicological reference values depends on the consumption of the specific food items. For foods that are highly consumed and are part of a recommended healthy diet, lower percentages might be preferable compared to rarely consumed foods.

It might happen that contaminated foods are pooled with non-contaminated foods in a TDS, which will result in dilution of the analytes. Therefore, to ascertain that low levels of chemical substances can also be quantified, an additional effort to reduce LODs and LOQs is required. This is particularly important when broad ranges of different foods are pooled. The more disparate the foods in a pooled sample, the lower the LODs and LOQs should be. Because of the extra demands on the analytical performance in a TDS, attention to the performance of the analytical equipment is crucial as is the

[9] Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs. OJ L 088 , 29/03/2007 P. 29-38.

[10] Commission Directive 2002/69/EC of 26 July 2002 laying down the sampling methods and the methods of analysis for the official control of dioxins and the determination of dioxin-like PCBs in foodstuffs. OJ L 30, 31.1.2002, p. 50–51.

knowledge and experience of laboratory staff in introducing new or optimising existing methods in relation to LOD and LOQ.

9.5 Presentation of analytical results

Every measurement has an uncertainty associated with it, resulting from errors arising in the various steps in sampling and analysis and from the imperfect knowledge of factors affecting the data. A statement of uncertainty is a quantitative estimate of the limits within which the value of an analyte is expected to lie. Laboratories accredited according to ISO/IEC 17025:2005 (General requirements for the competence of testing and calibration laboratories) are required to evaluate the measurement uncertainty and similarly measurement uncertainty needs to be reported in TDS.

For consistency, specific templates should be developed for reporting of TDS results. General reporting of results should include sample code, name and definition of analytical substances, value, units and denominators, analytical method used, QA/QC measures, LOD and LOQ and in addition:

- Recovery - the analytical results shall generally be corrected for recovery and the level of recovery should be reported;
- Measurement uncertainty - the analytical result shall be reported as x +/- U whereby x is the analytical result and U is the expanded measurement uncertainty, using a coverage factor of 2 which gives a level of confidence of ~95 % (U=2u).

Often, additional comments are given if necessary on e.g. the state of the sample on arrival to the laboratory to assist in providing an explanation of odd analytical results.

Summary on chemical analysis

The laboratory and the analytical methods have to be selected with greatest care to assure high-quality analytical data in order to perform a relatively accurate dietary exposure assessment. In general, the analytical requirements for TDS are similar to food surveillance and monitoring programs (e.g. quality assurance, laboratory and method performance) but TDS call for lower LOD/LOQ and add extra difficulties because of the complex and varied food matrices.

SECTION C: EXPOSURE ASSESSMENT AND COMMUNICATION OF RESULTS

10 Exposure assessment to harmful and beneficial substances

A TDS is not set up to capture variations in individual food results, but rather through representative pooling of commonly consumed food to provide a baseline for the occurrence of chemical substances in the general diet. Because of this averaging nature, TDS results are best suited for calculating chronic exposure to food chemical substances, it may be also used for the analysis of trends and to assess the effect of risk management measures, where the sample size is sufficiently representative. If complemented by results from targeted monitoring and surveillance activities of individual food groups, specific dietary exposure scenarios can be also constructed in a suitable way for acute exposure assessments. The TDS survey will provide background information on harmful and beneficial chemical substance levels in the general food supply across the diet, while monitoring and surveillance activities can capture more highly contaminated individual food items. Their complementarities will allow the identification of the relative importance of individual sources of chemical substances in relation to their contribution in the whole diet.

10.1 Preparing the consumption data

Exposure is calculated by relating analytical data for the occurrence of chemical substances to the consumption of the respective food. Ideally, food consumption data should be available at individual level as consumed and be linked to the analytical data through the TDS food list (see Chapter 7).

Consumption data at individual level allow calculation not only of mean exposure for the population but also consideration of low and high percentiles of exposure due to low or high consumption. In order to calculate exposure for different population groups, the food consumption data should cover a sufficiently large sample size of the population and allow a matching between occurrence data to the different food patterns.

Data used to calculate individual food consumption are usually collected on a limited number of days (between 1 and 7 days), which could underestimate the number of consumers of particular foods and overestimate high percentile consumption of non-habitually eaten foods (FAO/WHO, 2009). Therefore, specific statistical methods (e.g. EFSA Art 36 project M-2009-0254[11]; Hoffmann et al., 2002) should ideally be applied to narrow the distribution.

If HBS data are used, dietary exposure can only be extrapolated to an adult equivalent level and be associated with significant uncertainty.

If food consumption data are available for different regions and/or seasons, it has to be decided if the consumption and occurrence data should be averaged to a year-round national mean value before calculating the dietary exposure, or matched at seasonal and/or regional level before being averaged. All the choices made for calculations should be clearly explained.

10.1.1 Relating consumption data to body weight

It is recommended that dietary exposure be expressed in the same unit as the reference health based guidance values. Moreover, a common unit will make comparisons easier among different regions or countries. Exposure can be expressed as a quantity of ingested chemical substances per capita, by day, by week or by month. Nevertheless, many health-based guidance values for food chemical substances

[11] EFSA-Q-2010-01342, M-2009-0254. Art 36 – Scientific co-operation - Data collection and analysis. Probabilistic tool to estimate "usual" intake distribution in the Comprehensive Food Consumption database.

are usually expressed as a quantity of ingested chemical substance per kg of body weight and per period of time. If available, the body weight of each subject should be used for individual exposure. If not, the international default of a mean weight of 60 kg for adults and 15 kg for children should be used (FAO/WHO, 2009). For specific populations other default values might better be used e.g. the European mean weight for adults of 72 kg (EC, 2006) and estimates for the body weight of children of 11.9 kg for the age of 1-3 years and 23 kg for the age of 3-10 years (The EFSA Comprehensive European Food Consumption Database, EFSA, 2011). In the case of nutrients, intakes are expressed per individual per day and compared with reference values also expressed in the same unit.

10.2 Preparing the occurrence data

The sample coding system, developed and applied to foods at the beginning of the study, will be used for all dietary exposure calculations to avoid possible mistakes. As the TDS provides a huge number of analytical results they have to be managed cautiously. It is recommended that all analytical data be stored in a database, together with their metadata, that allows matching between codes, pooled samples and their description (place of purchase, price, edible quantity, cooking preparation if any and so on). Data entry, storage, retrieval and calculation capacity of the software used has to be considered at the beginning of the project to avoid difficulties in the later stage of an on-going study.

If occurrence data are available for different regions and/or seasons, the same decisions need to be taken as described for regional/seasonal food consumption data (see Chapter 10.1).

10.2.1 Consideration of values below LOD and LOQ in estimating mean occurrence

Despite efforts to lower LODs and LOQs, it is not unusual to have analytical results below those limits (i.e. left-censored data), which introduces uncertainties in the exposure assessment as the value can be anywhere below the LOQ. Therefore, how to handle left-censored values in the dietary exposure assessment needs to be specified. Three possibilities exist: substitution, deletion and modelling.

It is recommended to use the lower and upper bound approach, which means that the values below LOD/LOQ will be replaced by zero for the lower bound and by the LOD/LOQ for the upper bound. In case the upper and lower bound values are close to each other, the upper bound value should be used as the exposure estimate. In case they are significantly different, the indicated range of dietary exposure should be used and, if sufficient data points are available, the left-censored data could be modelled (EFSA, 2010a). However, as most TDS surveys will not produce enough data points for modelling, it is recommended to use the lower and upper bound approach as the default standard. The middle bound, i.e. replacing the value by half of the LOD/LOQ, is introducing an unknown bias and is therefore not recommended.

Deletion of censored data could lead to considerable overestimation of the exposure and therefore it is not recommended.

10.2.2 Confidence intervals

Confidence intervals are useful measures to describe sampling uncertainty in exposure assessments. Normally for the calculation of confidence intervals repeated samples are used. In case of a TDS often just one sample or a low number of samples are available per food. If a normal distribution of mean values and likely standard deviations (e.g. as measured in food surveillance programs) are assumed, the respective confidence interval can be calculated applying the formula:

$$\text{Confidence Bound}_{lower/upper} = \text{mean} \pm 1.96 \times SD/\sqrt{n}$$

In the formula ‘n’ is the number of units of the same food that are pooled to one sample (in case of more samples with same number of units available it has to be multiplied by the number of samples)

and 'SD' the standard deviation. Lower and upper confidence limits should then be used in the exposure calculations as well to elaborate on uncertainty.

10.3 Match of occurrence and consumption data

To calculate exposure, consumption and occurrence data can be used in a full probabilistic approach, depending on the sample size and the level of pooling. However, as most TDS surveys will not produce enough data points to define a detailed distribution for occurrence data, it is recommended to use the simple distribution approach as the default standard (Kroes et al., 2002).

In the simple distribution approach the individual consumption values are used as empirical distributions and multiplied by the mean of the occurrence data as a point estimate. Ideally, exposure is calculated for each food eaten by each subject, which is then aggregated to the exposure per subject, food group, region and season and finally expressed for the whole population. The exposure can be calculated for the mean as well as for different percentiles (due to variation in consumption but not in concentration) for the population. The national exposure estimates take into account the regional and/or seasonal variation of food consumption and mean concentration data.

Potential bias in population coverage in the consumption survey has to be considered in the exposure assessment. This can be corrected through stratification and a weighting applied for each individual when calculating mean or percentile results. The more elaborate the population sampling is, the more complex the exposure calculations will be.

The accuracy of population exposure estimated using TDS results depends on the extent to which the foods included in the food list represent important contributors to total dietary exposure (Kroes et al., 2002). Hence, in discussing the risk assessment, the percentage of food consumption that is covered by the TDS approach as determined according to Chapter 8.1 should be taken into account.

10.3.1 Exposure assessment for high percentile consumers

High percentile consumers specifically refer to those individuals who consistently consume high amounts of specific foods and the respective exposure estimates obtained with the TDS approach should not be confused with acute exposure situations. In case individual food consumption information is not available but only the distribution of the information aggregated at population level, a more cautious approach should be applied when calculating high exposure. To avoid gross overestimation due to adding a lot of high percentiles, EFSA recommends an approach of using high percentiles only for the two main contributing food groups of the mean exposure estimate when dealing with about 20 food groups (EC, 1998; WHO, 2009; EFSA, 2008). When dealing with significantly more food categories the number of main contributing food groups should be adapted. EFSA concluded that up to eight main contributing food groups should be added using high percentiles when dealing with about 150 food groups (EFSA, 2011).

10.3.2 Intake assessment for nutrients

Calculating intake of nutrients is done in the same way as calculating exposure to contaminants. Special considerations might include the calculation of low percentiles, and not only high percentiles, to provide an overview of the whole distribution of the population intakes but in order to conclude on nutritional status of the population. The use of 5% exposure to represent the proportion of the population not meeting nutrient requirements is not recommended. In nutrition other approaches are used to determine the proportion of the population and they should be applied also in TDS (Murphy and Vorster, 2007).

10.4 Attribution of dietary exposure from individual food and food groups

At population or sub-population level, mean as well as 95th percentile dietary exposure linked to consumption of individual food or food groups can be assessed to identify their proportional contribution to total exposure in absolute terms or as a percentage. By reviewing the consumption and occurrence data corresponding to the major contributors it is possible to determine whether or not the contribution is due to high consumption or high occurrence levels or both. On the one hand, highly contaminated food could make a negligible contribution to overall exposure if it is consumed in small quantities. On the other hand, food carrying lower levels of the chemical could be a significant contributor to total exposure due to high consumption levels. Thus, for balanced risk management action it would be prudent to take account of both occurrence and consumption data and associated uncertainties when assessing the value of applying restrictions on exposure to the chemical substance.

10.5 Dietary exposure in sub-populations

Sub-populations should be considered in the case of particular at-risk groups for specific chemical substances of interest. As an example, in the case of chemical substances classified as endocrine disruptors, it would be important to specifically address dietary exposure in infants and in women of childbearing age. As a first step in considering sub-populations, the percentage of their food consumption that is covered by the TDS food list should be checked. If the TDS is conducted at a regional level, dietary exposure can be evaluated in each region separately to assess the contribution of local or regional food consumption and to issue specific local risk management measures. A typical example would be professional fishermen or recreational anglers and their families that regularly consume fish from the same region. There are several examples where localised contamination with heavy metals has influenced the health status in the local community, the most well known being mercury poisoning in the Minamata City of Japan.

For certain chemical substances found only in a few specific food items or food groups, calculation of dietary exposure for consumers only can be of interest. This is simply done by identifying consumers of the specific food and calculating exposure by using only consumption information from this group.

10.6 Accommodating new needs

Ideally, the overall expected outcome of the TDS survey and the intended use of the results for calculating dietary exposure should be part of the planning process when considering the appropriate food list, the sample size, sampling design, pooling strategies, and the selection of analytical methodology. However, it might not be possible to anticipate all future uses of the data.

A typical such situation could be when non analysed laboratory samples or sub-samples remaining from a completed TDS are stored to address future analytical needs. Often the food list might not be representative for the new chemical substances to be tested and important food varieties might be missing. An example could be the number of fish species covered in the TDS. In consumption surveys the number of fish species named can be very high, but normally only a limited number of fish species can be analysed in a TDS. Since some substances occur only in very specific fish species, the fish sample might not be suitable for the analysis of additional chemical substances. This has to be checked and possibly corrected by acquiring and analysing some additional samples.

In some cases there might be an interest in updating the dietary exposure calculations by matching occurrence data from the TDS with more recent food consumption data. However, because of possible changes in dietary habits the previous food list might not remain representative of the population diet or food group pooling could be skewed. Also cooking methods could be different. Care should be taken in any such further use of existing TDS results and potential uncertainties discussed in detail.

When storing samples to be able to address future analytical needs it will be important to establish the stability of the chemical substances during frozen storage. Degradation of certain chemicals might bias future analytical results. As a rule of thumb frozen storage should be limited to a maximum of three years.

Summary of exposure assessment of harmful and beneficial substances

Population exposure using TDS results is calculated as any other dietary exposure assessment, i.e. by multiplying the consumption data (ideally at individual level) with the occurrence data from the chemical analysis. Special attention should be given to data below the LOD and LOQ, and upper and lower bound dietary exposure estimates should be presented.

11 Communication

The availability of clear guidelines is a major step forward for supporting effective communication of future TDS work, including any that may be conducted as part of a pan-European survey or in an international context. It is particularly important to ensure that there is a common and clear understanding of the methodology, as well as the way the information is reported and disseminated. Consistency in the way the data are collected and in the way consumption data are applied for deriving dietary exposure estimates will determine the comparability of TDS data. This comparability, together with the number of food samples taken, will determine the reliability of trend analysis, as well as facilitate the planning of follow-up surveys.

The requirement for increased transparency in risk assessment of food has highlighted the issue of scientific uncertainty (EFSA, 2006). As a first step to increase transparency and describe uncertainties in the dietary exposure assessment, a clear description of statistical methods used and distribution parameters employed in the calculations should be included and the strength and weakness of the data sources and where they were derived from should be pointed out. In particular, the representativeness of the food sampling should be assessed as a contributor to uncertainty. Occurrence, consumption data and the kind of dietary exposure calculation used should be described in detail with its associated uncertainty (EFSA, 2006; WHO, 2008b).

A specific problem in communicating the dietary exposure results can be the reporting of high percentiles when only a simple deterministic approach was used. Here it will be important to explain the meaning of the high percentiles that just consider high levels of consumption but only mean occurrence in relation to chronic exposure considerations.

It is important to communicate the strengths of the dietary exposure assessment (what is known) as well as the uncertainties, and also to discuss the uncertainty affecting exposure compared to that affecting other parts of the overall risk assessment (e.g. toxicity). The aim should be to provide a balanced picture of what is known and what is uncertain, and avoid giving an exaggerated impression of either certainty or uncertainty.

Summary of communication

When communicating results from TDS surveys, transparency is of utmost importance. Clear descriptions of the full methodology should be provided in detail, including assumptions, limitations and an assessment of associated uncertainties.

12 Common database and data interchange

The implementation of TDSs allows the generation of a wealth of data on occurrence and estimates of dietary exposure to several beneficial or hazardous compounds from food products. In order to allow comparability of these data, it is very important to follow a standardised format to facilitate data handling and use. These data should be made available to risk assessors and managers through a central repository of occurrence data including those of TDSs.

Data transmission formats for occurrence data exists and their use is highly recommended.

At international level, WHO GEMS/Food participating institutions are requested to submit data through a web-based procedure (OPAL web) on standardised data forms. Recently a working group of experts recommended possible evolutions of the data structure and protocols for the electronic submission of such data[12]. The GEMS/Food format allows for electronic submission of individual and aggregate data on levels of contaminants including TDS data. A supporting document with 'Instructions for electronic submission of data on chemical contaminants in food and the diet' is available[13].

In 2010, EFSA issued the Guidance Document on Standard Sample Description for food and feed (EFSA, 2010b) and Guidance document on data exchange (EFSA, 2010c). This document specifies the data elements, the data structure of the samples and the analytical results for chemical contaminants and residues in food and feed, and provides controlled terminologies and validation rules to enforce data quality.

EFSA, FAO and WHO continue efforts to improve the harmonisation of formats for data submission in collaboration with national data providers and other international institutions.

The opportunities for EFSA, FAO, WHO to act as 'central repositories for TDS data' rely on the availability and implementation of proper links between all the diverse datasets involved. For this reason, the use of standard terminology is of primary importance when submitting the data to the competent authorities. The database as well as the interchange format should be able to hold additional information on TDS (meta-data).

Meta-data contains background information used for the planning of the TDS. These 'meta-data' should include sampling plans, pooling description, recipes and food processing information. For this reason, the use of standard terminology and proper linking tables is of primary importance when submitting the data to the competent authorities.

The development of standard reporting formats for all background information is advisable in the future. While standard reporting formats are not yet available for collecting this TDS 'meta-data', it is

[12] http://www.who.int/foodsafety/publications/chem/HOF_WG.pdf

[13] http://www.who.int/foodsafety/chem/gems/en/index.html

recommended to prepare at least a separate report describing the planning, development and results of the TDS carried out, in case competent authorities request additional information.

Database for data analysis

The process of populating this database should be as automated and standardised as possible in order to minimise the human resources required for data cleaning and management. This will strengthen data quality and comparability and prevent potential data loss and errors due to manual file submissions.

Security infrastructure - users and organisations directory

One of the challenges in implementing a common database is the data ownership and the access to the data collected. In order to implement a flexible and effective access policy, information on the users and organisations sending and accessing the database should also be collected and stored.

Data interchange security requirements

In the context of establishing an interchange agreement between the parties providing the data and the institutions collecting and storing the data, security requirements should be defined taking into account confidentiality, authenticity and trust.

Common database and data interchange

The reporting of TDS data (consumption, occurrence and dietary exposure) needs to be planned to conform to international requirements (e.g. EFSA, GEMS/Food). In general, this requires a detailed description of the analytical results as well as the transmission of meta-data such as TDS sampling plan, pooling, recipes, kitchen processing, and analytical methods. Incorporation of TDS data and associated meta-data in existing occurrence database would be important for future use.

CONCLUSIONS

A Total Diet Study (TDS) consists of selecting, collecting and analysing commonly consumed food purchased at retail level, processing the food as for consumption, pooling the prepared food items into representative food groups, homogenising the pooled samples, and analysing them for harmful and beneficial chemical substances. TDSs are designed to cover the whole diet and to measure the amount of each chemical substance ingested by the population living in a country, using average and high-level consumption data.

The TDS method is a complementary approach to traditional monitoring and surveillance activities, but instead of focusing on compliance it is designed to provide a solid basis for calculating population dietary exposure and estimate the impact on public health.

There is already a wealth of international TDS data available that have served as important resources for monitoring exposure to beneficial and harmful food chemical substances.

To enable international comparisons of results from TDS surveys it is important that methods used are harmonised to the extent possible. Recognising that a TDS can have different objectives, not all aspects of the TDS implementation can be harmonised.

There are two distinct approaches: TDS for screening or TDS for refined exposure assessment. Sometimes a TDS is used for screening purposes, analysing a limited number of broadly pooled food samples. It might be useful as a starting point towards setting future priorities for more detailed collections of data on beneficial and harmful substances in food. Such screening will generate an overview at fairly low costs for a limited number of food groups. Countries that already have established monitoring or surveillance programs can use the TDS approach as a more refined exposure assessment tool, which includes analysis of a greater number of less pooled samples often separately covering different seasons and regions.

Using pooled samples of individual food items means that the analytical data generated represent averages of concentration data. Therefore TDS results are best suited for calculating chronic exposure to food chemical substances and for trend analysis to assess the effect of risk management measures. The TDS approach will provide background information on hazardous and beneficial chemical substance levels in the general food supply across the diet, while monitoring and surveillance activities can capture more highly contaminated individual food items. Their complementarities will allow the identification of the relative importance of individual sources of chemical substances from the whole diet.

The main disadvantage of pooling is the so called "dilution-effect" inherent in combining a number of different food items into one sample. The dietary contribution of chemical substances in particular foods may be diluted by other components of the mixture to a point where the overall chemical substance level is below the limit of detection of the analytical method. It is, thus, important to select analytical methods with capability to quantify chemical substances at sufficiently low levels, meaning in general lower LODs/LOQs than for monitoring and surveillance programs.

A TDS is most suitable for collecting data on the occurrence of chemical substances that are ubiquitous in food, but is unlikely, as is any other monitoring and surveillance programs, to detect infrequently occurring contaminants in certain regions, seasons or in specific foods only.

It can be concluded that a TDS can be a useful complement to existing data from food monitoring and surveillance activities or be a cost-effective screening tool as a starting point for further analyses.

RECOMMENDATIONS

- It is recommended that more countries carry out TDS to assess population exposure to chemical substances in the whole diet and to complement existing monitoring and surveillance programs.

- It is recommended that a harmonised approach is undertaken for effective implementation of the three basic principles as outlined in this document: representative of the whole diet, pooling of foods, food analysed as consumed.

- It is recommended that:

  - a food list should be established on the basis of individual food consumption surveys, covering at least 90 % of a typical diet consumed by the population under consideration, as well as other special food expected to contribute to the chemical exposure of interest;

  - pooling is used to assure a representative coverage of the food market and offers cost saving options, however the extent of pooling should not compromise the objective of the study;

  - food is prepared as consumed, taking into account typical processing and cooking methods to mirror real life exposure to chemical substances;

- Sampling should take into account geographical and seasonal aspects.
- Laboratories should be ideally accredited (e.g. ISO/IEC 17025:2005) or alternatively they should prove that they comply with quality assurance and quality control procedures.
- All analytical method must be validated for food matrices and chemical substances under study.
- Limits of detection and limits of quantification should be fit-for-purpose and generally should be considerably lower than commonly used in monitoring and surveillance programs.
- Lower and upper bound approach should be used when presenting dietary exposure results.
- The reporting of TDS data to European or international institution should follow standardised formats as recommended by EFSA and WHO-GEMS/Food. For transparency reasons, associated information in relation to food list, food preparation, pooling and sampling should be made available (meta-data).
- It is recommended that future work includes a harmonised approach for classifying foods and a common format for data interchange (meta-data).
- The selection of chemical substances to be analysed should reflect national and international priorities.
- The TDS should ideally be repeated at regular intervals in order to allow temporal trends in dietary exposure to chemical substances to be established, and to evaluate the effectiveness of risk management measures undertaken.
- Stakeholders should be considered in the planning of TDS.

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APPENDIX

A. EXAMPLE OF ESTABLISHING A TDS FOOD LIST

Table 1: Example of establishing a TDS food list, taking vegetables as an example. There are 2 seasons (S1, S2), 3 regions (R1, R2, R3) and 6 food samples (from A1 to A6). Heavy metals including cadmium are to be determined. Three different scenarios have been defined as follows:

1. scenario Pooling for screening purpose at national level: A1 for analytical sample 1
2. scenario: Pooling for screening purpose at regional level: A1 for analytical sample 1
3. scenario: Pooling for refined assessment at seasonal and regional level: A1 for analytical sample 1, until A6

In the TDS for refined exposure assessment purpose, the different cooking methods could be analysed separately which would increase the number of analytical samples significantly.

Foods and respective preparations[(a)]	Consumption in g/d/p	Reason for inclusion in TDS food list	National/ regional food	Seasons	Regions	Scenario 1	Scenario 2	Scenario 3
Onions, raw,	10	Yes, as part of 90 % of food supply	Regional food	S1 (no expected difference to S2)	R1, R2, R3 as grown in all regions	A1	A1-R1 A1-R2 A1-R3	A1-R1-S1 A1-R2-S1 A1-R3-S1
Onions, boiled	40	Yes, as part of 90 % of food supply	Regional food	S1 (no expected difference to S2)	R1, R2, R3 as grown in all regions	A1	A1-R1 A1-R2 A1-R3	A1-R1-S1 A1-R2-S1 A1-R3-S1
Onions, fried	30	Yes, as part of 90 % of food supply	Regional food	S1 (no expected difference to S2)	R1, R2, R3 as grown in all regions	A1	A1-R1 A1-R2 A1-R3	A1-R1-S1 A1-R2-S1 A1-R3-S1
Tomatoes, raw	30	Yes, as part of 90 % of food supply	Regional food	S1, S2 (local production in S1 vs. imported in S2)	R1 as only grown in R1	A1	A1-R1	A2-R1-S1 A2-R1-S2
Tomatoes, boiled	35	Yes, as part of 90 % of food supply	Regional food	S1, S2 (local production in S1 vs. imported in S2)	R1 as only grown in R1	A1	A1-R1	A2-R1-S1 A2-R1-S2

Foods and respective preparations[(a)]	Consumption in g/d/p	Reason for inclusion in TDS food list	National/ regional food	Seasons	Regions	Scenario 1	Scenario 2	Scenario 3
Green salad, raw	45	Yes, as part of 90 % of food supply	Regional food	S1 (only available in S1)	R1 as only grown in R1	A1	A1-R1	A3-R1-S1
Leak, boiled	22	Yes, as part of 90 % of food supply	Regional food	S1 (only available in S1)	R1, R2, R3 as grown in all regions	A1	A1-R1 A1-R2 A1-R3	A4-R1-S1 A4-R2-S1 A4-R3-S1
Mushrooms, boiled	2	Yes, as expected major contributor to cadmium exposure	Regional food	S2 (only available in S2)	R2 as only grown in R2	A1	A1-R2	A5-R2-S2
Canned pickles	6	Yes, as part of 90 % of food supply	National food	S2 (as most samples are collected in S1, better to collect national foods in S2)	R3 to represent country and to be applied to all regions	A1	A1-R3	A6
Cucumber, raw	5	Yes, as part of 90 % of food supply	Regional food	S1 (only available in S1)	R2 as only grown in R2	A1	A1-R2	A6
Fennel, boiled	0.3	No, as not part of 90 % of food supply, nor expected major contributor	--	--	--	--	---	--
Total number of pooled samples						**1**[(b)]	**3** [(c)]	**11** [(d)]

a. Several food preparation methods (reflecting differing consumption habits) should be applied. Nevertheless, this approach is difficult to implement for technical reasons or because sufficient resources are not available. Therefore in case of choosing only one preparation method, depending on the chemical of concern, a worst case scenario could be chosen or as an alternative the preparation method most commonly used according to consumption habits.
b. all seasonal and regional food items are pooled into a vegetable group sample
b. one vegetable group sample, but analysed for 3 regions
c. 6 food samples, but some of them analysed separately according to season and region

GLOSSARY

Accuracy

Degree of agreement between average predictions of a model or the average of measurements and the true value of the quantity being predicted or measured (FAO/WHO, 2009)

Contaminant

Any substance not intentionally added to food, which is present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packaging, transport or holding of such food or as a result of environmental contamination. The term does not include insect fragments, rodent hairs and other extraneous matter (FAO/WHO, 2009).

Deterministic estimate

In exposure assessment, an estimate that is based on a single value for each model input and a corresponding individual value for a model output, without quantification of the cumulative probability or, in some cases, plausibility of the estimate with respect to the real-world system being modelled. This term is also used to refer to a model for which the output is uniquely specified based on selected single values for each of its inputs (FAO/WHO, 2009).

Dietary exposure

For the purposes of food and feed risk assessment, the amount of a substance (including nutrients) ingested by a person or an animal as part of its diet (via food, beverages, drinking water and food supplements). This term does not refer to whole foods. The 'intake' of whole foods termed 'food consumption' (FAO/WHO, 2009).

Dietary exposure assessment

The qualitative and/or quantitative evaluation of the likely intake of chemical substances (including nutrients) via food, beverages, drinking-water and food supplements. *Synonymous* with: Intake assessment (FAO/WHO, 2009).

Dish

A mixture of foods prepared according to a recipe (adapted from Bergström, 1994).

Duplicate diets/Duplicate portion study

A method for estimating dietary intakes that involves collection and analysis of identical portions of foods and beverages consumed by an individual (FAO/WHO, 2009).

Edible portion

Term refers to the edible material remaining after the inedible waste (e.g. bones, stones, and peel) has been trimmed away (Reinivuo and Laitinen, 2007).

Exposure

Concentration or amount of a particular agent that reaches a target organism, system or (sub)population in a specific frequency for a defined duration (adapted from FAO/WHO, 2009).

Food

In the Codex Alimentarius Commission context, any substance, whether processed, semi-processed or raw, that is intended for human consumption. It includes drink, chewing gum and any substance that has been used in the manufacture, preparation or treatment of food, but it does not include cosmetics or tobacco or substances used only as drugs (FAO/WHO, 2009).

Food as consumed

Food described in the state it is consumed, i.e. food without the inedible portions and cooked if applicable (FAO, 2011).

Food as purchased

Food in the state it is bought, i.e. generally including the inedible part and raw, for example, banana including peel (FAO, 2011).

Food grouping

A group of food items with similar characteristics within a hierarchical structure at a level below food group: e.g. Fruit and fruit products (**Food group**), citrus fruit (**Food-sub group**), Grapefruit (**Food item**).

Food surveillance and monitoring program

The systematic ongoing collection, collation and analysis of data of physical, chemical and microbiological contamination in food to evaluate their compliance with existing legislation.

Health-based guidance value

A numerical value derived by dividing a point of departure (a NOAEL, BMD or BMDL) by a composite uncertainty factor to determine a level that can be ingested over a defined time period (e.g. lifetime or 24 h) without appreciable health risk. *Related terms:* Acceptable daily intake, Provisional maximum tolerable daily intake, Provisional tolerable monthly intake, Provisional tolerable weekly intake, Tolerable daily intake (FAO/WHO, 2009).

Individual food approach

Mixing of individual food items into pooled samples containing foods of the same type before being analysed (e.g. a fruit sample comprising of 10 different varieties of apples).

Ingredient

Any substance, including additives used in the manufacture or preparation of a foodstuff and still present in the finished product, even if in an altered form. Contaminants and adulterants are not considered to be ingredients. Also refers to a foodstuff which is a component or constituent part of a recipe (adapted from Commission Directive 2000/13/EC[14]).

[14] Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs. OJ L 109, 6.5.2000, p. 29–42.

Intake assessment

See dietary exposure assessment.

Left censored data

A statistical term used to describe data which is known to be below a certain value but it is not known by how much, for instance, data below the LOD or LOQ. Also referred to as non-detects (ND).

Limit of detection or limit of determination (LOD)

The minimum concentration of a component in a dietary sample that can be qualitatively detected, but cannot be quantitatively determined, under a pre-established set of analytical conditions (FAO/WHO, 2009). Different definitions exists for LODs.

Limit of quantification (LOQ)

The minimum concentration of a component that can be determined quantitatively with acceptable accuracy and consistency. It often approximates to a value of 3 times the limit of detection **(**FAO/WHO, 2009). Different definitions exists for LOQs.

Linearity

The ability of a method of analysis, within a certain range, to provide an instrumental response or results proportional to the quantity of analyte to be determined in the laboratory sample. This proportionality is expressed by an a priori defined mathematical expression. The linearity limits are the experimental limits of concentrations between which a linear calibration model can be applied with a known confidence level (generally taken to be equal to 1%). (Codex, 2005)

Lower bound approach

n general, for chemicals likely to be present in the food (e.g. naturally occurring contaminants, nutrients and mycotoxins), both lower and upper bounds should be calculated for the mean food concentration. The lower bound is obtained by assigning a zero value to those samples in which the chemical was non detected or non quantified and using these values to estimate dietary exposure (FAO/WHO, 2009).

Market basket

An approach to sampling for surveys in which a wide range of food items collected from consumer points of sale and in proportions approximating consumption patterns in the local or national population. Samples are prepared for analysis according to various methodologies, such as the Codex guidelines i.e. minimal preparation. This approach is distinctly different to that of a TDS in that the samples are analysed as purchased, as opposed to as consumed (adapted from IUPAC).

Maximum level (ML)

For contaminants, naturally occurring toxicants and nutrients, the maximum concentration of a substance recommended by the Codex Alimentarius Commission to be legally permitted in a given commodity. For food additives, the level of permission of use given in food standards for the additive in that food or food category (FAO/WHO, 2009).

Measurement uncertainty

The analytical result shall be reported as x +/– U whereby x is the analytical result and U is the expanded measurement uncertainty, using a coverage factor of 2 which gives a level of confidence of approximately 95 % (U = 2u) (Commission Regulation 333/2007[9]).

Mixed food approach (also known as food group approach)

Mixing of individual food items into pooled samples containing different type of foods of the same food group, before being analysed (e.g. a fruit sample comprising of 10 different types of fruits like apple, pear, banana…).

Nutrient

Any element or compound necessary for or contributing to an organism's metabolism, growth or other function. Six nutrient groups exist, classifiable as those that provide energy and those that otherwise support metabolic processes in the body. Some of them are essential because they cannot be synthesized in the body and must be obtained from a food source (FAO/WHO, 2009).

Pesticide

Any substance or mixture of substances intended for preventing, destroying or controlling any pest, including vectors of human or animal disease, unwanted species of plants or animals causing harm during or otherwise interfering with the production, processing, storage, transport or marketing of food, agricultural commodities, wood and wood products or animal feedstuffs, or substances that may be administered to animals for the control of insects, arachnids or other pests in or on their bodies. The term includes substances intended for use as a plant growth regulator, defoliant, desiccant or agent for thinning fruit or preventing the premature fall of fruit, and substances applied to crops either before or after harvest to protect the commodity from deterioration during storage or transport (FAO/WHO, 2009).

Pooled sample

It is often prepared as a representative mixture of samples of an individual food or several different food items, from which laboratory sample is taken. It may be a combination of the same food or combinations of different brands or cultivars (e.g. 10 apples or 10 yoghurts) or of several food sub-group items (e.g. 10 different fruits) (also known as composite or aggregated sample).

Precision

A measure of the reproducibility of the predictions of a model or repeated measurements, usually in terms of the standard deviation or other measures of variation among such predictions or measurements (FAO/WHO, 2009).

Quality assurance

A set of activities whose purpose is to demonstrate that an entity meets all quality requirements. These activities are carried out along with all stages of the study including design, implementation and reporting, ensuring both customers and managers that all quality requirements are met (adapted from FAO/WHO, 2009).

Quality control

A set of activities or techniques, providing routing and consistent checks, whose final purpose is to ensure that all quality requirements are met. In order to achieve this purpose, processes are monitored and performance problems are solved (adapted from FAO/WHO, 2009).

Raw Agricultural Commodity

It is the agricultural product before it has undergone any form of processing; it is the raw part (or parts) of the plant or animal as moving in trade.

Recipe

A list of ingredients needed to prepare a dish and a description of the preparation of that dish (Bergström, 1994).

Repeatability

Repeatability (*'r'*) the value below which the absolute difference between single test results obtained under repeatability conditions (i.e., same sample, same operator, same apparatus, same laboratory, and short interval of time) may be expected to lie within a specific probability (typically 95 %) and hence r = 2,8 × sr. (*'sr'* = Standard deviation calculated from results generated under repeatability conditions) (Commission Regulation (EC) 401/2006[15] and 333/2007[9]).

Reproducibility

Reproducibility (*'R'*) the value below which the absolute difference between single test results obtained under reproducibility conditions (i.e., on identical material obtained by operators in different laboratories, using the standardised test method), may be expected to lie within a certain probability (typically 95 %); R = 2,8 × sR ('sR' = Standard deviation, calculated from results under reproducibility conditions) (Commission Regulation (EC) 401/2006[15] and 333/2007[9]).

Relative standard deviation

Relative standard deviation ('RSDR') calculated from results generated under reproducibility conditions [(sR/) × 100]. (Commission Regulation (EC) 401/2006[15] and 333/2007[9])

Robustness

Robustness of methods applied to TDSs is referred to its performing capacity to small variations in the experimental conditions. It is important to identify steps in the method requiring special attention because different laboratories even if they use the same method inevitably introduce small variations in the procedures which may o may not have an influence on the data generated.

Sampling plan

A detailed plan including all steps required to produce the required sizes and frequencies of samples to be taken as part of a study.

[15] Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs. OJ L 70, 9.3.2006, p. 12–34

Seasonal sample collection

Food samples collected during particular seasons.

Selectivity

Selectivity of a method refers to the extent to which it can determine particular analyte(s) in a complex mixture without interference from the other components in the mixture. A method which is selective for an analyte or group of analytes is said to be specific. The applicability of the method should be studied using various samples, ranging from pure measurement standards to mixtures with complex matrices. In each case the recovery of the analyte(s) of interest should be determined and the influences of suspected interferences duly stated. Any restrictions in the applicability of the technique should be documented in the method. This work will allow a clear description of the measurand to be made (CITAC/Eurachem, 2002).

Total Diet Study

A Total Diet Study (TDS) consists of selecting, collecting and analysing commonly consumed food purchased at retail level, processing the food as for consumption, pooling the prepared food items into representative food groups, homogenising the pooled samples, and analysing them for harmful and beneficial chemical substances. TDSs are designed to cover the whole diet and to measure the amount of each chemical substance ingested by the population living in a country, ideally using average and high-level consumption data for final exposure calculations or the consumption distribution to estimate the proportion of the population with inadequate nutrient intake levels.

Total Diet Study used as a screening tool

TDS based on a limited number of samples to represent the whole diet (e.g. 20 to 30 pooled samples).

Total Diet Study used as a tool for refined dietary exposure assessment

TDS based on a more detailed list of foods in order to identify those foods contributing to dietary exposure (e.g. 200 to 300 pooled samples).

TDS Food list

The selected and prepared foods, pooled for analysis are called the TDS food list. The TDS food list is normally constructed in several steps. Initially the most representative foods are selected according to food consumption patterns, followed by decisions on preparation/cooking methods to employ and on where and when foods are sampled. The final step involves decisions about which prepared foods to combine for each pooled sample before analysis.

Uncertainty

In risk assessment, imperfect knowledge concerning the present or future state of an organism, system or (sub)population under consideration.

In exposure assessment, lack of knowledge regarding the "true" value of a quantity, lack of knowledge regarding which of several alternative model representations best describes a system of interest or lack of knowledge regarding which probability distribution function and its specification should represent a quantity of interest (FAO/WHO, 2009).

Upper bound approach

In general, for chemicals likely to be present in the food (e.g. naturally occurring contaminants, nutrients and mycotoxins), both lower and upper bounds should be calculated for the mean food concentration. An upperbound dietary exposure is estimated by assigning the LOD to all samples with ND results and the LOQ to all samples with less than the LOQ but more than the LOD. In some cases, the LOD may equal the LOQ (FAO/WHO, 2009).

Variability

Heterogeneity of values over time, space or different members of a population. Variability implies real differences among members of that population. For example, in exposure assessment, different individual persons have different intake and susceptibility. In relation to human exposure assessment, differences over time for a given individual are referred to as intraindividual variability; differences over members of a population at a given time are referred to as interindividual variability.

Yield factor

The percentage weight change in foods and recipes due to cooking.

KITCHEN TERMINOLOGY

Kitchen terminology refers to all those terms that describe the food processing aiming at obtaining the food ready to be eaten. These processes might imply physical or chemical changes in the status of the food product. In view of a common understanding of the food preparation procedure, it is suggested to refer to the *Langual Thesaurus facet G "COOKING METHOD"* (available at: http://www.langual.org). Additional terms adapted from literature on TDS (Vannoort, 1997; FSZANZ, 2005 and 2008) can be used, as listed below.

- Blend: Put food items into the appropriate blender and blend until a homogenous mixture is obtained.
- Chop: Put food product into the appropriate size processor and chopped until a homogenous mixture is obtained.
- Wash: Foods are to be washed in accordance with local practice and the food concerned.
- No process: to prepare samples with foods as bought (e.g. beverages, yogurt, sausages).

ABBREVIATIONS

ADI: Acceptable Daily Intake

AESAN: Spanish Agency for Food Safety and Nutrition

AFFSA/ANSES: French Food Safety Agency

CRM: Certified Reference Material

CRL: Central Reference Laboratory

EFSA: European Food Safety Authority

FAO: Food and Agriculture Organization of the United Nations

GEMS: Global Environment Monitoring System

HACCP: Hazard Analysis and Critical Control Point

HBS: Household Budget Survey

IPCS: International Program on Chemical Safety

IUPAC: International Union for Pure and Applied Chemistry

JECFA: Joint FAO/WHO Expert Committee on Food Additives

JMPR: Joint FAO/WHO Meeting on Pesticides Residues

JRC: Joint Research Centre

LOD: Limit Of Detection

LOQ: Limit Of Quantification

LB: Lower Bound

ML: Maximum level

QA/QC: Quality Assurance / Quality Control

RAC: Raw Agricultural Commodities

SC: Steering Committee

SOPs: Standard Operating Procedures

SPS Agreement: Agreement on the Application of Sanitary and Phytosanitary Measures

TDS: Total Diet Studies

UB: Upper Bound

WHO: World Health Organization

WTO: World Trade Organization