



TDSEXPOSURE

Total Diet Study Exposure

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WP 7– Variation and trends

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IV. Abbreviations

3-MCPD	3-monochloropropane-1,2-diol
ADI	Acceptable daily intake
ARfD	Acute reference dose
BfR	Federal Institute for Risk Assessment
dl-PCBs	(dioxin-like) Polychlorinated biphenyls
EDI	Estimated daily intake
FM	Food monitoring
IESTI	International estimated short-term intake
LOD	Limits of detection
LOQ	Limits of quantitation
ML(s)	Maximum level(s)
PAHs	Polycyclic aromatic hydrocarbons
PCBs	Polychlorinated biphenyls
TDS	Total diet study
WP	Work package

1 Introduction

This deliverable is dedicated to objective 7.4 “Develop an exposure assessment approach combining benefits from TDS and food monitoring data” of work package (WP) 7 “Variation and trends”.

Both, total diet study (TDS) and food monitoring (FM), aim to collect data about contaminants in food stuff. However, although both approaches pursue the same objective, they are different in ways of food sampling, preparation and analysis. Consequently, the results are of different quality depending on the research question. It is therefore of interest to clarify for which questions TDS or FM data are the suitable choice and where both approaches can optimally be combined to achieve the best possible results for example for risk management decisions.

The deliverable D7.5 is divided into four main parts. In section 2 the methods of the literature research and the establishment of the decision tree are explained. In section 3 as a first step the terms TDS and FM are defined, the characteristics are compared, the main differences are described, and the benefits of both approaches will be explained. In section 4 as a second step a bibliographical work is carried out to get insights into scientific applications of TDS and FM data. Simultaneously with use of knowledge of section 3 a decision tree for using these two methods is drafted. This decision tree is systematically filled and further developed by the identified publications and contents. In a last step in section 5 a flow chart is developed for combining the characteristics of both approaches.

The whole task was carried out by the Federal Institute for Risk Assessment (BfR).

2 Methods

Sub-task 7.4.1 consisted of a bibliographical search to gain insights in the use of TDS data and food monitoring data in risk management. Literature search was carried out in the databases PubMed, Web of Science, Scopus and LitDok (internal database, BfR). The applied search terms were “(*food monitoring*) OR (*total diet study*) AND (*risk assess**) NOT *microbio**”. Results were filtered for “*Human*” and “*last 5 years*”. After automatically cleaning results for duplicates a total of 363 publications were included for final evaluation. At first titles and subsequently abstracts were screened for relevance which led to an exclusion of 79 publications by title and 53 by abstract. In the further course of data evaluation additional 33 publications were excluded after screening the full text and 17 due to “other reasons” (full text not available, full text in other language than English or German, etc.). 15 duplicates were detected in remaining papers, 14 publications categorized as “methodological paper” with use of TDS or/and food monitoring data, four as “untypical TDS” and another four were classified as “secondary studies”.

Finally, 144 publications were classified as “unequivocally relevant”. Of those 25 were assigned to “TDS”, , 119 to “food monitoring and others¹” (8.1). The publications included in the literature research are listed in the annex (8.2.1., 8.2.2).

¹ For definition see section 3.2

The information extracted from the literature was based on a previously drafted decision tree, which included the main characteristics and differences of both survey types (see also section 3.3, Differences between Total diet studies and Food monitoring). An overview of the extracted characteristics can be found in the annex (8.3). During the process the characteristics were refined and finally defined as shown in annex, Table 3.

The TDS-Exposure partners agreed the used strategy for bibliographical search and documentation presented at the 5th TDS-Exposure meeting on the 23rd of September 2015 in Berlin.

Sub-task 7.4.2 consisted a systematic description of advantages and disadvantages of TDS and FM (3.3). Based on the advantages, a combined food safety approach was derived which connects the beneficial characteristics of TDS and FM (5).

The combined food safety approach was presented to the partners at the Final TDS-Exposure meeting on the 14th of January 2016 in Paris."

3 Definition and main differences of Total diet studies, Food monitoring and Food surveillance

This section gives very brief definition of the here used terms of the different surveillance methods to generate concentration data in foods. TDS is a general recognized and well-defined term, whereas the distinction between monitoring, surveillance and other study types is often unclear. After definition of these terms the main differences between TDS and food monitoring are worked out to provide the basis for the interpretation of the decision tree in section 4.1.

3.1 Total diet studies

TDSs are a systematic tool of estimating the mean concentration of chemical substances in a wide range of foods. Main characteristics are the coverage of at least 90 % of the total diet, the preparation of foods "as consumed", and the pooling of foods into composite samples before analysis (EFSA/FAO/WHO, 2011).

Two different approaches can be distinguished. A *screening TDS* is applied to obtain an overview on the actual situation of substances in the diet. For this purpose a limited amount of broadly pooled food samples are analyzed (e.g. pooling fruits to one composite sample). A *refined TDS* covers more foods in less aggregated pooled samples (e.g. pooling just apples to one composite sample) and gives detailed information about exposure (EFSA/FAO/WHO, 2011).

3.2 Food monitoring and Food surveillance

In contrast to the TDS term, there is no official and harmonized definition to differentiate between food monitoring, food surveillance and "other" study types dealing with chemical substances in foods. All of them take several meanings and are used interchangeably. As Germany can rely on a comprehensive and well-defined food control system the terms used in this report are based on the description applied there and can be summarized as follows (BVL, 2015).

► **Food monitoring:**

Food monitoring is a continuously performed systematic measurement and monitoring program where food selection is based on a representative food basket (not risk-oriented) in terms of preventive consumer health protection (national food control system). Originally established to measure percentage of ML exceedances on the German market, but in the meanwhile also used for risk assessment purposes (Lindtner et al., 2013).

► **Food surveillance:**

Food surveillance is a continuously performed control program, where food selection is based on risk assessment (targeted, risk oriented) in terms of controlling nationwide compliance with the food law (e.g. violation of maximum residue limits or protection against fraud) (national food control system).

This is in line with a previously applied definition which describes both terms in a complementary manner, where the surveillance can be seen as an extension of the food monitoring, to follow up analytical outcomes with unacceptable values (see Figure 1).

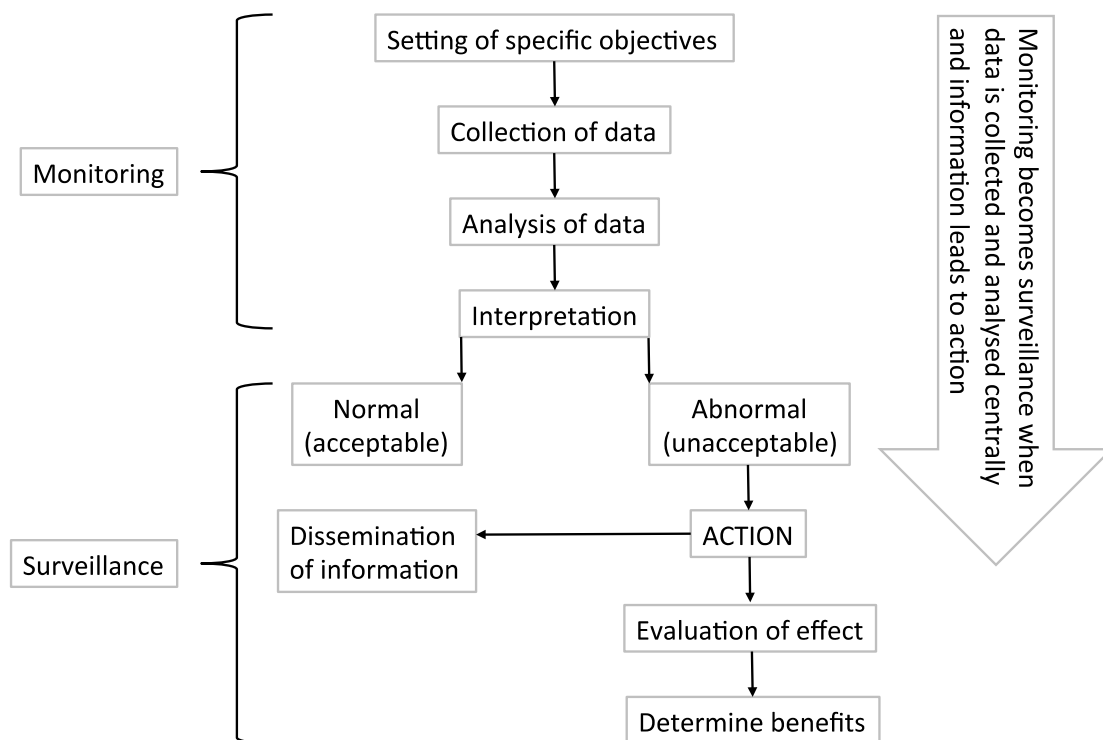


Figure 1: Relation between food monitoring and food surveillance (modified according to Lo Fo Wong et al. (2004)).

► **Other food control projects:**

In addition, there are food control and food analysis projects, which are performed by universities or research centers. These projects do not belong to the national food control system. They aim to reveal the contamination status of certain products, regions, or populations.

In summary, monitoring programs are nationwide routine measurement, whereas surveillance programs are directed actions advised by monitoring outcomes or other risk related sources. Both are executed by official food control authorities. Additionally there are “other” food risk related projects, their implementation is not instructed by official authorities and they do not occur nationwide. Figure 2 displays the here presented classification of these three categories.

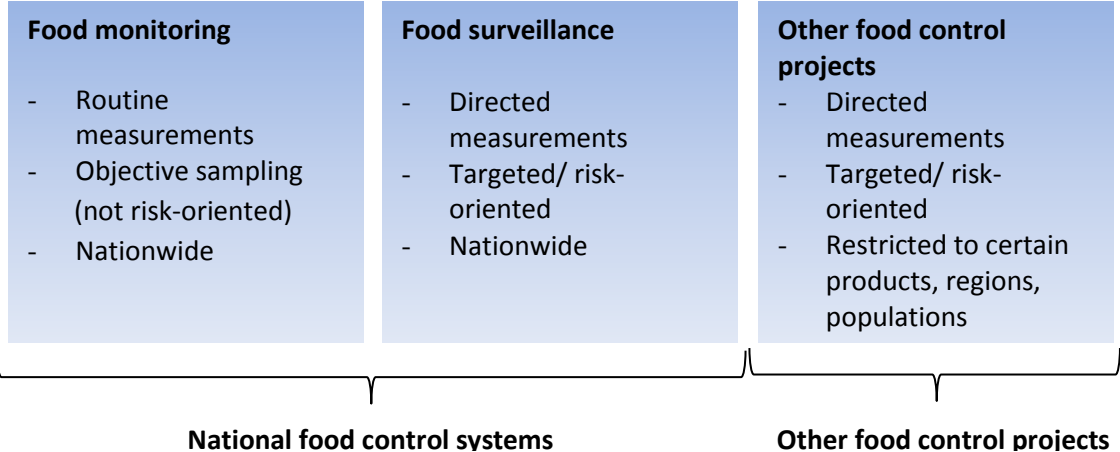


Figure 2: Graphic classification of food monitoring, food surveillance and other food control projects.

As already mentioned, the differentiation between these terms is not always clear in the publications of the literature research. Therefore, it was decided to sort the publications according to “TDS” or “food monitoring, food surveillance and other food control projects”; latter including all publications which indeed included the key word “food monitoring” but could not be unequivocally classified as such. Therefore the term “food monitoring” refers in the following sections to all publications dealing with “food monitoring including others”.

3.3 Differences between Total diet studies and Food monitoring

As mentioned above monitoring and surveillances programs are intended to check compliances with legislative regulations, whereas a TDS aims to obtain information about the background exposure to evaluate the risk status of a whole population. The different objective targets result in different study set ups, each serving the particular objectives of the respective approach. The main aspects are listed in Table 1 and will be described in brief in this section which is oriented on the EFSA/FAO/WHO (2011) TDS Guidance document and on the comparison between the German food monitoring approach with TDS approach by Lindtner *et al.* (2013).

In a TDS the **food sampling** is based on a representative sampling plan covering at minimum 90 % of the population’s consumption. For food control systems instead it is of interest to sample products in a targeted manner where a risk is assumed. However, also sampling based on a representative food basket is applied in the monitoring; but as samples are analyzed on a single food basis, just a certain part of this basket can be realized each year (BVL, 2015).

One of the main characteristic of the TDS is the **preparation of the foods** as the consumer would do, prior to analysis. This involves two main advantages. Firstly, the chemical concentration as the consumer actually ingests through the diet is measured; and secondly, process related contaminants

can be considered, such as process contaminants (e.g. PAHs² or acrylamide) or food additives. This results indeed in a less conservative but more realistic picture of dietary exposure. The food monitoring is mainly based on the analysis of raw commodities or processed foods (e.g. cold cuts). The analysis “as purchased” involves the analysis in total, mostly including inedible parts. Consequently, default factors (like edible or yield factors) need to be applied which introduces additional uncertainty in the estimations. Those uncertainties mostly result in overestimation of real exposure.

Table 1: Main differences between total diet study and food monitoring.

Survey method Characteristic	Total diet study	Food monitoring
Purpose	chronic exposure assessment	acute exposure assessment chronic exposure assessment (conservative)
Food Sampling	representative >90% of the diet	single food(s)/ food basket
Food preparation	preparation as usually consumed (table-ready)	as purchased (raw and already processed)
Substances	screening of a lot of substances; including process related contaminants	selected substances in selected foods (focus on risk basis)
Sample preparation prior to analysis	sample pooling	single sample analysis
Variability	poor information about variability	high information about variability
Analysis/Sensitivity	high sensitivity (as sensitive as achievable)	poor sensitivity (detection limits oriented on legislative MLs)
Budget	cost-effective (pooling)	more cost-intensive (high sample numbers)

MLs: Maximum Levels

Next to the fact, that a TDS enables the analysis of process related contaminants, it also enables the screening of a large amount of different **substances** due to its **cost-effective study design**. The **pooling** of the subsamples to a composite sample prior to analyses allows the coverage of a large amount of foods with, at same time, reduced amount of analytical samples. As the food monitoring is analyzing each single sample, just selected substances in selected products can be realized in a certain period.

However, it must be realized, that on the other side costs are enhanced in a TDS as more **sensitive analytical methods** are required. Monitoring programs are oriented to detect exceedance of Maximum Levels (MLs) and work with comparatively high limits of detection (LODs) or limits of quantitation (LOQs). A TDS is oriented to detect baseline contamination which is located in much lower ranges than regulative limits are. This results in a higher amount of detected measures which decreases uncertainty introduced by left-censored data.

² Polycyclic aromatic hydrocarbons

Analyzing a TDS pooled sample results in mean value of a particular number of subsamples (e.g. 15 subsamples). This indeed allows the consideration of a lot of food items by a few analytical measurements, but bears one main disadvantage regarding **variability**. High concentration samples may be diluted in the composite and information of the concentration of each sample gets lost. The higher the degree of pooling the more a chemical gets diluted and can even drop under the detection limit. But the main limiting factor of TDS is that pooling makes acute exposure assessment impossible in a TDS. Food monitoring programs instead provide the whole range of variability by analyzing each single food item; allowing for acute exposure assessment and assessment based on high concentration percentiles.

In conclusion, a TDS is best fitted for the **purpose** of chronic exposure estimates as foods are samples representatively, covering the whole population. This is just affordable by the cost-reducing approach of pooling. On the other side, information about variability gets lost. This information is just achievable with single food analysis of monitoring programs giving detailed results for acute exposure estimation. Chronic exposure assessment based on monitoring data is also possible. Nevertheless, concentration data are not available for the whole range of food supply and estimates will be conservative as detection limits are high and preferably food under suspicion are sampled.

3.3.1 Advantages of Total diet study and Food monitoring

As 3.3 and Table 1 collect together the main differences between TDS and FM this additional section will be a short conclusion of the main beneficial aspects of both surveying methods which will be picked up later in this report again (section 5).

One of TDS's benefits is a representative food selection which covers over 90% of the whole diet of the population of interest. Since the food samples are prepared as usually consumed (table-ready condition), possible processing contaminants and degradation processes are considered. The pooling afterwards leads to a broad coverage of food variety in a cost-effective matter but therefore only the background level of concentrations is detectable. However the analytical sensitivity is as sensitive as achievable to determine even low baseline concentration caused by dilution of pooling.

The main advantage of FM is that single sample analysis is conducted so a higher variability may be achieved and high concentrations are detectable to check compliance with legislative MLs and estimate acute exposure.

4 Literature review

4.1 Application of Total diet study and Food monitoring data - results from the literature review

One possible scenario that will be described in the following section is the situation where FM and TDS data are available. In this case the question arises: Which data could (better) be used for exposure assessment? The decision tree (see Figure 3) gives support to solve this question with help of the results of the literature research in a stepwise procedure while answering the three indicated subquestions:

1) What is the objective of the exposure assessment?

The literature research revealed four recurring main objectives when collecting FM or TDS data.

Acute exposure assessment

For assessment of short-time exposure only publications dealing with FM data were identified. Reason therefore is the required analysis of single samples, which is impossible with the TDS approach. However, only in ten out of 119³ FM publications acute exposure was assessed, mostly in combination with chronic exposure assessment and/or check compliance of MLs. In eight of these ten publications acute exposure was assessed for pesticide residues in raw agricultural commodities, six times in the course of national food control and monitoring programs. Methodical mostly the international estimated short-term intake (IESTI) was compared with the acute reference dose (ARfD).

Check of compliance of maximum levels (MLs)

In one third of the FM publications the compliance of MLs was checked. Only in four of these 41 publications “Check compliance of MLs” was the main objective (Pareja-Carrera *et al.*, 2014; Rabbitto *et al.*, 2011; Sackett *et al.*, 2013; Wilson *et al.*, 2012), whereas in 35 publications it was checked in addition to chronic exposure assessment. 32 of the 41 publications concerned heavy metals and/or arsenic, 13 from that concerned mercury in seafood, mostly in combination with other heavy metals. Our data confirm the use of FM data to determine the exceeding of MLs because of the analysis of single samples, while a TDS is oriented to detect baseline contamination. However, also two TDS publications evaluating MLs were extracted from the literature. In the second French TDS chronic exposure for pesticide residues was assessed. Although MLs are not currently available for composite dishes, the calculated mean exposures were compared to the legislative MLs of the raw commodities (Nougadere *et al.*, 2012). In a publication of the Cameroonian TDS the mean concentrations of 25 trace elements and the exceeding of MLs of lead, mercury and cadmium was presented (Gimou *et al.*, 2014a).

³ The assignment of a publication to more than one category was possible (e.g. Question: What is the objective of the exposure assessment? Answer: Analysis of trends and chronic exposure assessment). Therefore the sum of n/N is not generally equal to N.

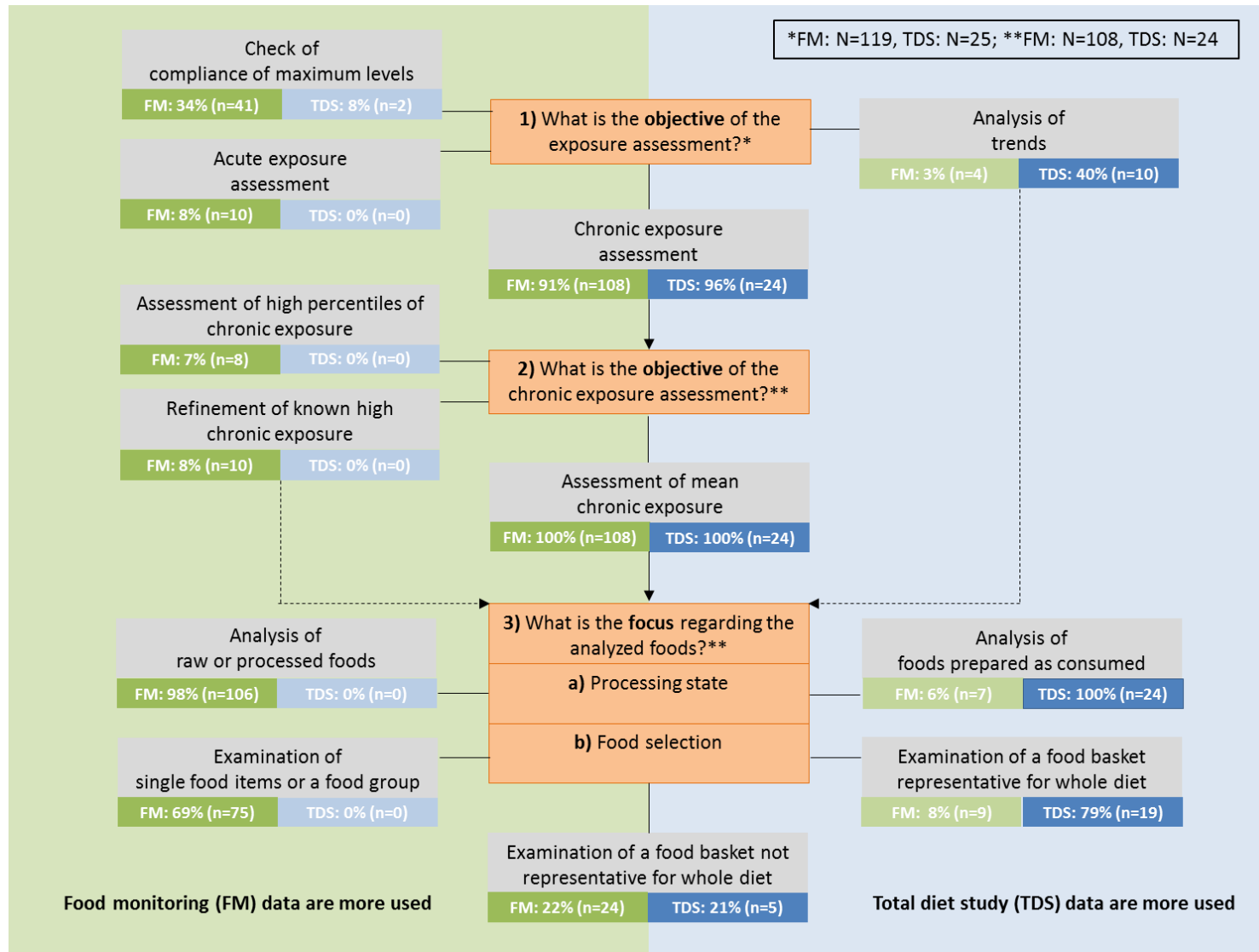


Figure 3: “What data could be used for exposure assessment?” - Decision tree based on the results of the literature review about the application of total diet study and food monitoring data. FM: Food monitoring N: Number of publications TDS: Total diet study

Analysis of trends

In ten of 25 TDS publications trends were analyzed. Of these, four publications of the 4th Chinese TDS and four publications of the 2nd French TDS compared their results with previous TDS data of their country. Only four of 118 FM publications contained a trend analysis (Jooste *et al.*, 2015; Li *et al.*, 2012; Moon *et al.*, 2011; Tlustos *et al.*, 2014), e.g. for the exposure assessment for mercury from seafood consumption in Korea, 26 species were collected annually for four years and compared with each other (Moon *et al.*, 2011).

A reason may be the better comparability of the TDS data because of the consistent approach and the wide data pool. However, to compare single food data or amounts in raw foods FM data have to be used (see subquestion 3).

Chronic exposure assessment

The main objective figured out in the literature research was to estimate the long-time exposure. There was just one TDS publication which not directly assessed chronic exposure (Gimou *et al.*, 2014a). This study described only concentration data but refers to two other publications in which chronic exposure was assessed based on this data (Gimou *et al.*, 2013; Gimou *et al.*, 2014b). Furthermore, 108 of 119 FM publications dealt with chronic exposure assessment. In principle, mostly the estimated daily intake (EDI) was compared with the acceptable daily intake (ADI). In addition, for both study types the proportion of single foods/food groups on exposure, the food items with the highest levels was described. In the TDS studies the influence of season was evaluated, in FM studies separated exposure according to species or origin and calculated consumption limits. In 92% of all publications with assessment of chronic exposure, the population of interest was the adult or general population and in 43% of the FM publications and in 63% of the TDS publications more sensitive groups like children, pregnant or breastfeeding women were considered.

In summary, FM and TDS data were equally used to estimate chronic exposure. To decide which data are suitable for the present case, the research question has to be considered in more detail:

2) What is the objective of the chronic exposure assessment?

Assessment of high percentiles of chronic exposure

With the objective to assess high concentration percentiles only publications dealing with FM data were found. In addition, in these eight retained publications mean chronic exposure was assessed, e.g. the exposure of children to 3-MCPD⁴ in selected bakery products (Starski *et al.*, 2013). Our data confirm the use of FM data to estimate high percentiles of exposure which is possible by analyzing single samples. Instead all included TDS publications dealt with pooled samples like described in the characterization (see section 3.3).

Refinement of known high chronic exposure

If high contributors to dietary exposure are identified, a refinement is necessary for a final evaluation. In the here present literature just FM data were applied. In ten publications FM data were used for a refined assessment of chronic exposure regarding the substance concentration in

⁴ 3-monochloropropane-1,2-diol

single foods, e.g. the Chinese TDS indicated that the lead exposure is much higher in China than in other countries, hence data of national food contamination monitoring program of Jiangsu, China, were used to identify the main dietary sources for chronic exposure (Sun *et al.*, 2011). Hence, it was expected that a TDS can be used to refine exposure assessment in terms of prepared foods. However, no TDS publication with the objective to refine known high exposure regarding the content in prepared foods was found. Subquestion 3b describes this fact more detailed.

Assessment of mean chronic exposure

Unsurprisingly, all of the TDS and FM publications dealing with chronic exposure assessment were calculating dietary exposure by the mean concentration, which is the common approach in chronic exposure assessment.

In summary, FM and TDS data were equally used for estimating mean chronic exposure. Question 3 subdivides the different intentions in chronic exposure assessment to support the decision which data to apply for the present research question.

3) What is the focus regarding the analyzed food?

a) Processing state

Analysis of raw or processed foods

Except of two publications (Jeong *et al.*, 2014; Lee *et al.*, 2013) all 106 FM publications with assessment of mean chronic exposure dealt with foods “as purchased”. In 83 of the considered publications only foods in raw condition (e.g. seafood, vegetables, fruits, cereals, meat) were analyzed while 15 publications dealt with food baskets including foods in raw condition or processed foods (e.g. cereal, dairy, and meat products). Even if the foods were in raw condition, mostly just the edible parts were examined. In five publications a mixture of raw and/or processed and/or prepared foods was examined (Chung *et al.*, 2013; Phan *et al.*, 2013; Rahman *et al.*, 2013; Serrano *et al.*, 2014; Zhu *et al.*, 2013), e.g. to show the influence of the processing state. However, the sample sizes in this studies were very small. In three publications only processed foods were examined (de la Torre-Robles *et al.*, 2014; Minorczyk *et al.*, 2012; Starski *et al.*, 2013), e.g. for estimating the intake of phenol compounds from virgin olive oil (de la Torre-Robles *et al.*, 2014). As expected no TDS publication dealt exclusively with data of raw foods or foods “as purchased”.

Analysis of food prepared as consumed

All TDS publications were analyzing foods prepared as consumed after purchase, like described in the characterization of TDS approach (see section 3.3). Three of these 24 TDS publications included process contaminants like acrylamide or PAHs in their examination (Chan-Hon-Tong *et al.*, 2013; Wong *et al.*, 2014; Zhou *et al.*, 2013). Just seven of the 108 FM publications analyzed prepared foods, while in five of these publications raw and/or processed foods were additionally examined (see section “Analysis of raw or processed foods”). In contrast to the TDS publications, in six of the seven FM publications foods were collected in already prepared condition, e.g. the examination of the exposure to sodium from children's ready-to-eat foods distributed at major amusement parks in Korea (Lee *et al.*, 2013). Another example is the assessment of the exposure to PCBs⁵ and

⁵ Polychlorinated biphenyls

organochlorine pesticides from homemade baby food sampled in private households in Korea (Jeong *et al.*, 2014). Only in one FM publication the analyzed tea infusions were prepared after purchasing the herbal flowers (Zhu *et al.*, 2013).

b) Food selection

Examination of single food items or a food group

75 of 108 FM publications concerned the examination of single foods or one single food group. Most of these publications focused on a particular context like a special food (group) in a limited or risk area. Data sampling in principle was focused on a single food or single food group, e.g. the assessment of chronic exposure of hunters to cadmium, lead and chromium in wild boar samples from Viterbo Province, Italy (Danieli *et al.*, 2012) or of consumers to trace elements of reef fish from New Caledonia lagoon, that is subjected to important chemical inputs due to intense land-based mining activities (Metian *et al.*, 2013). Only in very few cases data came from bigger data pools like food basket based on National Food Control and Monitoring programs, e.g. the identification and estimation of chronic mean exposure of the main pesticide residue mixtures to which the French population is exposed to by using data of raw agricultural commodities from control and monitoring programs carried out by French administrations (Crepet *et al.*, 2013). In 34 of the 75 retained FM publications fish and/or seafood was examined followed by vegetables, fruits or cereals in 26 publications. Furthermore, data were often used to compare different origins or varieties with each other. No TDS publication dealing with a single food or food group was identified.

Examination of a food basket not representative for whole diet

In five of 24 TDS publications a TDS-like approach has been described (Chen *et al.*, 2013; Ling *et al.*, 2015; Sirot *et al.*, 2013; Vogt *et al.*, 2012; Wong *et al.*, 2013). Only a part of the TDS food basket was considered and therefore categorized as not representative for whole diet, e.g. the 1st Hong Kong TDS covered just 24 % of the populations diet, when assessing dietary exposure to dioxins and dioxine-like (dl-PCBs), as most of the foods were not considered as significant sources (Wong *et al.*, 2013). Furthermore in 24 FM publications a food basket not representative for the whole diet was covered, e.g. the assessment of the dietary intake of dioxins, furans and dl-PCBs in Austria, where a national monitoring program was conducted, where just foods with expected high concentrations were considered (Rauscher-Gabernig *et al.*, 2013).

Examination of a food basket representative for whole diet

In the remaining 19 of 24 TDS publications a food basket representative for whole diet of observed population was examined and in nine of 108 FM, e.g. for health risk assessment of cadmium via dietary intake by adults in China foods mostly consumed to represent about 85% of the total intake were nationwide randomly purchased (Yuan *et al.*, 2014).

4.2 Discussion

Only the last five years of publications were considered and so the results are not necessarily complete. But the publications considered refer to a lot of different studies of several countries and can give a good picture of recent understanding of FM and TDS. Internationally, there is no common approach in FM and the term is not clearly defined. Consequently with the key word „food

monitoring“ also many publications about „other food control projects“ not belonging to National Food Control Systems were found and included. In addition, the researched journals contained nearly no regulatory publications of national institutions. That could be a reason for the possibly too few results for „Check compliance of MLs“. By searching for „exposure“, results where just concentrations were determined (without exposure assessment) are probably underrepresented too. Consequently as objective of exposure assessment in FM „Check compliance of MLs“ and „Analysis of trends“ probably were underrepresented. Moreover, in some of the FM publications the informations about the methodology contained gaps, e.g. about the representativeness of the food basket. A known purpose of the TDS approach is „Screen a lot of substances“. This fact has to be cancelled out of the decision tree because this objective was not specifically mentioned in the TDS publications. A reason therefore could be, that in the TDS publications only a part of the examined substances of the whole TDS was described. Another fact that was searched for, but not specifically mentioned in the TDS publications, is the objective “Refinement of known high possibly exposure regarding the content in prepared foods”. However, the research of the selected publications could contain gaps, but gives a very good overview of the application of FM and TDS data in the exposure assessment.

Additional information extracted from the literature was about the population of interest and the substances of interest, as described in the previous section. The evaluation showed that especially adults (n=110) and children (n=57) were considered in the exposure assessment and to minor extent vulnerable groups like pregnant women or women of childbearing age (n=17). Furthermore, mainly metals and organic pollutants are in the focus of dietary exposure assessment in both TDS and FM studies and the data suggest that certain substances, e.g. veterinary drug residues, and vulnerable population groups, are still underrepresented in dietary exposure assessment.

4.3 Conclusion

The literature review shows what data have been used for exposure assessment in the researched publications. Based on these findings a decision tree was developed to answer the question: “Food monitoring or total diet study: What data could (better) be used for exposure assessment?” The key messages can be summarized as follows:

- For estimating **chronic exposure** both approaches could be used, but there are differences regarding the objective of the chronic exposure assessment.
 - If the objective of chronic exposure assessment is to calculate the **mean exposure** in general both approaches could be used but TDS
 - is a more cost-effective method
 - can cover whole diet in a shorter period
 - avoid uncertainties related to use concentration data on unprocessed foods to foods as consumed
 - opens the list of substances to be considered to those occurring mainly in processed foods.
 - For representing **high percentiles** of exposure FM data are more suitable, because the results of pooled samples in the TDS approach do not allow a statement about high amounts in single food samples.

- If there is a **known high exposure** from screening assessments in the population and the purpose is to realize the mean contribution of single foods or to reduce possible overestimation by only analyzing unprocessed foods, TDS data are preferable to use.
- If the objective is to assess **acute exposure** or to check the **compliance of MLs**, it is the better choice to use FM data because of the analysis of single samples.
- For analysis of **trends** in most of the researched literature TDS data are used. This seems to be logic when total dietary exposure is considered because FM needs normally several years to cover a sufficient percentage of the whole diet and TDS can do this within a shorter period. However, if interest is in trends of just a single food group also FM data can be used.

Because of the diverse objectives of exposure assessment both, FM and TDS data, are necessary and should be available. The following section gives a proposal for the combined application of TDS and FM data in National Food Control.

5 Combined Food Safety approach

5.1 Combination of Total diet study and Food Monitoring

Due to different objectives, TDS and FM data are set up in different methodical procedures and therefore data of different quality are provided. Both approaches have advantages and also gaps due to their methodology. The advantages were listed separately under 3.3.1. The optimal combination of both methods can lead to an integrated approach with optimal utilization of the representative strengths of the methods.

Aiming a combined Food Safety approach (see Figure 4) the required different tools for food data collection are connected to maintain a comprehensive food data base for exposure assessment purposes.

“Generally, it is best to conduct preliminary screening analyses to conserve resources and to guide the design of more refined analyses.” (Moy & Vannoort (2013))

(I) With a **screening TDS**, as starting point, first data can be established and helps to identify food groups with potential high contamination. This TDS approach analyzes a small number of foods/food groups, mainly related to former concern, and uses a high degree of pooling (EFSA/FAO/WHO, 2011). Consequently limited data is accessible but to lower expenses than a complete TDS which nevertheless is also a possibility to get a more comprehensive overview at the beginning.

Since there are different possibilities to start collecting first food data also the provided information can be of different quality. If there is already a sound data base, step (III) can follow directly in connection.

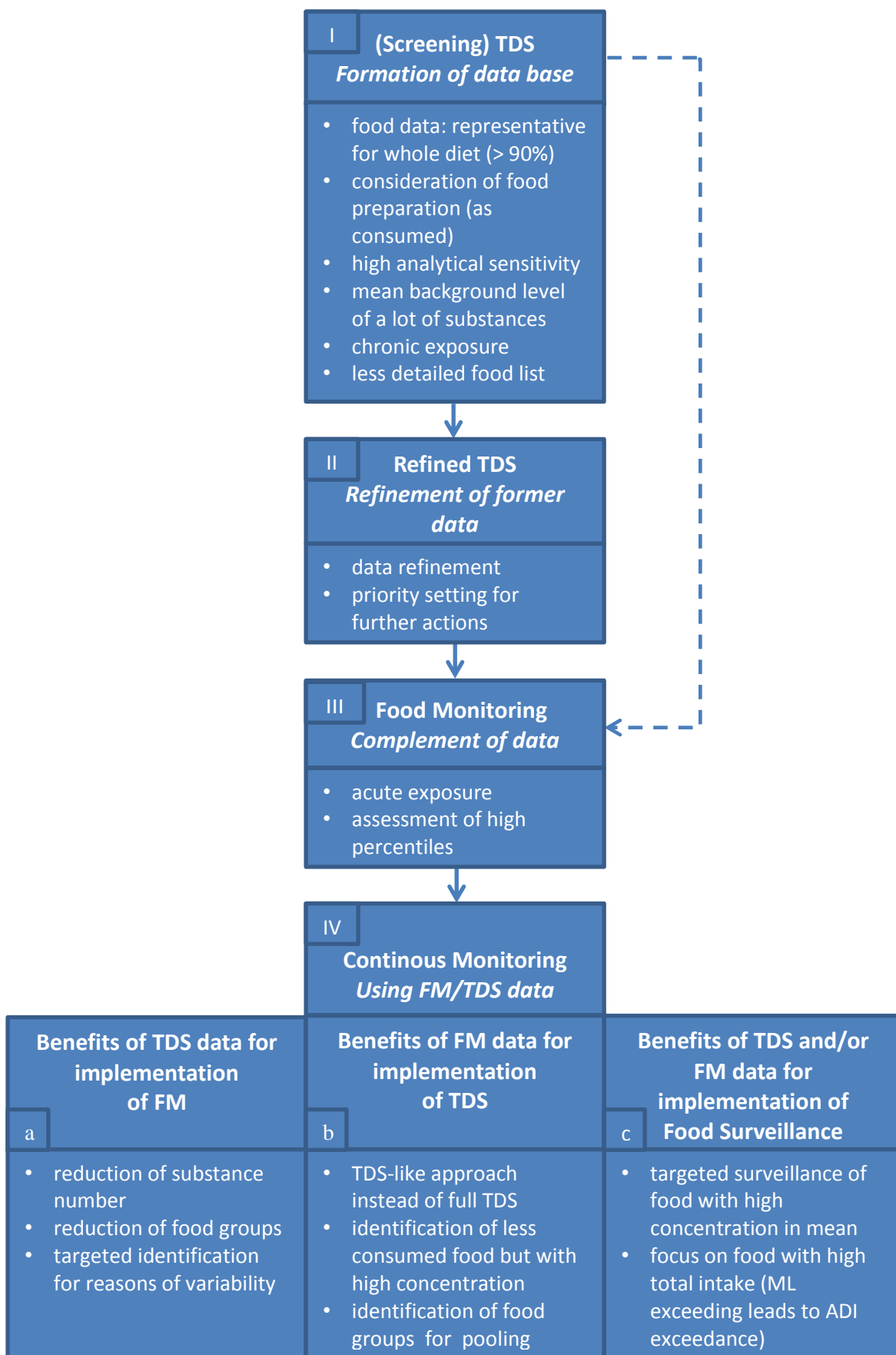


Figure 4: Combined Food Safety Approach.

ADI: Acceptable Daily Intake FM: Food monitoring ML: Maximum Level TDS: Total diet study

(II) If a refinement of this preliminary data is deemed necessary, subsequently a **refined TDS** can be carried out and used for priority setting for further monitoring actions. A refined TDS uses a low degree of pooling and considers several population groups, regions and seasonality. A high number of foods as well as many single foods are analyzed. This variant is more expensive but it is more likely to detect contaminations as well as the exposure assessment is closer to reality (EFSA/FAO/WHO, 2011).

(III) **Food monitoring** completes the former data. Since it carries out single sample analyzing of many more foods than TDS, high percentiles as well as acute exposure can be assessed and more variability received. Those information are necessary to check legislative compliance of MLs but cannot be obtained with a TDS.

The implementation of a screening and refined TDS, or a full TDS instead, which are complemented by FM, lead to a comprehensive data base which is desirable for founded decisions in risk management.

(IV) Since basic data is comprehensive at this point following monitoring to continuous food control can build on this. Advantages of each method can be used to support a more specified implementation of further **FM, TDS** or even risk orientated **food surveillance**.

(a) If the intention is to ensure food safety with continuous FM, this profits of the availability of TDS data. So the number of substances of interest could be limited and reduced since the focus is on those substances for which TDS evaluation identified a potential risk that is possibly better identifiable with higher variability. Further the number of food groups could be more targeted and restricted to food groups with potential ML exceedance. In addition TDS could help to identify reasons for variability.

(b) Not only FM profits of already available TDS data, also FM data helps to support the implementation of a TDS. If there is already a comprehensive data base from FM, this data can be used to develop a more focused modification of a TDS but which concentrates to cover data gaps like a food selection that is representative for a high percentage of the food consumed of the target population and preparation of this food in table-ready condition. Thus for continuous monitoring it may be not necessary to conduct a full TDS in so far a TDS-like approach may be sufficient. Furthermore the risk orientated food selection and analysis of many individual foods of FM helps to identify food which is less consumed but high in concentration of substance of interest while TDS identifies only mean concentration due to sample pooling. But this higher number of individual samples can be used to identify similar foods which thereupon in a TDS can be grouped to one pooled sample without losing too much of variability and thus lower the expenses.

(c) Also risk orientated food surveillance profits of available FM and/or TDS data. The surveillance can be more targeted if foods on risk are previously identified. This may be foods which have a high mean concentration of the substance of interest (identified by TDS) or foods whose total intake is so high that already one ML exceedance leads to exceeding of AD (identified by FM).

5.2 Discussion

Often the question arises whether it is better to use TDS or FM to collect food concentration data, or whether the implementation of TDS would replace the FM. As already discussed each method has advantages and disadvantages as well as different outcomes. Hence using only one method leaves data gaps. Using TDS and FM could complement these.

Nevertheless guidance for using only TDS or only FM is not desirable. Decisions on which method to use should be a balance between envisaged objectives and available resources. Commonly, resources limit the extend of data collection. Hence advantageous would be to focus from the outset on the strengths of each method and combine them in the way needed. As mentioned before that will cover the vulnerabilities of each other. The more targeted data collection also helps to lower the expenses. This first approach of a combined Food Safety approach is flexible and can be adapted in several more variants. The core statement is that identification of beneficial characteristics and combining them in a useful way could achieve a (cost-) effective approach of food data collection as already considered by Lindtner *et al.* (2013) who compared the possibilities of dietary exposure assessment using German food monitoring data to possibilities by using TDS data . There is the possibility to use the existing methods stepwise as discussed but it is also possible forward-looking to consider the development of a totally new approach of data collection of food concentration which combines the wanted attributes of TDS and FM from the start.

5.3 Conclusion

In conclusion a stepwise food data collection starting with screening TDS, possible refining of this data with refined TDS and complementation of data gaps with following FM leads to a comprehensive data base that covers all necessary information which are required for profound risk management decisions. These data can be further used to support continuous monitoring. Already available data can help to develop more targeted study designs of food data collection. TDS and FM, with its different approaches, complement each other. In combination an increase of more realistic and risk assessment is possible.

6 Overall Conclusion

TDS and FM data are set up in different methodical procedures and hence of course lead to mainly different outcomes. Literature review had shown that dependent on the desired objective it is better to use either FM or TDS data. But using only one method always leaves some data gaps and not a comprehensive data base which is desired as prerequisite to make adequate risk management decisions. Therefore a combined use of TDS and FM supplies the most available extent of information and consequently a higher food safety.

Our literature review showed that the interpretation of setting up TDS or Food Monitoring data is internationally inconsistent. This shows the importance of harmonization as tried to be reached by the TDS-Exposure project. Based on this a more harmonized study design for each TDS and FM should be aimed in future projects.

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8 Annex

8.1 Number of publications

Table 2: Number of screened publications

Study type	Number of screened publications
TDS	25
FM	119
<i>SUM</i>	<i>144</i>

8.2 References included in final literature review

8.2.1 References TDS (n=25)

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8.3 Categories literature review

Table 3: Information extracted from the identified literature considered as relevant for the development of a decision tree combining total diet study and food monitoring.

Characteristic	Explanation
Reference	
Study type	<ul style="list-style-type: none"> • TDS: total diet study and TDS-like approach • FM: food monitoring and food surveillance • Untypical TDS: publications in which the term TDS was used without the typical characteristics like preparation and/or pooling of food • Methodological publications: Using TDS or FM data for methodological establishment • Secondary studies: Using TDS data in combination with FM data
Objective	<ul style="list-style-type: none"> • Chronic exposure assessments: contact with a substance that occurs over a longer time (more than 1 day), e.g. EDI • Acute exposure assessments: contact with a substance that occurs once or for only a short time (up to 1 day), e.g. comparison with ARfD • Trend analyses • Check compliance of MLs • Others
Purpose of chronic exposure assessments	<ul style="list-style-type: none"> • Assess mean exposure • Assess high percentiles of exposure • Screen a lot of substances • Refined exposure assessment <ul style="list-style-type: none"> - regarding content in single foods - regarding content in prepared foods
Supplements/Explanations to Objective and Purpose	Further information of methodology for risk estimation
Processing state of analyzed food	<ul style="list-style-type: none"> • Raw commodities • “As purchased” (processed/prepared condition) • Prior preparing “as consumed” (table ready)
Contaminant(s)/substance(s) of interest	<ul style="list-style-type: none"> • Analyzed substance(s) or substance group(s)
Food selection	<ul style="list-style-type: none"> • Food basket representative for <i>whole</i> diet of population of interest • Food basket not representative for <i>whole</i> diet of population of interest: (e.g. different food groups or representative food basket excluding certain food groups) • Single Food(s)/Food group(s)
Supplement/Explanations to food selection	<ul style="list-style-type: none"> • Which specific food(s), food group, food basket, crops • Variety • Food(s) with/without burden
Sample size	<ul style="list-style-type: none"> • Food samples

Characteristic	Explanation
(of selected food(s))	<ul style="list-style-type: none"> • Food groups • Subsamples • Pooled samples
Sampling strategy* – food	<ul style="list-style-type: none"> • Objective: selection of a random sample from a population on which the data are reported, e.g. representative food basket excluding food groups without the substance of interest • Not objective: selective (selection of a random sample from (a) subpopulation(s) of a population on which the data are reported. The subpopulations are determined on a risk basis or not; or suspect (individual product or establishment in order to confirm or reject a suspicion of non-conformity. It's a not random sampling.) • Not specified
Population of interest	<ul style="list-style-type: none"> • General population • Adults • Infants, Children • Sensitive groups: pregnant, breast feeding women, vegetarians, vegans etc.
Purpose of risk assessment / objective	<ul style="list-style-type: none"> • Legislative purposes, Regular/periodic screening, justified concern, alert/emergency situation, confirmation of former data, renewing of data, control function etc.
Risk management (option)	<ul style="list-style-type: none"> • Consequences/ conclusions/ advices based on results
Limitations of study type / method	<ul style="list-style-type: none"> • Lack of data, disadvantages of study design, selection of methodology • Were limitations mentioned in discussion of study? Were limitations recognized besides mentioning in study?
Additional Notes	

* definition based on EFSA (2010)