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Approches alternatives de l'évaluation de l'exposition – Alternative Ansätze der Expositionsabschätzung

Total Diet Studies (TDS)

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Introduction

Toxic chemicals and nutritional imbalances may cause serious health problems, many of which are irreversible and chronic. It is therefore essential to have accurate information on people's actual dietary exposure to toxic chemicals and important nutrients. Food contamination monitoring is an essential component of assuring the safety of food supplies and managing health risks.

A national monitoring programme provides accurate data on levels and trends in food contamination which can be used as the basis for regulations and preventive interventions. As well as protecting domestic consumers, monitoring strengthens a country's position in international markets by ensuring the safety of its food exports. In fact, the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) of the World Trade Organization (WTO) requires that health and safety requirements related to food be based on scientific risk assessments. Risk assessments are based on both toxicological information and estimates of exposure of the population to the chemical. The SPS Agreement has referenced the standards, guidelines and other recommendations of the FAO (Food and Agriculture Organization)/WHO (World Health Organization) Codex Alimentarius Commission as representing the international benchmark for health and safety requirements. However, countries may implement stricter standards if the need for such standards can be demonstrated based on sound scientific risk assessment.

National monitoring programmes can therefore:

- determine the extent of national food contamination levels and the risk they pose to public health;
- identify foods which are likely to become contaminated, and determine the source of, or reason for, their contamination;
- point out the need for control to producers and governments, and provide guidance for regulations, if necessary;

- provide the impetus for cooperative action among government agencies responsible for health, agriculture and environmental protection, and the food and chemical manufacturing and processing industries;
- furnish monitoring data to ensure the effectiveness of existing government regulations;
- improve access to international markets by ensuring the safety of exported food;
- prevent entry of unsafe food from abroad; and
- advise other bodies carrying out food and environmental monitoring.

Despite this, little attention has been given so far worldwide and at national level to assessing the actual dietary intake of these chemicals by humans. One reason is that most of the potential effects of these chemicals are chronic in nature, appearing often years after exposure, and thus cannot be traced to individual foods. In many cases, some of these effects are caused by exposure to groups of different chemicals. In such situations, the concentrations of each individual chemical in the group may be quite low and within current safety limits. However, when the group as a whole is assessed, exposure may be significant. Thus, it is becoming increasingly important to assess human exposure to background concentrations of a large number of chemicals (see for example the United States Total Diet Study program, on http://www.cfsan.fda.gov/~comm/tds-toc.html.)

For national authorities to ensure that toxic chemicals, such as pesticides, heavy metals, environmental contaminants and naturally occurring toxins, are not present in foods at levels that adversely affect the health of consumers, two complementary monitoring approaches are used. The first one is to monitor individual foods for compliance with national and international regulatory standards. However, monitoring data of this type are focused on individual chemicals in raw commodities, and may not provide a direct link to the health assessment of the population.

The second approach is to measure the actual dietary consumption of chemicals by the population, and compare intakes with toxicological reference points, such as the Tolerable Daily Intake (TDI) or Provisional Tolerable Weekly Intake (PTWI). These comparisons provide a direct link to the health of the population, and Total Diet Studies (TDS) are the most reliable way to estimate the dietary intake of toxicants by large population groups.

Therefore, TDS are essential to answer the fundamental question of whether or not the national diet is safe. TDS are the primary sources of information on the levels of various contaminants and nutrients in foods for human consumption. In addition, TDS results can be an indicator of environmental contamination by chemicals, such as (persistent organic pollutants) POPs, and can be used to assess the effectiveness of specific risk management measures. TDS are internationally recognized as the least expensive way to estimate the average dietary intakes of toxic and nutritional chemicals for a range of population groups.

Practically, a total diet study consists of purchasing foods commonly consumed, processing them as for consumption, combining the foods into food composites or

aggregates, homogenizing them, and analysing them for toxic chemicals. The analytical results are then combined with food intake information for different population groups, and the dietary intakes of the chemicals by the groups are estimated. WHO recently issued a concise brochure on TDS (1).

Since 1976, the World Health Organization (WHO) Global Environment Monitoring System – Food Contamination Monitoring and Assessment Programme, which is commonly known as GEMS/Food, has informed governments, the Codex Alimentarius Commission and other relevant institutions, as well as the public, on levels and trends of contaminants in food, their contribution to total human exposure, and significance with regard to public health and trade. The Programme was implemented by the WHO in cooperation with a network of WHO Collaborating Centres for Food Contamination Monitoring and participating institutions located in over 70 countries around the world.

GEMS/Food has for many years supported the concept of TDS as one of the most cost effective methods for generally assuring the dietary intake of chemicals is within safe limits and for setting priorities for further study. GEMS/Food has indeed also developed lists of analytes to be investigated for total diet studies: GEMS/Food Core, Intermediate and Comprehensive Lists of Contaminant/Commodity Combinations (see first chapter of this report). GEMS/Food however recommends, that countries should always consider including in their own total diet studies the following groups of chemicals: persistent organic pollutants (PCBs, dioxins, dibenzofurans); toxic elements (lead, mercury, cadmium, arsenic, chromium); mycotoxins (such as aflatoxin, patulin and deoxynivalenol); specific chemical species (such as organotin compounds, methylmercury, nitrate, nitrite and nitrosamines), volatile organic compounds and nutrients such as vitamins, minerals and essential fatty acids.

The experience collected so far in other countries, is showing that the accuracy of total diet studies strongly depends on two fundamental data components:

- the quantity of each prepared food consumed by individuals, usually collected in national surveys, and
- the background concentration of toxic chemicals in the foods as ready for consumption.

In order to not overestimate the dietary intakes, the analytical methods used to measure toxicant levels should have appropriately low detection limits. Often, such methods are complex and require advanced instrumentation. Thus, total diet studies could generate high costs. However, the cost of total diet studies and the laboratory infrastructure built around them is minuscule compared with their value in supporting good health and active trade.

Overview of TDS studies from different countries

Some countries have developed and carried out TDS within a nationally tailored framework, depending on food consumption and contamination patterns. Some

examples of TDS are given below for Australia, France, Canada, United States, Czech Republic

Australia

The Australian Total Diet Survey (2), formerly known as the Australian Market Basket Survey, is Australia's most comprehensive assessment of consumers' dietary exposure (intake) to pesticide residues, contaminants and other substances. The survey is conducted approximately every two years, and, while the 21st and 22nd are ongoing, the 20th survey has been recently completed (see table 1).

Table 1
Australian Total Diet Study (ATDS)

ATDS No	*sampled published*	*No Foods*	*No. composite samples*	*Analytes*
19th	1998 2001	69	1107	**pesticides** & **fungicides** screening **metals:** antimony, arsenic, cadmium, copper, lead, mercury, selenium, tin, zinc **toxins:** Aflatoxins
20th	2000/2001 2003	65	1107	**pesticides** & **fungicides** screening **metals:** antimony, arsenic, cadmium, copper, lead, mercury, selenium, tin, zinc **toxins:** Aflatoxins and ochratoxins **inhibitory substances:** Penicillin, streptomycin, oxytetracyclin
21th	2003 2004	60	702	**Additives:** sulphites, nitrates, nitrites, benzoates, sorbates – mainly processed foods
22nd	2004 2005	95	1128	**trace elements:** iodine, chromium, molybdenum, selenium and copper plus nitrates and nitrites

The survey estimates the level of dietary exposure of the Australian population to a range of pesticide residues, contaminants and other substances through the testing of food samples representative of the total diet. These samples were prepared to a "table-ready" form; for example, the potatoes were cooked. Like the 19th survey, food consumption data derived from the 1995 National Nutrition Survey have been used in the calculation of dietary exposures to pesticides, contaminants and other substances.

Sixty-five types of foods representative of the Australian diet were tested for pesticide residues, contaminants and other substances from foods sampled during July and November 2000 and February and April 2001. These food types incorporate foods central to the Australian diet (core foods), foods that might be expected to show regional variation of residue, contaminant or other substance levels

(regional foods), and foods that are available nationwide and are not expected to show regional variation (national foods). These food types were sampled in each of the States and the Northern Territory and some were sampled at four different times throughout the year.

All foods were screened for pesticide residues, including chlorinated organic pesticides, organophosphorus pesticides, synthetic pyrethroids, carbamates and fungicides; as well as antimony, arsenic, cadmium, copper, lead, mercury, selenium, tin and zinc. Breads, biscuits, rice, oats, processed wheat bran, breakfast cereals (including infant cereal), instant coffee, peanut butter, almonds and milk chocolate were tested for aflatoxins (B1, B2, G1 and G2) and ochratoxin A. A range of meats, dairy products, eggs, offal meat and infant formula were tested for inhibitory substances (penicillin G, streptomycin and oxytetracycline).

The survey also provides valuable background data that can be used for the development of food regulatory measures.

The results of this survey have been provided to the World Health Organization as a contribution to the Global Environmental Monitoring System (GEMS) that collects data on the levels of pesticide residues and contaminants in the food supply worldwide.

France

The results of the first french TDS were published in 2004 by the Institut National de la Recherche Agronomique (INRA) (3). The methodology applied by the Mét@risk* unit of l'INRA (unité des méthodologies d'analyse du risque alimentaire) follows the standardized approach of the study of total diet study (TDS) used by several other countries for the risk assessment. This method, at the contrary of the studies which try to quantify the exposure based upon contamination of foodstuffs, yields a much more realistic assessment of the exposure. Indeed foodstuffs are analyzed "as eaten" by the consumers. This 3-years study allowed to observe a level of contamination of the diet globally satisfying for mycotoxins, minerals and trace elements, for what regards the legislation. It also shows that probability for the population under scrutiny, to suffer from excessive risks originating from the alimentation is low. The study results are based on the analysis of the diet from 3003 subjects involved in the "enquête nationale de consommations individuelles" (INCA). This representative sample of the French population included 1985 people aged ≥15 years, more than 1018 children (3 to 8 years old) and teenagers (9 to 14 years old). The representativity of this national sample was insured by stratification (location of home and size of the agglomeration) as well as by the quotas method (age, sex, size of family).

Canada

Since 1969, Health Canada has conducted Total Diet Studies in five different periods of time to estimate the levels of chemicals to which Canadians in different

age-sex groups are exposed through the food supply. The first Total Diet Study was conducted between 1969 and 1973, the second ran from 1976 to 1978, the third from 1985 to 1988, the fourth from 1992 to 1999, and the most recent one started in 2000 (4). These studies are organized by the Food Research Division in the Bureau of Chemical Safety, and are supported by partners both within Health Canada (e.g., the Nutrition Research and Evaluation Divisions, the Regional Laboratories of the Health Products and Food Branch, Pest Management Regulatory Agency) and outside of Health Canada (e.g., the Canadian Food Inspection Agency). Each study is conducted in several major Canadian cities over the period, normally one city each year.

For each city, each individual food item (there are about 210 individual food items for the current Canadian Total Diet Study) is purchased from three to four supermarkets. The food samples are sent to Kemptville College where they are processed as for consumption in the average household kitchen (i.e., raw meats are cooked; fresh vegetables cooked or properly peeled, trimmed or otherwise cleaned for serving if not cooked). The processed foods are then mixed according to each category to make composites (there are about 140 different food composites in the current study). The food composites are analysed for toxic and nutritionally important chemicals, and the measured concentrations are then combined with food intake information to give estimates of the dietary intakes of these chemicals for Canadians in 16 different age-sex groups.

USA

This TDS involves purchasing samples of food throughout the U.S., preparing the foods as they would be consumed (table-ready), and analyzing the foods to measure the levels of the analytes of interest. Food samples are purchased by FDA (Food and Drug Administration) personnel from supermarkets or grocery stores in selected cities, and the samples are sent to FDA laboratories for analysis. Dietary intakes of these analytes are then estimated for the U.S. population by multiplying the levels found in the TDS samples by the amounts of foods consumed based on surveys conducted by the U.S. Department of Agriculture (USDA). The overall strategy and goals of the TDS have remained constant since its inception in 1961, but the specific methodology has been revised periodically. The number and type of foods collected and analyzed in the study are updated from time to time to reflect changing eating patterns in the U.S. The number of different foods sampled in the TDS has increased from 82 food items when the study was initiated to about 280 foods in the current program. Major revisions of the food list were implemented in 1982 and early 1991. Later in 1991, in response to the Food Quality Protection Act, additional infant and toddler foods were added to the TDS to provide more information on levels of pesticides and lead in the diets of young children. The most recent revision of the food list was completed in 2003; the new list of foods will be posted on the FDA website when the analytical results become available (5). Besides

changes in the number and types of foods purchased in the TDS, the way in which the foods are analyzed has also changed over time. In some of the earlier studies, similar foods were combined before analysis to form composites representing major commodity groups (e.g., dairy, meat, grains). Beginning in the early 1980s, TDS foods were analyzed individually; this approach is still used in the TDS today.

Since 1982, sample collections (also referred to as market baskets) have generally been conducted four times each year, once in each of four geographic regions of the country (West, North Central, South, and Northeast). For each of the four collections, samples of each food are purchased in three cities in the region and are shipped to a central FDA laboratory. The foods are prepared as they would be consumed (table-ready), and the three samples are combined to form a single analytical composite for each TDS food. Current TDS analytes include pesticide residue, industrial chemicals, elements, and folate.

Dietary exposure to TDS analytes can be estimated by multiplying the levels of the analytes found in the TDS food by the amount consumed of that food. The food consumption amounts are compiled for the total US population and 14 age/sex subgroups, and are collectively referred to as the TDS diets. The TDS diets are derived from the national food consumption survey data and are generally compiled in conjunction with updates of the TDS food list. During the food consumption surveys, detailed information is collected on the types and amounts of foods consumed. In all, over 5000 different foods were reported in the each of the surveys upon which the TDS food lists and diets are based (1987–88 NFCS and 1994–96, 1998 CSFII). Although there are many fewer TDS foods (~280) than survey foods (>5000), the TDS diets attempt to account for consumption of all foods. To accomplish this, the survey foods were grouped (or mapped) according to their similarity to TDS foods. Next, average per-capita (eaters and non-eaters) daily consumption amounts were calculated for each survey food and the consumption amounts of all survey foods in each group were subtotaled to derive a consumption amount for each TDS food. This approach assumes that the analytical profile of the survey foods are similar to that of the TDS foods to which they are assigned, and that the TDS diets could provide an estimate of total exposure to the analytes from all foods in the diet, not just from the TDS food alone. This process was repeated for consumption estimates for the total US population as well as 14 age/sex subgroups. All TDS samples collected and analyzed between 1991 and 2002 are based on the food list compiled in 1990 (Pennington 1992). The food list was last updated in 2003; this is the basis for all samples collected and analyzed from 2003 to the present.

Czech Republic

The Czech Total Diet Study (6) is part of the integrated Environment and Health monitoring system of the Ministry of Health and it is linked with the monitoring activities of the Ministry of Agriculture and the Ministry of Environment. The selection of food groups and of representatives of food groups was done based

on the requirements that the considered food basket should include more than 90 % of the consumption (160/202 items). Only food items whose availability was more than 1 g/person/day were selected. Preference and acceptance by consumers were also adopted as criteria to select particular brands and include them into the study. As far as the preparation of the food is concerned, the kitchen followed recipes based on selected catering standards, the habits of the population, the utensils most commonly in use. The TDS studies that were performed since 1999 involved 12 sampling places in 4 regions. 196 samples were taken each year at each sampling place for a total of 2352 samples yearly for the whole Republic. The samples were either individual items from regions or kitchen preparations. As some samples were combined into *composite samples* (Figure 1) a total of 432 samples was finally subjected to the analysis. The food was prepared in a central kitchen and samples were also centrally analyzed.

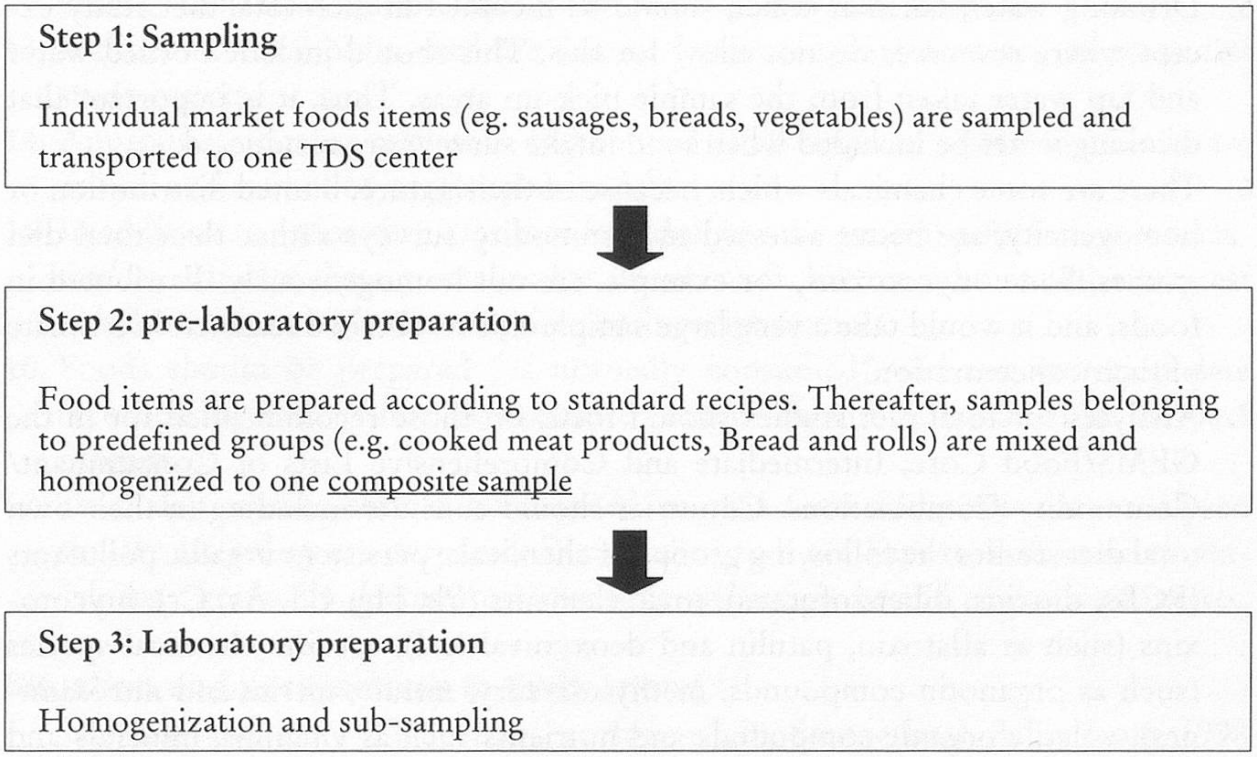

Figure 1 **Production of composite samples for TDS**

WHO recommendations for the development of a TDS studies

Numerous aspects of total diet studies can and should be harmonized if the results are to be comparable. However, it is important to also recognize that each study should reflect the health concerns and resources of the country in which it is conducted. Following WHO GEMS/Food EURO recommendations dealing with these aspects, it is therefore suggested that:

1. A TDS protocol should be harmonised with internationally recognised standard protocols for total diet studies.
2. When conducting a total diet studies a team approach should be used, with all team members, including those recognizable for sample collection, sample processing, risk assessment, statistics and laboratory analysis, involved at the planning stage.
3. A TDS should be documented in detail when it is reported. As a result of resource limitations or for strategic reasons, there will always be differences, such as analytical detection limits or choice of samples, in the design of studies in each country. These can have a major impact on the dietary intake results obtained for the survey and their interpretation.
4. Consider potential impact of individual differences in the design and implementation of the studies. Factors, such as different foods, age-sex groups, climates, agricultural practices, limits of detection/reporting and quality assurance and control practices, can affect results.
5. Drinking water, taken as water, should be included in each total diet study except where resources do not allow for this. This should include bottled water and tap water taken from the sample pick-up areas. Thus, it is important that drinking water be included when food intake surveys are conducted.
6. There are some chemicals which, because of their nature, limited distribution or homogeneity, are better assessed in commodity surveys rather than total diet studies. Some mycotoxins, for example, are not homogeneously distributed in foods, and it would take a very large sample size to obtain a reasonable estimate of their concentration.
7. Analytes for total diet studies should focus on those recommended for in the GEMS/Food Core, Intermediate and Comprehensive Lists of Contaminant/Commodity Combinations. Countries should consider including in their own total diet studies the following groups of chemicals: persistent organic pollutants (PCBs, dioxins, dibenzofurans); toxic elements (Pb, Hg, Cd, As, Cr); mycotoxins (such as aflatoxin, patulin and deoxynivalenol); specific chemical species (such as organotin compounds, methylmercury, nitrate, nitrite and nitrosamines), volatile organic compounds and nutrients such as vitamins, minerals and essential fatty acids.
8. Prioritization when selecting analytes should be based on a) information available (has the analyte been included recently in a total diet study), b) toxicity (could the analyte act by itself or additively with other toxic chemicals to cause harm at low concentrations), c) susceptibility to technology changes, and d) potential for adventitious or deliberate contamination.
9. When selecting chemicals for total diet studies, countries should consider less common chemicals which may pose a significant health risk to their population.

10. Managers of total diet studies should define the limit of reporting required of the laboratory performing the analyses so that the exposure results will be meaningful and cost-effective.
11. Dietary exposures can vary widely depending on how results at or below the limit of reporting are handled. Regardless of the approach taken, it should be clearly described when the total diet study results are reported. Managers of total diet studies should define how results below the limit of reporting are to be used in risk assessment. The technique used should be practical, logical, scientifically valid and consistently applied. While there is still no general agreement about how this should be done, WHO draws attention to the GEMS/Food EURO recommendations that appear as Appendix V to the GEMS/Food Instructions for Electronic Submission of Data on Chemical Contaminants in Food, available at the WHO Website www.who.int/fsf.
12. Food consumption data used for TDS should be as recent as possible and maintained current. Because local dietary patterns may change quickly, the date and basis of the consumption data should be defined in each study.
13. National consumption data are critical for the highest accuracy of total diet study results.
14. Appropriate quality assurance and control at all stages of a total diet study are critical and cannot be overemphasized.
15. In addition to estimating exposure for adults or the general population, it is critical to estimate dietary intakes for infants and children who face the greatest risk due to their high consumption/body weight ratio.
16. Foods should be prepared "as normally consumed" and concentration data recorded as such. If not so, moisture content should be included in the data submitted.
17. Total diet studies should be planned so that food composites are analysed shortly after they are prepared. Even if the foods are kept frozen, some chemicals may gradually decompose over time or become bound to the food matrix.

Situation and perspectives in Switzerland

The last and only TDS study performed in Switzerland dates from 1998 (Kuchen 1998 (7)). In this study, in order to estimate the daily intake of pesticides and other contaminants, a total of 36 ready-to-eat food samples representative for the daily nutrition were analysed using a multi-residue method capable of detecting more than 300 contaminants. This allowed the quantitative determination of a total 66 different pesticides and pesticides metabolites, 8 plasticizers and 6 PCB-congeners. The "market basket" considered for this study was based on the paper of *Erard et al.* (8). This paper dates from 1986 and the data should be updated. Indeed, food habits most probably have changed in the mean time. Moreover, this estimation of the food consumption of swiss people mostly relied on food balance sheets. This approach requires to convert food utilisation data into food consumption data

using risky assumptions on amounts of food wasted or lost during process and storage. For fruit and vegetables consumption Pomerlau (9) has shown that the estimation obtained with food balance sheets may deviate as much as a factor 2.7 from the estimation based on food survey. Finally, food balance sheet data are averaged on the whole country and on the whole population. This is probably inappropriate to define the market basket this way in Switzerland as the "Nutritrend study 2000" (10) confirmed significant differences between the food habits of french-, italian- and german-speaking parts of Switzerland. Thus, one major prerequisite before planning a new Swiss TDS, would be to evaluate the Swiss market basket in all three regions with the required accuracy.

Summary

The current paper presents an introduction to the theme of Total Diet Studies (TDS). The basis principles are presented as well as the possible advantages and drawbacks compared with other approaches. One of the most important strengths of TDS is to allow the estimation of excessive exposure due to the summation of multiple below-limit doses. This may eventually be hidden in the case where some foodstuffs are sampled and analysed individually. Some examples of TDS, taken from others countries, are briefly presented and commented. Finally, some recommendations for the development of a swiss TDS are given.

Zusammenfassung

Diese Arbeit ist eine Einführung zum Thema der TDS (Total Diet Studies). Die Grundprinzipien werden vorgestellt, die Stärken und Schwächen dieser Methode werden diskutiert und mit anderen Methoden verglichen. Ein Hauptvorteil der TDS-Studien liegt darin, dass sie den Nachweis einer übermässigen Exposition aufgrund der Aufsummierung mehrerer Dosen unterhalb der Grenzwerte ermöglicht. Dieser Nachweis wäre sonst im Fall individuell erhobener und analysierter Lebensmittelproben schwierig oder würde gar nicht in Erscheinung treten. Beispiele von TDS aus anderen Länder werden kurz vorgestellt und besprochen. Zum Schluss werden einige Empfehlungen zur Entwicklung einer schweizerischen TDS abgegeben.

Résumé

Ce travail présente une introduction au thème des études de la diète totale (TDS). Les principes de base sont présentés et les possibles avantages et défauts de cette méthode sont comparés avec les autres approches. Un des points forts des TDS est qu'elles permettent par exemple la mise en évidence d'une exposition excessive due à la somme de multiples contributions en dessous des valeurs limites, laquelle ne serait pas forcément apparente dans le cas où les denrées ne font l'objet que de prélèvements et d'analyses ponctuels. Des exemples de TDS d'autres pays sont brièvement présentés et commentés. Finalement, des recommandations pour le développement d'une nouvelle TDS suisse sont données.

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