

tds ► exposure

Newsletter

A word from the coordinator ...



Jean-Luc Volatier (ANSES, FR)

Thank you and goodbye! TDS-Exposure project is reaching its end. Research activities have provided new insights in the determinants of dietary exposure to chemical contaminants that will contribute to risk assessment and management of chemicals in food. This project has built a complete toolbox from standard operating procedures to statistical modeling software and e-learning tools for those in Europe and elsewhere who want to plan a total diet study using a harmonised approach. A EU network has been set up using these harmonised and cost-effective methods, and it is now possible to compare dietary chemical exposure between countries to better protect the EU population. New national TDS are on the way in Europe. Fruitful interaction with stakeholders has enlarged this network and the work will continued in another context although this still needs to be defined with the help of DG RESEARCH, DG SANTE, EFSA and others. I would like to thank all the participants and partners for their strong commitment to the success of the project, and wish all exciting new research projects that will continue to develop the EU Total Diet Study community.

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Final TDS-Exposure Meeting 14th January 2016, Paris (FR)

The objective of this, the final General Assembly, is to share the results from TDS-Exposure across the consortium, and to conclude four years of very productive work. Please join us at ANSES, rue Pierre et Marie Curie 14, F-94700 Maisons-Alfort, FRANCE (09.00-17.30).

Outputs of TDS-Exposure at a glance (2012-2016)

- > Common methodologies defined for the selection of target substances and populations, food list, culinary treatment and chemical analysis
- > Software developed for gathering TDS information (FoodCASE) and calculating the exposure (MRCA) in a harmonised way
- > Quality framework introduced for TDS
- > Three Summer Schools, six workshops and seven individual training exchanges
- > Four newsletters, two stakeholder workshops, and an updated website
- > Pilot studies successfully implemented in five countries

› 01: Final Stakeholders' Meeting Brussels, BE - 8th October 2015



Karine Vin and Jean-Luc Volatier (ANSES, FR) and Cyril Feidt (University of Lorraine, Nancy, FR)

As TDS-Exposure finishes at the end of January 2016, a stakeholder workshop was held to update stakeholders on the state-of-the-art in total diet studies (TDS) in Europe and obtain feedback about the project outputs and plans for sustainability after cessation of funding from the European Commission. Professor Franz Ulberth (Head of the Standards for Food Bioscience Unit at the Joint Research Centre's [JRC] Institute for Reference Materials and Measurements [IRMM], BE) chaired the workshop with co-chair Dr Robert Dabeka (Research Scientist at Health Canada). In total, 75 participants from European Member States (24) as well as the USA, Canada and Colombia attended this workshop representing food authorities (63%), academia (17%), NGOs (13%) and food companies (7%) as well as DG Sante and DG Research.

SESSION 1: Total Diet Studies - Methodologies

Chair: Cyril Feidt (University of Nancy, FR)

› **Welcome, introduction & workshop objectives - Jean-Luc Volatier, ANSES (FR)**

For quite a few chemical substances, diet is one of the main, if not the foremost, routes of exposure for the general population. When we talk about heavy metals like cadmium, pesticide residues or even phthalates and bisphenol A, dietary exposure assessment is a critical step in risk assessment and risk management.

Unfortunately, it is not possible to compare different populations across Europe according to their dietary exposure to these chemical contaminants. Methodological differences in exposure and risk assessment from one country to another are obscuring the risk assessment process and results.

Risk management decisions at the EU-level need to be based on transparent, representative and robust exposure data, with good control of the uncertainties. Total Diet Studies can provide a harmonised methodology for dietary exposure assessment with high coverage of the whole diet and representative contamination data of food as consumed. It is for this reason that the EU FP7 TDS-Exposure project was launched in February 2012 to harmonise exposure assessment and create a network of trained TDS centres using common tools such as databases and modelling software. With 26 participants in 19 countries, and strong links with European and international organizations like the World Health Organization (WHO), the Food and Agriculture Organization of the United Nations



Jean-Luc Volatier and Karine Vin (ANSES, FR)

(FAO) and the European Food Safety Authority (EFSA), TDS-Exposure covers the majority of issues for TDS including prioritisation of substances, food sampling, preparation and analysis, database management, statistical modelling, quality procedures, training and communication as well as implement TDS pilot studies in several countries that have not used such an approach previously. After the first successful stakeholders' workshop in February 2014, the primary goal of this second and final stakeholders' meeting is to share and obtain feedback from all relevant stakeholders about the TDS-Exposure activities and, in particular, the outcomes of the project, which finishes in January 2016.

› **Choosing Substances of Interest and Populations of Importance - Véronique Sirot, ANSES (FR)**

Generally, total diet studies consists of selecting, collecting and analysing commonly consumed food purchased at the retail level, processing the food as consumed, pooling the prepared food items into representative food groups, homogenising the pooled samples, and analysis for harmful and beneficial chemical substances. International organisations, such as the Food and Agriculture Organization of the United Nations (FAO), the World Health Organization (WHO) and the European Food Safety Authority (EFSA) have supported the TDS approach for several years, and provided general methodological guidelines. However, none of these documents has proposed a methodology to target populations for study or validate the relevance of this approach for the different types of substances, or to prioritise substances for analysis. An objective of TDS-Exposure was to first identify populations of interest for TDS, and develop a list of specific foods for TDS-Exposure pilot studies. This approach also provides a general method to validate the relevance of the TDS approach for different groups of substances, and prioritise substances for which a TDS has been considered as relevant.



Véronique Sirot, ANSES (FR)

› **Food Sampling: Food Products Collection - Aida Turrini, CREA Food and Nutrition (IT)**

Collection of food products is the first step in a total diet study. The food list is formulated including all items intended to be representative of the reference diet in a given population. Selecting population groups and relevant substances prioritised formerly, according to the overall aims of a TDS, drives elaboration of the food list in combination with data from food intake surveys.

The process leading to food shopping is designed to start with the food list taking into account background information about the wider food environment within which the study is carried out. The strata are defined according to the relevant parameters in a specific country; methods for selection of shops are linked to information available about the retailing system.

This information allows a sampling plan for food product collection to be prepared and ensures all possible variants (strata) are represented. The importance of factors like geographical area (regional vs. national) and season is linked to types of food (fresh vs. processed), numbers of retail outlets, and processing, preparation and consumption.

Knowledge of the market allows the number of varieties and/ or branded products to be estimated and ensure food samples are representative. Detailed instructions are prepared and equipment provided in advance to minimise the time spent shopping.



Aida Turrini (CREA Food and Nutrition, IT)

› **Food Preparation, Composite Formation and Chemical Analysis - Laurence Castle, formerly FERA (UK)**

TDS food preparation must reflect actual consumer behaviour as it can influence the results. Methods for pooling, homogenisation and storage of the composite food groups, and chemical analysis performed subsequently, must all be reliable (within known uncertainty limits) to derive reliable exposure estimates when concentration data are combined with food consumption statistics. Specific objectives addressed have, therefore, been to ensure preparation

methods reflected consumer practice, and composite formation and storage maintain the integrity of food samples, as well as establishing the requirements and capabilities of analytical methods, particularly at low concentrations expected for diluted composites, and evaluate the impact of analytical method performance (measurement uncertainty) on uncertainties in exposure assessment.



Laurence Castle, formerly FERA (UK)

› **TDS Data Management Tool: FoodCASE - Karl Presser, ETH Zurich (CH)**

The proper management of scientific data, such as TDS data, is important because it can impact on the quality of data, which in turn can impact risk assessment, scientific theories and policy decisions.

Using Excel or other Office software to manage TDS data is not appropriate because these tools are limited in support of quality maintenance and manual work is error-prone. For instance, it is possible to save text where numbers are expected or delete data, and more advanced data quality checks are only possible with programming knowledge.

FoodCASE is a software system for managing food composition data, and was

designed to European standards defined by EuroFIR AISBL. With this experience and knowledge, the goal in the TDS-Exposure project was to extend FoodCASE so that TDS data could also be managed and support institutions performing TDS.

Advantages include that all TDS data are stored in a central repository, kept in the same format, extended search functionalities are provided, and export in different formats is possible with a single click. The automated linkage tool in FoodCASE, to combine TDS data with food composition data, offers the potential for investigation and research. Data quality receives special focus in FoodCASE as scientific data needs to be of the best possible quality.



Karl Presser, ETH Zurich (CH)

Session 2: TDS Exposure Evaluation and Quality Assurance

Chair: Sue O'Hagan, PepsiCo International (UK)



Sue O'Hagan (PepsiCo International, UK - Session Chair), Franz Ulberth (JRC IRMM, BE) and Robert Dabeka (Health Canada).

› Quality Framework and European TDS Centres - Paul Finglas, IFR (UK) & EuroFIR (BE) and Luísa Oliveira, INSA (PT)

A total quality management system (TQMS) for the planning and operation of TDS in Europe would benefit nutrient intake and risk assessment by helping to improve the quality and the comparability of data between countries, and has been developed, tested and implemented in the TDS-Exposure pilot studies.

Development of a TQMS for TDS centres was based on the approach used by EuroFIR for quality management review of national food composition database compiler organisations and food composition data. This approach is based on ISO 9001, which is a prescriptive standard and focuses on compliance, adapted for more flexible use within the European Foundation for Quality Management (EFQM) model.

The EFQM model focuses on results, best practice and benchmarking, which means it can be used continuously to help an organisation improve their records and outputs. Methodologies for identifying desirable results for a TDS centre were tested by TDS-Exposure members and stakeholders, and four TDS centres were reviewed to test applicability of the framework to assessments based on either ISO or EFQM

principles, with a view to third party recognition in the future. These facets of the proposed TQMS should be maintained and updated to ensure sustainability of the TDS network expertise in Europe.

TDS-Exposure has established a network of European TDS centres covering most EU Member States, (MS) based on experts from the project as well as EFSA and FAO/ WHO. The network comprises 22 organisations from 16 MS, seven from four other European countries and 17 experts from 14 countries outside Europe.

A flowchart for TDS processes has been produced and critical control points identified. Generic standard operating procedures were developed along with a range of guidance documents for TDS planning, risk assessment and publication of results, which are also being tested by the pilot studies.

To ensure consistent use of terminology, a TDS vocabulary has been produced and, because consistency in food identification, description and classification is very important for easy comparison of data, strengths and weaknesses of the systems currently

available as well as thesauri, specifically EFSA's FoodEx2 classification and description tool and LanguaL, have been evaluated. Analytical methods, assay quality and performance factors used in TDS were reviewed, and a collection of tools to help selection of analytical methods and performance parameters have been developed.



Luísa Oliveira, INSA (PT)

› Variation and Trends: Understanding Data for Better Assessment - Oliver Lindtner, BfR (DE)

Total diet studies are considered the most cost-effective method to analyse a high numbers of substances over the short term in the diet. To achieve this, it is necessary to create a pool of units to be analysed simultaneously. Even if pooling is appropriate for estimation of long-term mean concentrations, it causes information on variability to be lost. Knowing not only the mean, but also the (upper) distributions of concentrations is essential, for example, to determine acute risks. Furthermore, knowledge about variability provides support to inform risk management and communication. Thus, it is worthwhile exploring ways to extrapolate from the mean, as measured in TDS, to higher percentiles.

TDS-Exposure has illustrated this using estimates on variability obtained from food monitoring programmes. In TDS used for refined exposure assessment, some variability is described using more than one pooled sample per food (e.g. for different seasons). Three different approaches were compared to consider TDS seasonal sampling. TDS are also considered useful for trend analysis. The feasibility of trend analysis depends on sample size and numbers of years/ periods available for analysis. Based on Czech TDS data, TDS-Exposure has shown how multiple regression analysis and piecewise linear regression with break point can be applied to test for trends in dietary exposure. Uncertainties in TDS have also been explored.



Oliver Lindtner, BfR (DE)

› TDS Exposure Assessment Tool: MCRA - Jacob van Klaveren, RIVM (NL)

TDS consider exposure from whole diets, and are based on food contamination as consumed rather than contamination from raw commodities, thus ensuring a realistic measure of exposure. Within TDS-Exposure, exposure assessment approach was harmonised among the European countries performing TDS at the national level and countries setting up new TDS. Partners received trained on how to organise TDS data and how to use such data to refine exposure assessment using Monte Carlo Risk Assessment (MCRA) software.

MCRA is a model platform including several probabilistic models for cumulative and aggregate exposure to pesticides, and estimating the usual exposure over a lifetime. Although TDS have advantages over other methods, there are uncertainties such as numbers of sub-samples taken, the extent of pooling before analysing, and how the sampling plan accounts for regional and seasonal variation. Partners collected additional information on seasonal,

regional and annual variation from their national monitoring programmes and expressed the variation in the data as a coefficient of variation (CVs). We created a new TDS assessment model that combined the mean concentration of each food item from a TDS database and CVs from monitoring data, and we applied the model to several chemicals.

Risk assessors can use the model to examine the effect of uncertainties on exposure in cases where variation for a chemical is not well described by the TDS sampling design. Furthermore, the new MCRA model offers risk managers (e.g. the Codex Alimentarius or the European Commission) the opportunity to explore the impact of residue limits aimed at reducing exposure levels where these exceed toxicological reference values.

Information about MCRA is available at <https://mcra.rivm.nl>



Jacob van Klaveren, RIVM (NL)

› Towards Harmonised TDS in Europe: Pilot Studies - Jiří Ruprich, SZÚ (CZ)

During TDS-Exposure, specific effort dedicated to implementation and feasibility testing of newly proposed 'harmonised methodology'. The testing was limited to five countries (Czech Republic, Finland, Germany, Iceland, and Portugal), most without previous TDS experience. Implementation was divided into nine steps (tasks). Six tasks were required for the harmonisation of the TDS methodology, while the remaining three were related to the pilot (feasibility) studies. Individual partners developed specific (national) TDS food and TDS samples. A list of sampled foods, country specific sampling protocols defining quantity, frequency, places, seasons and standardised cooking recipes, reflecting typical/ dominant kitchen preparation, and other possible factors were suggested, harmonised and documented.

Protocols for TDS sample composition and/or aggregation, laboratory analyses and pre-laboratory treatment (e.g. effective homogenization of samples) prior to analyses were tested and described in Standard Operating Procedures (SOPs). These model SOPs were tailored for specific country conditions without affecting harmonisation. Deskwork was followed by national one-year pilot studies. The studies (2014/2015) covered the same seasons, specific population sub-groups (adults and elderly 18-74 years) and chemicals in all participating countries. TDS samples were analysed for total copper, manganese, mercury, and selenium. MCRA was used for calculation of individual exposure. Finally, results (OIM, LNN calculation methods) for nine food groups (FoodEx2) were compared.



Jiří Ruprich, SZÚ (CZ)

› Sustainability of TDS-Exposure Results - Paul Finglas, IFR (UK)

Total diet studies (TDS) allow information about consumption of food contaminants to be obtained and exposure to, for example, pesticide residues in foods and environmental contaminants to be calculated. TDS consider exposure from the whole diet based on food contamination "as consumed" rather than raw commodities, ensuring a more realistic measure. Thus, TDS facilitate risk assessment (RA) and exposure monitoring.

Some EU Member States (MS) and candidate countries had no TDS programme at the start of the project (2012) or used a variety of different methods to collect data preventing international comparisons. It was important to harmonise methods across MS and candidate countries as well as other world regions to facilitate risk assessment and exposure monitoring; harmonised approaches and comparable data are also important for EFSA and WHO-FAO activities.

TDS-Exposure has developed or enhanced a number of key outputs including FoodCASE for compiling and interrogating data, Monte Carlo Risk Assessment (MCRA), total quality management system, training, and an extensive network of TDS centres in Europe and beyond (22 organisations from 16 MS, seven from four other European countries and 17 experts from 14 countries outside Europe).

Plans for the sustainability of tools and knowledge are being developed, and will enable outputs to be maintained and extended after cessation of EC funding. This will meet one of the key aims of the project, which was to spread excellence in TDS through stakeholders and establish a legacy of harmonised methods for sampling, analysis and modelling, and science-based recommendations for future studies. Engaging with the TDS network with other experts will also continue to identify user needs after the project ends.



Paul Finglas, IFR (UK)

› Workshop Conclusions - Franz Ulberth, JRC IRMM (BE)

- Harmonisation and standardisation are not the same things. For example, methods are harmonised whilst data are presented in a standardised manner. With 28 Member States, it is necessary to appreciate and accommodate differences, but also to identify the causes triggering these differences. TDS-Exposure has created Standard Operating Procedures (SOPs) that allow TDS to be harmonised whilst developing a common vocabulary allows the results to be presented in a standardised fashion and to be compared between studies across countries.
- There are a number of sources of uncertainty in TDS. Some can be controlled, such as uncertainty related to analytical measurements. Others, such as culinary practices, are not so easily controlled and vary country-to-country due to different cooking practices. TDS-Exposure SOPs describe what needs to be done and where deviation is allowed, building in quality and ensuring TDS encompass 'quality by design'.
- On the experimental side, historically, laboratories have invested in sophisticated techniques, such as LC-MS/MS, ICP-MS etc. For TDS, investment in appropriate equipment to deal with sample preparation and processing on a larger scale is also needed.
- TSD can be a useful tool for checking whether official controls are effective in providing consumer protection. They can also be used to evaluate the likely impact of any proposed measures to help optimise their effectiveness and cost-benefit.
- Sustainability of project outputs has started to be addressed, but what would also be interesting is a clear statement on how stakeholders benefit immediately from the project.
- TDS-Exposure has presented elearning and other training tools, electronic tools and databases, and certification as well as the potential for accreditation of TDS laboratories. These outputs should prove useful for stakeholders and should all be made publicly available as soon as possible.

Acknowledgements: *The organising committee would like to thank all the chairs, speakers and the rapporteurs for their work to ensure the success of the workshop and participants for their valuable contributions.*

Final TDS-Exposure Summer School, Helsinki FI (5-10th July 2015)

The third and final TDS-Exposure Summer School, hosted by EVIRA, was held on 5-10th July 2015 at Best Western Hotel Rantapuisto in Helsinki (FI). There were 27 delegates; 25 from TDS-Exposure partners including two visiting workers, one external from Chr Hansen (DK) and an observer, Liisa Valasta from THL (FI).

Several of the lecturers who had attended previously were unable to participate this year; new lecturers included Davide Archella (EFSA), Martin Rose (FERA), David Weber (ETHZ) and Oliver Lindtner (BfR).

Thanks again go to Gerald Moy for introducing total diet studies in the first lecture, and presenting a copy of Total Diet Studies by Gerald G. Moy and Richard W. Vannoort to Fabrice Elegbede.

Although this is the last summer school much of the information presented will be available via the TDS-Exposure elearning, which will be available at the end of the year at www.tds-exposure.eu



› 02: Project partners

Coordinated by ANSES, the TDS-Exposure consortium includes 26 beneficiaries, including 10 research centres, six food safety agencies, five universities, four national institutes of public health, and one SME. The range of expertise covers: analytical chemistry, exposure assessment, food safety, epidemiology, statistics and modelling, and social sciences.



French Agency for Food, Environmental and Occupational Health & Safety



Ghent University



National Food and Nutrition Institute



Croatian Food Agency



National Health Institute



European Food Information Resource



Institute of Food Safety, Animal Health and Environment



TUBITAK Marmara Research Centre Food Institute



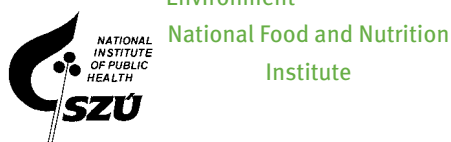
National Institute for Public Health and the Environment



Finnish Food Safety Authority Evira



University Rovira i Virgili



National Food and Nutrition Institute



Agencia española de consumo, seguridad Alimentaria y Nutrición



Flemish Institute for Technological Research NV



Consiglio per la Ricerca e la Sperimentazione in Agricoltura Institute



FERA Science Ltd.



National Food Agency



Federal Institute for Risk Assessment



National Health Institute Dr Ricardo Jorge



University of Granada



Norwegian Institute of Public Health



International Life Sciences Institute European Branch AISBL



University College Dublin



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› 03: Contact us

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TDS-Exposure at a glance

- › Duration: 4 years
- › Budget: over 7.5 million Euros
- › Partners: 26
- › Countries: 19
- › Work Packages: 11

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