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July 2014

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Summary

Total Diet Studies (TDS) are a public health tool used to determine population-wide exposure to both beneficial and harmful chemical substances in the diet, analysing foods as consumed. Exposure is based on whole diets, as consumed, rather than on analysis of raw commodities.

TDS-Exposure is a four-year FP7-funded Collaborative (Research) Project with 26 partners from 19 countries, and led by *Agence Nationale de Sécurité sanitaire de l'alimentation, de l'Environnement et du travail* (ANSES, FR). The project focuses on designing a European system to perform TDS to assess exposure to food contaminants including heavy metals, mycotoxins and persistent organic pollutants, which pose a risk to human health and the environment, and estimate chronic exposure to pesticide residues in food as well as food additives intake.

The objectives of TDS-Exposure are to:

- Identify the information TDS can provide for exposure and risk assessment
- Estimate dietary intake of contaminants in foods as consumed
- Increase numbers of TDS in Europe
- Harmonise the TDS methods
- Develop a European TDS database for risk assessors and risk managers

In the frame of the TDS Exposure project, after two years of work, a stakeholder consultation was organised in Brussels (BE), 5th February 2014, with the following objectives:

- Update on the state-of-the-art in total diet studies
- Information about what is happening in Europe with respect to total diet studies
- Appreciate the importance of better data for better decision making
- Understand why participants are/ are not in favour of total diet studies
- Explore what information participants are seeking from TDS
- Obtain feedback about TDS-Exposure activities and results
- Determine what steps can be taken to ensure applicability of TDS-Exposure outputs
- Ensure dissemination channels are optimised

Chair of the Workshop was Prof. Franz Ulberth, Head of the Standards for Food Bioscience Unit at the Joint Research Centre's Institute for Reference Materials and Measurements (JRC IRMM). The co-chair was Dr Liisa Valsta, Senior Scientific Officer in the Evidence Management Unit of the European Food Safety Authority.

In total, 46 participants attended this workshop, 33 stakeholders and 13 representatives from the beneficiaries. Stakeholders came from food authorities, food companies, academia and NGOs, and were from 15 European countries as well as the USA.

The presentations given at this TDS-Exposure workshop are presented in Annex 1 of this report.

Session 1: Total Diet Studies – Introduction and background

Chair: Benjamin Smith, Firmenich (CH)

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, route of exposure for the general population. When we talk about heavy metals, such as cadmium, pesticide residues or even phthalates and bisphenol A, the dietary exposure assessment is a critical step in risk assessment and risk management. Unfortunately, it is not really possible today to compare dietary exposure to chemical contaminants amongst 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 obscure the risk assessment process and results.

Risk management decisions at the EU-level need to be transparent and based on robust exposure data, with a good control of all the uncertainties. Total diet studies (TDS) can provide a harmonised methodology for dietary exposure assessment with a high coverage level of the whole diet and representative contamination data from food as consumed. It is for these reasons that the EU FP7 TDS-EXPOSURE research project (TDS-Exposure) was launched in February 2012 to harmonise exposure assessment and created 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 organisations like the WHO, the FAO and the EFSA, the TDS-EXPOSURE project covers all the main issues of TDS including prioritisation of substances, food sampling, preparation and analysis, database management, statistical modelling, quality procedures, training and communication. TDS-Exposure is also a unique opportunity to implement TDS in several countries that do not yet use such a methodology.

The aim of this stakeholder workshop was to inform stakeholders about the first results from the project and consult stakeholders about their interest in such exposure assessment studies. The outcomes will help considerably to make the project as useful as possible by producing better data for better decisions in the fields of chemical and dietary risk assessment and management.

Exposure Assessment and Total Diet Studies

Philippe Verger, WHO (CH)

Generally, it is most efficient to use a stepwise approach to assess dietary exposure, beginning with very conservative assumptions and methods, and refining those as the situation demands, e.g. when results are above the Health Based Guidance Value for the chemical under consideration. Further steps should be designed in such a way that potential high dietary exposures to a specific chemical contaminant are not under-estimated and should aim to:

- Define more precisely the group of consumers exposed;
- Focus on food categories containing the chemical;
- Analyse food samples as consumed;
- Estimate occurrence over eating occasions.

Beside its use as a screening tool to estimate the actual occurrence of chemical in broad food groups, TDS can also constitute a refined step in the exposure assessment process if the following conditions are fulfilled:

- Sampling and chemical analysis should be performed at food item level rather than the food group level;
- Raw data from an individual food consumption survey should be available to match occurrence with consumption.

Because analysis is performed on pooled samples, TDS are not relevant for a probabilistic approach. However, a combination of TDS results with the distribution of food consumption can constitute the ultimate refinement for long-term dietary exposure assessment.

Substances of interest and populations

Karine Vin, ANSES (FR)

A total diet study (TDS), generally, consists of selecting, collecting commonly consumed food purchased at retail, processing foods as consumed, pooling prepared foods to create representative food groups, homogenising pooled samples, and analysing them 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 have proposed a methodology to identify relevant populations, validate the relevance of this approach for the different types of substances or prioritise the substances. The objective of TDS-Exposure was to identify the populations of interest and to develop a list of specific foods to be included in the study as well as propose 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 relevant.

Questions and answers

There was a lively discussion, with most questions focussed on the substance prioritisation tool.

Question: The methodology presented for the prioritisation of substances is elegant, but is it pragmatic? Also, it seems to be based more on hazard than on risk. Since different organisations will put different weightings on the criteria used, will it be possible to harmonise?

Response: The criteria used include the potential for exposure to exceed a health-based reference value and so it does have elements of risk as well as hazard. With respect to harmonisation, organisations are likely to place different emphasis (weighting) on the criteria used and so will come up with a distinct list of substances, but the chief substances will always feature. The main output of TDS-EXPOSURE is the prioritisation tool rather than the list, which should not be viewed as a definitive (harmonised priority) list of substances for everyone.

Question: The prioritisation exercise deals only with harmful chemicals and not with beneficial chemicals. Insufficiency in micronutrients can be a big problem in some populations.

Response: Within the scope of TDS-Exposure only potentially harmful chemicals are considered. The prioritisation tool proposed here could be adapted for beneficial substances too.

Question: The populations and sub-populations of interest were described to a high degree of refinement, such as athletes and health-compromised individuals. In order to cover these, how many of the individual food items would have to be tested and is this realistic?

Response: TDS may not be best suited for all these tasks, and the general population and children should be considered first. Beyond a broad screening TDS, it is theoretically possible to have greater and greater levels of refinement, but then TDS may not be the only, or even the best, approach to estimate exposure (compared to a duplicate diet survey, biomonitoring, using survey data, etc.). But, it is important to keep an open mind for the population groups and sub-groups of interest.

Question: Regarding the economic aspects, there is always limited money and so should the focus not really just be on the general population?

Response: Chemical analysis is the main cost in a TDS. In the first instance, exposure of the general population can be assessed. Then, the concentration data can be re-used for different sub-populations using their different consumption of the affected foods.

Question: How are uncertainties dealt with? Is there a systematic study of the uncertainties associated with each criterion?

Response: Uncertainty was dealt with in another Work Package (Variation and trends, Oliver Lindtner, BfR (DE), page 17 – WP8) and dealt with in a separate workshop (Assessing and reporting uncertainties in dietary exposure analysis, 6th February 2014, Brussels – BE, ILSI Europe Food Intake Methodology Task Force, see report at http://www.ilsi.org/Europe/Documents/Uncertainties%20Workshop%20report_06-02-2014.pdf).

Question: Is the prioritisation exercise too broad and will we ever reach the goal? Would it be better to focus not on individual substances but on a sub-population or a harmful effect - e.g. children and endocrine disrupting chemicals?

Response: The prioritisation tool does not make a link between populations and substances (except via the criteria of potential exposure), but this could be done.

Remark: Prioritisation of substances lays at the boundary of science and policy, and so it is natural that the prioritisation tool and the prioritised list given as an example will attract much comment.

Question: The weight given to the availability and capability of analytical methods to test the food are too low.

Response: The project participants felt the balance was correct. If a substance is prioritised this indicates an analytical method is needed and should be developed if it is lacking. A substance is not

prioritised for analysis because you have a method available. Also, the economic aspects were not covered by TDS-Exposure. If samples are available, and a reliable, cheap analytical method validated, then additional data may be obtained at low cost even for less important substances.

Question: The prioritisation tool is a rational and transparent approach, especially for the public. However, how is the degree of potential harm factored in?

Response: The nature and extent of harm associated with any toxicity or health-based value is not factored into the prioritisation tool. But, there is no reason why this could not be added.

Question: Is there the risk that the prioritisation is biased if the background information is missing? For example, if exposure is not recognised then a substance may not get the priority that it merits. So, as an example, since we have no methods for nanoparticles, we really have little idea about possible exposure from food.

Response: This is linked with dealing with uncertainties (see above). In the prioritisation exercise, when you do not know, then a middle score (e.g. 3) is given.

Question: Public perception features in the prioritisation exercise; this is difficult to obtain and shifts with time. How did the project get this information?

Response: In developing the prioritisation tool, food safety experts were interviewed and so this is the experts' perception of what the public are worrying about. Clearly, for a formal prioritisation a tool is needed to ask the public more directly what concerns they have with regard to chemical aspects of food safety. Many food safety agencies do engage with the public to seek their concerns.

Session 2: TDS design and quality

Chair: Jacob van Klaveren, RIVM (NL)

Food sampling

Aida Turrini, Centro di Ricerca per gli Alimenti e la Nutrizione (CRA-NUT, IT)

Food sampling represents the first practical step in obtaining a representative sample for a reference diet. This activity is performed, after a desk analysis, leading to a food list. Selecting population groups and relevant substances, prioritised according to the overall aims of a total diet study, drives the elaboration of the food list based on food intake statistics. A sampling plan for collection of food products is prepared to ensure all the possible variants (strata) are represented in the sample for each food category.

The importance of factors like geographical area (regional vs. national) and season is linked to the type of food (fresh vs. processed); the number of food shopping locations is linked to habits in food procurement; and the degree of processing related to the food shopping habits.

The protocol should be designed to take account of background information describing context. The strata must be defined according to relevant parameters in a specific country, and methods for retailer selection linked to the kinds of information available. The selection technique for foods within a outlet should guarantee that each food has the same probability of being purchased proportionally to its relative importance (weighting).

Knowledge of the market allows the number of varieties and/or branded products to be estimated ensuring the diet is represented appropriately.

Questions and answers

Question: How do you deal with sandwiches? They are complicated and, in the UK, people eat a lot of sandwiches. TDS in the UK used family purchase data, but have changed to nutrition surveillance. They are also thinking of using food diaries to see if further changes can be made to facilitate the case with sandwiches. Also, how do you deal with water for hot beverages?

Response: The basic philosophy is to get as much detail as possible at all levels, i.e. both raw and composite food, and it would be nice to analyse all levels: analyse what is really in the food basket.

Water: there are examples from previous surveys in Italy, where the water was measured (also for pasta) and weighed after cooking. It is not possible though to have all this information in a single survey; it is too complicated for the participants. Therefore, we have to compromise, and try to get as much information as possible and rather take notes of everything.

Question: How do you consider composite food and food waste?

Response: From experience, left-overs and kitchen waste should be measured. You can also take use recipes and have direct measures in these cases. For composite food, you have to consider at what importance the food has (frequency of consumption by the whole population). There are several ready-to-eat foods in the stores and they have increased relevance in dietary surveys. In some countries the foods are described/ elaborated in food composition databases.

Analytical methods

Laurence Castle, FERA (UK)

A key part of TDS work is that exposure estimates are based on chemical concentrations measured in the food as eaten. Depending on the characteristics of the food and the chemicals targeted, food preparation methods can cause concentrations to rise, fall or remain unchanged. Unless care is taken during preparation, methods may also introduce additional extraneous contaminants. So, it is important to ensure food preparation methods used in TDS work, properly reflect consumer practice.

Individual food items are then pooled to reduce the cost of analysis. The TDS work should be designed so that this pooling does not give rise to a dilution of the target chemicals such that analytical methods result in a large number of non-detects. Similarly, pooling can make the sample matrix more complex and this has implications for the validation of analytical methods. The availability and performance requirements of analytical methods and reference materials will be discussed.

Questions and answers

Question: Oxidative state of some elements is important in risk assessment. Do you measure the oxidative states? Chromium (VI) is most common. Arsenic (III) is more toxic than arsenic (V). As(V) is found in fish and As(III) in water. This may change the risk assessment.

Response: Arsenic and mercury for example have different organic states and so some TDS work has studied element speciation. The most recent Italian TDS work for example. I am not aware of anyone doing TDS of Chromium (VI).

Quality standards

Paul Finglas, Institute of Food Research (IFR, UK) and European Food Information Resource (EuroFIR, BE)

Luísa Oliveira, National Health Institute Doutor Ricardo Jorge (INSA, PT)

One of the key objectives in TDS-Exposure is to encourage the development of total diet studies (TDS) across Europe and globally in order to improve the quality of chemical risk assessments and encourage and support the implementation of new TDS in EU Member States. TDS-Exposure (Work Package 5) is developing and implementing an overall quality standard framework for TDS centres in Europe utilising a Total Quality Management System, based on the European Foundation for Quality Management (EFQM) Excellence Model, and including a TDS-centre network, commonly agreed concepts and associated terms, and quality tools including SOPs and analytical methodology (linking to Work Package 4). The overall aim is to improve the quality of data and comparability of results among countries.

Questions and answers

Remark from the Co-Chair: FoodEx2 was published online in 2011. It is to be used with food names and facet descriptors, and inter-facet descriptors (e.g. unpeeled/peeled potatoes) can be found.

General discussion

Comment from the audience (to complete the discussion on sandwiches): Resolving these issues depends on consumption data. If sandwiches are frequent, you include more of these samples. Regarding water: some EU countries use distilled water; this also indicates the approach depends on decision before the start. TDS-Exposure uses tap water. But, these decisions depend on the intentions. For example, should we use salt? If you are looking for iodine, you should not use iodised salt.

Question: Shall we add salt/water?

Response: If 90% of the population uses iodised salt then you should use iodised salt in the study.

Comment: The main principle is in 'decomposing' substances, actions will depend on the decisions made before the start.

Question: The beauty of TDS is that foods are analysed as consumed. How good is the information we have on culinary preparations? What information do we lack? And what are the recommendations to improve?

Response: This work is still under way. But, there is a significant lack of knowledge and, at the moment, recommendations on how to improve cannot be made.

Question: Will the project produce any such information?

Response: TDS-Exposure is reviewing these 'as consumed' aspects.

Question: Concerning analytics: Is producing Standard Operating Procedures (SOPs) straightforward and how are these achieved? Will TDS-Exposure provide information on the influence of different SOPs?

Response: This depends on the substance of interest. Heat is the most important factor. Other work is necessary to obtain information about the influence of culinary practice on substances (e.g. furans in barbecue). But, this depends on the intention of the TDS. Is it screening of a broad range of chemicals? Or cooking out water for trace elements? Or are you looking into a narrow range of substances. The purpose of the study will inform you on the effort you have to put into it.

Question: What is your opinion about transformation factors - pesticide processing factors for example?

Response: These do not have a place in TDS, because foods are as eaten compared with survey data.

Question from the Chair: What is the interest of the stakeholders?

Comment: TDS can be helpful in studying contaminants, but information on micronutrients is scarce. This can be helpful in some countries where you have a lack of micronutrients in food.

Question from the Chair: Do you have an opportunity to adjust existing TDS?

Response from the audience: The UK heavily relies on TDS, but limited resources reduce flexibility in TDS studies. However, by keeping foods and samples, we can extend TDS and save money. We use TDS when doing a risk assessment. But, context needs to be taken into account and there needs to be more than one food sample. For example, looking at aluminium, if you find it in a pooled sample,

how do you know where it came from? How can you reduce levels if you do not know the food source?

Question from the Chair: Can we store the samples for the future?

Response: Aspects of storage and stability needs to be considered. If undertaking screening, samples should be stored for subsequent analysis. Need to decide whether to freeze or freeze dry. A good example is the case of acrylamide: when it was discovered, analysts went back to the archived TDS samples and the correct judgement made.

Question: Are there Certified Reference Materials (CRM) applicable for both raw and cooked food and are they available for most of the matrices?

Response: The simple answer is no. They do not exist for many composite foods. CRMs are recommended, but labs can demonstrate performance in other ways.

Question from the Chair: What is the situation with the shopping lists? How stable are these coding systems?

Response: Fairly stable, updates and comments from users applied. The system has been around for 30 years. But, its applicability for TDS has to be demonstrated.

Remark from the Co-Chair: In FoodEx2, information for modifications is collected, and EFSA will continue to use it without significant changes. Whether it is useful for TDS has to be shown.

Question: Classification systems are used for food items and not for pooled samples. How do you do this in the FoodEx system?

Response: This is solved pragmatically with variable data and calculation of exposure doses. It is a binary system classifying to higher foods. There are 20 basic food groups meaning aggregating down with 20 different facets to describe individual foods. For harmonisation, we use a hierarchy of aggregation: going from deepest to highest. This is one solution, but there are others.

Remark from the Co-Chair: FoodEx2 is a combined system of hierarchy and descriptors, and you can combine all showed foods with 20 different facets and descriptors.

Further remark: It is hard to find a stable base. FoodEx has benefits. It was designed for estimating exposure, which is good when comparing different countries. Many other systems are based on consumption.

Session 3: Methodology, tools and implementation

Chair: Matthias Greiner, BfR (DE)

Database management

Karl Presser, ETH Zurich (CH)

The proper management of scientific information, such as Total Diet Studies data, is important as it can have impact on the quality of data that in turn can impact risk assessment, scientific theories, and policy decisions. Using Excel or other Microsoft Office software to manage TDS data is inappropriate because these tools are limited in maintenance of quality. For instance, it is possible to save text where numbers are expected and delete data accidentally, and more advanced data quality checks, such as range checks for contaminant values, are only possible with some expert knowledge. In addition, users often struggle with these tools once the file reaches a certain size.

FoodCASE is a software system to manage food composition data and was designed to European standards, defined by EuroFIR AISBL. With this experience and knowledge, the goal of TDS-Exposure is to extend FoodCASE (FoodCASE-Risk) to manage TDS data. Advantages in this approach are that all TDS data are stored at a central place, in the same format, extended search functionalities are provided, and export in different formats are possible with a single click. The combination of TDS data with food composition and food consumption data offers new possibilities to combine these data and explore them. Data quality is a particular focus in FoodCASE-Risk as risk data needs to be the best possible quality.

Questions and answers

Question: What substance thesaurus was chosen for FoodCASE-Risk?

Response: The EFSA thesaurus within SSD was chosen as it has over 9000 chemical substances and is the most comprehensive one.

Question: About pooled food: How are they connected to food list/shopping list?

Response: Value documentation is a crucial issue for scientific data such as TDS data. So the food list and the shopping list are linked to the analysed foods so that it is possible to trace back these food items.

Question: How to link food consumption data to exposure data and link to acceptable daily intake? (MCRA does it)

Response: It must be defined where FoodCASE-Risk ends and where MCRA starts. FoodCASE-Risk will have a tool to semi-automatically link food items from different data sets. There will always remain some food items that cannot be matched and need manual work. MCRA will also be able to connect TDS data and consumption data. This is necessary because MCRA uses data for a certain purpose.

Question: How does the spreading work? Spreading should not be used because combining several foods or even mixing different foods produces diluted results and a contamination of one food can maybe not be detected.

Response: That is right. Combining and mixing of food items should be avoided as far as possible. The biggest constraint is the project funding. If only few foods are combined or even mixed the dilution is reduced and the observed concentration can be used with care. FoodCASE-Risk wants to enable user to document their TDS data according to their approach. If somebody is doing the mixed food approach for whatever reason, it should be possible to document that in FoodCASE-Risk.

Remark from the audience: The slide referring to the example with the pear/apple is a controversial example. It should be better illustrated (i.e. clarification needed).

Variation and trends

Oliver Lindtner, BfR (DE)

Two of the main characteristics of TDS are at least 90% of the diet is covered and foods are pooled for analysis. However, according to the EFSA, WHO and FAO working group, there are some limitations in the TDS approach: calculation of exposure for populations with different dietary habits and high dietary exposure given that pooled samples provide only mean concentration values (EFSA 2011).

Therefore, in TDS-Exposure (WP7), we have studied variation in consumption in Belgium, France, Czech Republic and UK and how food lists of existing TDS cover the dietary habits of several sub-populations. Comparing consumption behaviour of pregnant women and the general population Norway has allowed the scope of TDS to be extended. Preliminary results show that dietary behaviour of sub-populations as sex, age groups, high exposure, and pregnant women is adequately addressed by TDS food lists derived for the whole adult population.

Studying variation in concentration data had already started and how linear models can be applied to explain variation, in the case of confounding factors, can now be demonstrated. Data have been made available to perform simulations in food monitoring data for metals to be included in WP9 Pilot Studies. Based on these simulations, procedures necessary to extrapolate from mean concentrations in pooled samples to high concentrations will be determined.

Other aspects that will be investigated are practically application of TDS as tool for trend analyses; compare TDS with food monitoring to create a decision tree for determining which approach should be used for different questions; and describe uncertainties associated with TDS data.

Questions and answers

Question: How can 2 or 3 levels of aggregation in FoodEx be dealt with?

Response: This was studied only for dairy products. For lower aggregation, sub-populations might not be covered adequately by food list of general population.

Question: What data are available for the Czech Republic?

Response: Household surveys are not used, so it is aggregated data. The level of aggregation impacts the data.

Question from the Chair: What is the main advantage of TDS if the variability is too high?

Response: Some variation can also be covered by TDS when having more than one pooled sample per food, e.g. seasonal or regional samples. Simulate different situations by using monitoring and TDS

data. We hope to be able to use variation factors to extrapolate. We analyse food as consumed, so we don't have additional variation introduced by processing factors.

Methodology and software

Jacob van Klaveren, RIVM (NL)

Exposure assessment is an important aspect for risk evaluation of data generated in a total diet study (TDS). An important aim of the TDS-Exposure is to improve the exposure assessment methodology and to harmonise TDS exposure assessment across Europe. The current level of harmonisation is FoodEx1.

All European countries, having performed a TDS study in the past, have been trained to organise TDS data consistently. The TDS data are linked to consumption data using the web-based Monte Carlo Risk Assessment (MCRA) software (<http://mcra8.rivm.nl>) to guarantee a standardised approach in performing exposure assessments at the international level. In the MCRA software, most of the uncertainties are taken into account.

TDS data differ significantly among countries because of study design and the level of detail provided for individual foods and samples pooled and analysed. Countries like Belgium, Spain and the Netherlands performed a less detailed TDS study, with lower number of pooled samples, compared to France or the Czech Republic. In the UK, a well-designed TDS study has been performed for years, but the sampled foods were pooled in broad food categories before being analysed for the presence of residues and contaminants.

TDS data, which will become available from TDS-Exposure, will be stored in the FoodCase Risk database and linked to the exposure assessment software MCRA. MCRA has a module enabling a stakeholder to link residue findings to the TDS data collection, and the TDS exposure assessment methodology, providing those generating the data have agreed access. The platform will include new countries (maybe up to 29). The next step is to study the source of the uncertainties.

Questions and answers

Remark from the Co-Chair: This exercise was done with FoodEx1 (2008-2011), which did not include the food descriptor.

Remark: FoodEx 1 uses national data. Dioxin as an example may not be a wise choice as it is present in many foods and spreads over different food categories. It would be better to look at another contaminant that does not spread throughout the whole diet, e.g. lead.

Response: With lead, the spread was greater.

Remark: I recommend doing a survey using TDS as it is a good vehicle.

Response: We are more looking to the future rather than at the past. It should be discussed how historical data can be incorporated.

Question from the Chair: Is feedback from modelling in the areas of planning/sampling planned?

Response: Yes. This has been implemented in the TDS-Exposure pilot studies (WP9), and is based on the analysis of MCRA programme.

Remark: If we have limited data it gives room for interpretation.

Implementation – Pilot studies

Jirí Ruprich, National Institute of Public Health of the Czech Republic (CZ)

Specific effort has been dedicated to implementation and feasibility testing of “harmonised TDS methodology”. It is tested in a limited number of countries (CZ, DE, FI, IS, PT) that have not harmonised or do not yet have a TDS programme. The work is broken into nine steps (tasks). Six tasks are required for the harmonisation and implementation of TDS methodology, while three others are related to the pilot studies testing feasibility. TDS-Exposure partners developed a specific (national) TDS sample/food list defining food items to be sampled for standard kitchen preparation and chemical analyses. A list of sampled foods, a country-specific sampling protocol defining quantity, frequency, places, seasons, and standardised cooking recipes, reflecting typical/dominant kitchen preparation, and other possible factors were created, harmonised and documented. As there are no theoretically based recommendations on the number of TDS samples, these were reduced to about 100 by excluding the irrelevant ones for investigated chemical substances. This is possible because the pilot study does not address dietary exposure for particular countries but study feasibility of TDSs in specific conditions of every piloting country. Protocols for TDS sample composition and/or aggregation, are procedures needed before laboratory analyses and protocol for pre-laboratory treatment (e.g., effective homogenisation of pooled TDS samples) before terminal analytical process in accredited laboratories will be tested. These processes are described in harmonised (model) Standard Operating Procedures (SOPs), which should be tailored for country-specific conditions. This deskwork will be followed by a one-year pilot study to test feasibility of suggested procedures in the various countries. The pilot study covers the same sampling seasons of diet for population sub-groups (adults and elderly) in all participating countries. TDS samples will be analysed for a limited number of chemicals (total Hg, Cu, Se, Mn). MCRA software will be used for calculation of individual exposure doses distribution. Finally, results for specific food groups will be compared, commented and published.

Questions and answers

Question: The most frequent problem is that most of the people use the wrong data for consumption of coffee and tea. Why do you indicate “no treatment” for coffee and tea when talking about expected kitchen operations?

Response: It means that these were not selected for analysis in the pilot studies, not that these beverages were not prepared before analysis. But the question is very relevant. Analyses are performed usually in raw coffee and tea, which does not reflect real life where usually only the “infusion” is consumed.

Remark of the Co-Chair: The partner in Finland is not the institution collecting the data. Data 'as consumed' in Finland are available (since 1990). So, it may not be the best data.

Response: as far as we know, data was provided within a subcontract from institute collecting the data. Details have to be discussed with our partner EVIRA.

General discussion

Question from the Session Chair: Is there a uniform understanding for repeating samples? (Standard Operating Procedures, harmonisation). How do you deal with results, which are high from regulatory point of view? How do you disaggregate, particularly if there are no subsamples?

Response: In the case of unexpected high results, for the first level, the decision has to be made whether this is the final result or be resolved by further analysis (e.g. by comparing with previous results). For the second level, when the final results are accepted, and it is concluded that it is too high, it has to be decided how to deal with the results and the disaggregation, e.g. samples in a repository for further testing. Pooling samples may help to resolve the issue. If the suspicion is confirmed, the surveillance authorities should be warned.

Comment from the audience: Not sure this would be addressed in TDS-Exposure. If there is an expected very high concentration, this should be discussed immediately with all the people involved in the sampling, preparation and analysis. These people should be from the same place in order to be more efficient. As all samples are stored, they can easily be re-analysed.

Remark: Referring back to a previous comment on data 'as consumed' in Finland, it was asked whether this is an advantage or a disadvantage. It might be an advantage for TDS to use such data because when you know the composition of food, it is better than if you know only the culinary process, because you can disaggregate. For TDS, it is better to work on food ingredients and if both are available, they should certainly be used.

Comment from the Vice-Chair: 'As consumed' data has additional information, such as preparation process and recipes, and this can be used for example when defining process contamination.

Session 4: Dissemination and next steps

Chair: Jean-Luc Volatier, ANSES (FR)

Training and spreading of excellence

Siân Astley, European Food Information Resource (EuroFIR AISBL, BE)

Within Total Diet Studies Exposure, “Training and spreading of excellence” has only one objective, namely to promote knowledge and development of skills amongst organisations and individuals running and evaluating Total Diet Studies for food safety and risk assessment in Europe. This is being achieved through a coherent set of closely related training events, which bring a high level of integration to existing and new training activities as well as exchange of methods and sharing of facilities. Training and spreading of excellence will continue throughout the project lifetime and, whilst there are organisations with specific tasks in these activities, it is expected that all beneficiaries will contribute and the entire consortium benefit from the outputs as well as external parties (e.g., countries planning TDS).

Questions and answers

Question: What are the objectives of the e-learning?

Response: The e-learning should constitute a starting point for new TDS, and will be open to everyone.

Question: A website with e-learning tools dedicated to exposure assessment already exists (GUIDEA). Could it be possible to make a link between these tools?

Response: Yes, we will think about it.

Question: How will the link be made with the pilot studies?

Response: The link with the pilot studies will be made through the presentation of Jiri Ruprich (and other WP9 beneficiaries) at the summer school. This presentation will evolve over time and will integrate the outcomes of the pilot studies in the next few years. Results will also be available on the project web page.

The speaker encouraged again all stakeholders to share their comments with the project team.

Workshop conclusions

Franz Ulberth, JRC (BE)

Professor Ulberth emphasised that harmonisation is a driving force and is important as one of the main objective of this project.

He reiterated that the prioritisation tool is only a tool and the objective is to harmonise, not standardise. He underlined the fact that activities dedicated to the quality management are good and that a 'certification process' always helpful for improving the quality.

He also explained that TDSs are flexible: if you have to know what you want to do, you can adapt the recommendations to your purposes. As an example, samples can also be stored for further analysis (under certain conditions including storage conditions and monitoring). He also recommended that certified reference materials be used when they are available and underlined the importance of cooking practices and the gap existing between science and culinary methods, which causes uncertainties. He also repeated that it is difficult to use monitoring data because inadequate methodology, and that LOD and LOQ may be determined by different ways, which may induce different results.

Professor Ulberth summarised that it is important to specify the method used when determining requirements. He also stated the importance of economic considerations, and the fact that although pooling of samples reduces the cost, it also induces loss of information. He also underscored that specialised instrumentation is needed to homogenise huge quantities of food and there can be a lack of both equipment and knowledge at this stage. He encouraged the use of existing knowledge to fill the gaps (missing data appearing when populating the data).

To conclude, he wished all the best to the project for the coming years.

General conclusions

Jean Luc Volatier, ANSES (FR)

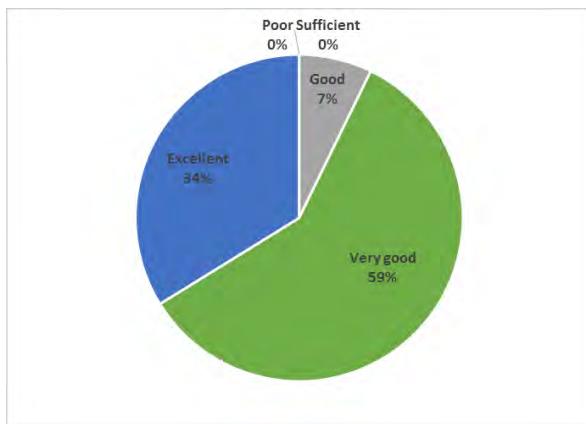
Dr Volatier concluded the day by accentuating the fact that this workshop is only the beginning of interactions between the project and the stakeholders, and all the speakers can be contacted by email. He also explained an interactive section will be added to the TDS-Exposure website to allow exchanges with the project team and a final workshop will be organised at the end of the project to inform stakeholders about the results/ outcomes.

Dr Volatier thanked the organisers, participants, speakers and the coordination team of the project.

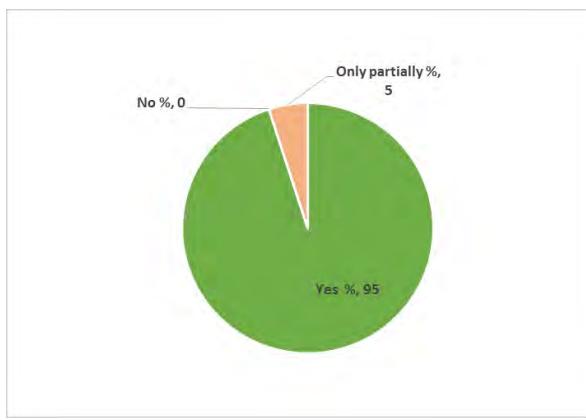
Feedback from the participants regarding the organisation and quality of the workshop

The day after the stakeholder workshop was carried out all participants received an invitation to fill in a SurveyMonkey satisfaction questionnaire. A total of 19 answers were received from the 46 attendants of the workshop.

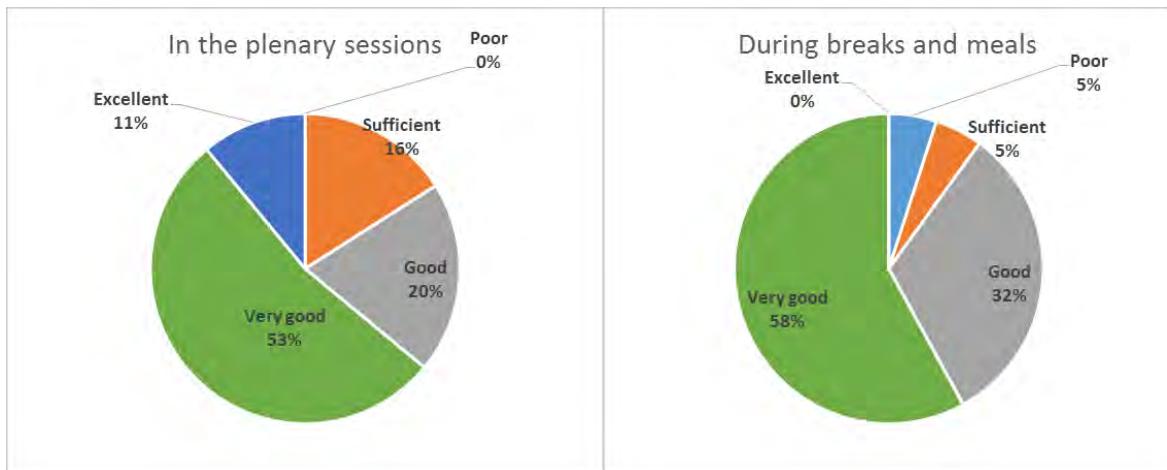
1. How would you rate the overall quality of the workshop and the quality of the scientific presentations and discussions?



2. Were the intended aims of the workshop met?



3. How would you rate the available time for discussions, both formal and informal?



4. How would you rate the practical / organisational information sent to you before the workshop?

	Poor	Sufficient	Good	Very good	Excellent
	%	%	%	%	%
Quality	0	5	5	53	37
Comprehensiveness	0	5	5	58	32
Timeliness	0	5	0	63	32

Conclusions

Science has become increasingly complex and its interaction with society is no longer the exclusive domain of those willing to engage with national authorities, healthcare and, more rarely, consumers. Similarly, strategies for sustainability of outputs are recognised to be insufficient if the products, tools or services arising do not meet the needs of stakeholders. Thus, large-scale initiatives, such as TDS-Exposure, which seeks to clarify information total diet studies (TDS) can provide for dietary exposure and risk assessment, estimate intake of contaminants in foods as consumed, increase numbers of TDS in Europe, harmonise TDS methods and develop a European TDS database for risk assessors and risk managers, need to sustain the interest and goodwill of partner organisations and stakeholders.

Feedback works best when stakeholders are given the opportunity to discuss proposals with experts. Whilst this takes time, the approach enables suggestions to be discussed, and avoids the assumption that everyone is familiar with the entire process, areas of emphasis and existing problems, which can lead to unhelpful or inappropriate feedback/ comments. TDS-Exposure has sought to make use of existing documentation and knowledge, and avoid burdening established TDS centre with additional work. Information for stakeholders has been provided in the form of an annual newsletter, but it cannot be assumed that all stakeholders have access to this.

This Stakeholder Meeting put TDS-Exposure activities into context by providing an *update on the state-of-the-art in TDS and information about TDS in Europe* as well as describing the project organisation and potential outputs. In organising this meeting, TDS-Exposure has tried to *optimise dissemination channels*, and find a balance between delivery of unsought information (spam) and only interacting at the beginning and end of the project when outcomes either lack substance or cannot be modified in response to feedback. There will a second follow-up meeting in the final year (2015).

Amongst the aims of the Stakeholders' Meeting was a desire to promote ownership of the proposed harmonisation as well as *obtain feedback to ensure outputs are sustainable*. Presentations focused on the process as well as the outputs, establishing the rationale behind new or alternative practices and potential benefits for stakeholders and citizens. Organisations are often reluctant to adopt changes in practice because of the need for new technical skills or processes, which are initially time-consuming and, in the short-term, costly.

TDS-Exposure demonstrated how TDS could be improved with better tools and understanding of underlying issues (e.g. target populations and appropriate compound selection, variation and trends in data including uncertainty), and the *importance of better data for better decision-making*. Issues identified during discussions included: maintaining focus on risk not hazard, inclusion of beneficial compounds (e.g. nutrients, bioactive compounds), applicability of TDS for different sub-groups, links between populations and substances of interest, analysis of composite dishes, water and with or without salt, speciation, pooling, sample storage, aggregation, spread, certified reference materials and suitability of FoodEx2 for TDS.

The majority of *participants were in favour of TDS*, but want them to offer value-for-money and sufficient flexibility to examine a wide range of substances, including nutrients and those with putative health benefits, and (potentially) other substances of interest in the future, using stored samples, and comparison between populations. Together, these needs provide insight into what *information participants are seeking from TDS and ensure the applicability of TDS-Exposure outputs*, especially data management systems and standards.

Acknowledgments

The organising committee would like to thank all the chairs, speakers and the rapporteurs for their outstanding work to ensure a successful workshop and also to all participants for the valuable contribution, the useful comments and the inspiring debate experienced throughout the workshop. The organising committee also wants to express its sincere gratitude to the experts involved in the development of this report.