

Fifth International Workshop on Total Diet Studies



13–14 May 2015
Seoul, Republic of Korea



Participants of the Fifth International Workshop on Total Diet Studies
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WORLD HEALTH ORGANIZATION
REGIONAL OFFICE FOR THE WESTERN PACIFIC

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MEETING REPORT

5TH INTERNATIONAL WORKSHOP ON TOTAL DIET STUDIES

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NOTE

The views expressed in this report are those of the participants of the 5th International Workshop on Total Diet Studies and do not necessarily reflect the policies of the conveners.

This report has been prepared by the World Health Organization Regional Office for the Western Pacific for Member States in the Region and for those who participated in the 5th International Workshop on Total Diet Studies in Seoul, Republic of Korea, from 13 to 14 May 2015.

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Keywords:

Diet / Diet survey / Data collection-methods / Food analysis –standards / Food contamination-analysis / Risk assessment

ABBREVIATIONS

CVs	coefficients of variation
DALYs	disability-adjusted life years
FAO	Food and Agriculture Organization of the United Nations
FERG	Foodborne Disease Epidemiology Reference Group (WHO)
GEMS	Global Environment Monitoring System
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
KHIDI	Korea Health Industry Development Institute
MFDS	Ministry of Food and Drug Safety
STDF	Standards and Trade Development Facility (WTO)
TDS	total diet studies
WHO	World Health Organization
WTO	World Trade Organization

SUMMARY

National food safety authorities have the responsibility to ensure that toxic chemicals, such as pesticides, heavy metals, environmental contaminants and naturally occurring toxins, are not present in food at levels that may adversely affect the health of consumers. When present at unacceptable levels, chemicals are known or suspected to be responsible for a range of chronic human health problems such as cancer, kidney and liver dysfunction and mental disorders.

For many years, WHO has supported the concept of total diet studies (TDS) as one of the most cost effective methods for assuring the dietary intake of chemicals is within safe limits. This workshop was organized to promote and assist countries to carry out scientifically reliable and comparable TDS to protect their populations from chemical hazards in the food supply and to facilitate trade in food.

A total of 89 participants from 17 countries attended the two-day workshop including technical experts, government representatives and researchers.

The workshop contributed to the promotion of TDS as a cost-effective method for strengthening food safety and encouraged countries, especially low-income countries, to explore opportunities for conducting TDS. The workshop also contributed to strengthening networks and partnerships among TDS experts and practitioners internationally, and harmonization of TDS approaches and methods across countries.

The participants recognized the importance of TDS to assess the safety and nutritional quality of diets and they agreed on a suggested list of core, intermediate and comprehensive chemicals including nutrients for inclusion in TDS.

1. INTRODUCTION

1.1 Background

The need for monitoring chemicals in the food supply is essential as consumers are unable to know what toxic chemicals and nutritional imbalances are posed by the foods they consume. When present at unacceptable levels, chemicals are currently known or suspected to be responsible for range of human health problems, including cancer, kidney and liver dysfunction, hormonal imbalance, immune system suppression, musculoskeletal disease, birth defects, premature births, impeded nervous and sensory system development, reproductive disorders, mental health problems, cardiovascular diseases, genitor-urinary disease, old-age dementia and learning disabilities. These conditions are prevalent in all countries, and to some extent such health problems can be attributed to past and current exposure to chemicals in foods. Consequently, the protection of our diets from these hazardous materials must be considered an essential public health function of any country. This is the main purpose of total diet studies (TDS).

Since the establishment of the Global Environment Monitoring System (GEMS) in 1976, the World Health Organization (WHO) has been responsible for implementing the monitoring and exposure assessment of potentially toxic chemicals in food under what is commonly called the GEMS/Food programme*. For many years, WHO has supported the concept of TDS as one of the most cost-effective methods for ensuring the dietary intake of chemicals is within safe limits and for setting priorities for further study. WHO in collaboration with national agencies engaged in TDS have sponsored four International Total Diet Study Workshops: the first in Kansas City in July 1999, the second in Brisbane in February 2002, the third in Paris in May 2004 and the fourth in Beijing in

* Global Environmental Monitoring System–Food Contamination Monitoring and Assessment Programme (GEMS/Food)

October 2006. The present workshop reflects the continued support by WHO and its Member States of the TDS approach, especially promotion of TDS in developing countries.

1.2 Workshop organization

The workshop was organized by Ministry of Food and Drug Safety (MFDS), the Korea Health Industry Development Institute (KHIDI) and the WHO Regional Office for the Western Pacific. The workshop was preceded by a half-day pre-workshop consultation between international experts in TDS and national representatives from approximately 10 countries wishing to promote or expand TDS in their countries.

The programme for the workshop is given in Annex 1. A total of 89 participants from 17 countries were present. A list of participants is given in Annex 2. The workshop included presentations and discussions concerning various aspects of conducting TDS, which resulted in conclusions and recommendations based on country experiences and international best practices. Presentations by selected participants covered TDS that are being planned or conducted around the world. Summaries of selected presentations are given in Annex 3.

The overall goal of the workshop was to promote and assist all countries to organize and carry out scientifically reliable and, where possible, comparable TDS to protect their populations from chemical hazards in the food supply and to facilitate trade in food.

1.3 Workshop objectives

The objectives of the workshop were:

- 1) to review and report on recent developments and results in the field of TDS;
- 2) to develop harmonized methodologies for TDS based on the latest science and best practices;
- 3) to promote the electronic exchange of TDS data to the Joint FAO/WHO Expert Committee on Food Additives (JECFA), Joint FAO/WHO Meeting on Pesticide Residues (JMPR) and GEMS/Food and other relevant bodies;
- 4) to develop strategies to mobilize support for TDS in all Member States;
- 5) to expand the network of national TDS practitioners; and
- 6) to provide recommendations to promote TDS in all Member States.

2. PROCEEDINGS

2.1 Opening session

Dr Hae Jung Yoon, Director, Food Contaminants Division, National Institute of Food and Drug Safety Evaluation, Ministry of Food and Drug Safety (MFDS), was elected as chairperson of the workshop. She was assisted by Dr Gerald Moy, Food Safety Consultants International, Geneva, Switzerland, who served as the rapporteur.

Dr Wang Jin-Ho, Director General, National Institute of Food and Drug Safety Evaluation, delivered opening remarks on behalf of the MFDS. He highlighted the importance of TDS and emphasized the Republic of Korea's commitment to use TDS to inform national policy and to support TDS at the international level. He appreciated the partnership with WHO and KHIDI in organizing the workshop and for the participants and TDS experts for contributing to the workshop.

Dr Jeong-seok Lee, Executive Director, KHIDI, delivered the welcome address in which he explained KHIDI's role as a government-affiliated institution that provides professional and systematic support to develop the domestic health industry and enhance health services in the Republic of Korea. He

appreciated the broad participation of national and international TDS experts and expressed his gratitude to MFDS and WHO for co-organizing the workshop.

On behalf of WHO, Mr Peter Sousa Hoejskov expressed his appreciation to MFDS and KHIDI for co-organizing the workshop with WHO. He noted the importance of TDS in guiding food safety policy and legislation and highlighted that much progress had been made by Member States in implementing TDS in developing countries.

2.2 Use of total diet studies to inform policy, standards development and trade

Discussion Leader: Peter Sousa Hoejskov

In an interconnected and globalized world with increased trade in food and agricultural products, food safety has become more important than ever. Countries need strong national food safety systems in order to protect consumer health and facilitate international food trade. Food safety measures must be based on scientific evidence which includes comprehensive dietary exposure assessments data. Total diet studies (TDS) provide information on a population's exposure to chemicals and nutrients in food and make up an important part of science-based risk assessments. TDS is one of the most cost-effective ways to ensure people are not exposed to unsafe levels of toxic chemicals through food. TDS provides important evidence for food control policy and food standards development as well as the establishment of tolerance limits for food contaminants and recommended daily allowance for priority nutrients. TDS also provides a basis for long-term monitoring of food contaminants and nutrition adequacy and a baseline in case of emergencies. Previous TDS workshops have highlighted the importance of harmonization of methodologies for TDS, while at the same time recognizing the need for TDS to reflect health concerns and resources of the country where they are conducted. WHO through its Global Environment Monitoring System – Food Contamination Monitoring and Assessment Programme (GEMS/Food) encourages countries to conduct TDS and provides technical support in line with regional and national priorities. Although the benefits of conducting TDS are clear, many developing countries are challenged by the costs associated with the studies and the technical and scientific capacity needed. Translating TDS results into appropriate and timely action is another challenge and an area where capacity-building is needed. Participants were encouraged to discuss initiatives to enhance high-level political support for countries to conduct TDS; options for capacity-building and resource mobilization in developing countries for them to conduct TDS; and actions needed to improve risk communication and use of TDS results to inform risk management options.

2.3 International status of total diet studies

Discussion leader: Robert Dabeka, Canada (with thanks to Gerald Moy, Richard Vannoort, Jiri Ruprich and Peter Sousa Hoejskov for developing the questionnaire).

1) Background

In 2011, a joint European Food Safety Authority (EFSA), Food and Agriculture Organization of the United Nations (FAO) and WHO survey indicated that approximately 33 countries in the world had conducted a TDS. To update this information, a questionnaire was sent out to countries through various channels to ascertain if they were conducting or planning to conduct a TDS. The purpose was to obtain an international snapshot on the status of TDS: how comprehensive were the studies in different countries; what chemicals were being measured; how many foods were being analysed; and other issues, such as funding. A presentation of the preliminary responses was delivered during the workshop, but since then more countries have submitted their questionnaires. This report includes information from submissions received after the workshop.

2) Responses to questionnaire

The questionnaire has now been completed by 25 countries.¹ Only Cameroon completed the questionnaire from countries that received funding from the World Trade Organization's Standards and Trade Development Facility (STDF). The STDF also supported regional TDS projects in the Caribbean and South America (Aruba, Chili, Columbia, Cuba, Dominican Republic, Jamaica, Nicaragua, Panama, Suriname, and Uruguay) as well as in Sub-Saharan Africa (Benin, Cameroon, Mali and Nigeria). The WHO Regional Office for the Eastern Mediterranean has funded TDS activities in four countries (Egypt, Kuwait, Lebanon and Tunisia). A number of countries are also known to be conducting a TDS did not respond to the questionnaire. This may be due to the questionnaire not being sent to the responsible person or because there was too little time for response.

3) Summary of status of TDS around the world

This survey, taken together with what is known from agencies funding TDS, has identified 20 more countries that are conducting TDS in addition to the 33 countries previously identified in the EFSA/FAO/WHO survey of 2011. Consequently, approximately 53 countries around the world are now conducting TDS. Some countries have been conducting TDS for many years. In this regard, the United States of America has been the most consistent by conducting a TDS at least once a year since 1961. Other countries, by design, have used a TDS cycle averaging at least once every three to four years. The interval has largely been governed by the need for regional information, the number and complexity of food composites, the selection of priority chemicals and the complexity and cost of their analysis, and the availability of experts to evaluate the information gathered, calculate dietary intakes and report the results.

The different chemicals and groups of chemicals reported analysed internationally are presented in Table 1 along with the number of countries analysing each chemical/group. The chemicals/groups most widely analysed are trace elements (for both nutritional and toxic levels) and pesticides. The chemicals of most interest to countries in their future TDS are listed in Table 2. These chemicals are in addition to those the countries have already analysed.

The need for regular financial support was expressed, not only by developing countries, but also by some developed countries. TDS are by nature expensive, including the costs of sampling, shipping, preparation of the foods as for consumption, the preparation of the composites and the analysis. For many of the chemicals/groups, the analytical methods require expensive analytical instrumentation and high-level expertise of the part of the analyst to achieve the sensitivity needed to measure the low concentrations of many contaminants. This means that selection of the priority chemicals for analysis TDS, to a great extent, is made within the limits of analytical capabilities and resources.

A critical issue regarding funding is that a TDS should not be seen as a one-off activity. To be fully cost-effective and beneficial, funding for all of the components of the study should be planned for the long term. The first TDS in the United States of America, the United Kingdom of Great Britain and Northern Ireland, and Canada limited the number of analytical samples to between 12 and 15 – one food composite for each food group, and some countries, such as the United Kingdom, still maintain this format because of resource limitations. Countries with larger numbers of composites to analyse, Australia for example, have reduced expenses by targeting different chemicals in each of their studies.

¹ The following countries completed the questionnaire: Australia, Belgium, Cameroon, Canada, China (four respondents), Hong Kong SAR (China), Macao SAR (China), Cyprus, Czech Republic, Finland, France, Germany, Iceland, Indonesia, Ireland, Italy, Japan, Republic of Korea, New Zealand, Poland, Sweden, Thailand, United Kingdom of Great Britain and Northern Ireland and United States of America.

Internal financial support was identified by all five countries that had not yet conducted a TDS. Most of these countries also noted the lack of external financing as well as the need for technical support.

Table 1. Chemicals/groups of chemicals included in total diet studies (number of countries)

Heavy metals (19)	Steroids (1)
Pesticide residues (18)	Phytoestrogens (1)
Polychlorinated biphenyls (11)	Alkylphenols (1)
Dioxins and dibenzofurans (11)	Ink photoinitiators (1)
Perchlorate (8)	Moisture (1)
Polybrominated diphenyl ethers (8)	Nitrate (1)
Mycotoxins (13)	Organo-tin (2)
Veterinary drug residues (8)	Iodine (4)
Phthalates (7)	Chloropropanol esters (1)
Bisphenol A (8)	Ethylcarbamate (2)
Additives/colours (9)	Fatty acids (2)
Acrylamide (10)	Melamine (1)
Mineral nutrients (16)	Furan (2)
Perfluorinated organics (3)	Polycyclic aromatic hydrocarbons (7)
Fluoride (2)	Heterocyclic amines (1)
Radionuclides (3)	Trans fatty acids (1)
Inorganic arsenic (3)	Aldehydes (1)
3-Monochloropropanediol (3)	Biogenic amines (1)
Sulfur dioxide (1)	Nitrosamine (1)
Hexabromocyclododecane (3)	Ethylene oxide (1)
Polybrominated biphenyls (1)	Benzene (1)
Tetrabromobisphenol A (2)	Trihalomethanes (1)
	Dichloropropanol (1)

Table 2. Chemicals of interest to countries for future total diet studies (number of countries)

Mycotoxins (2)	Bisphenol A (1)
Veterinary drug residues (3)	Phthalates (1)
Persistent organic pollutants (2)	Food additives (1)
3-Monochloropropanediol (1)	Allergens (1)
3-Monochloropropanediol esters (1)	Bio-active chemicals (2)
Chlorate (1)	Phenolic compounds (1)
New elements (3)	Nutrients (1)

Pre-workshop discussions indicated the need to better convey the enormous benefits from TDS. Trade benefits are slowly being recognized by the active funding of TDS by the WTO Standards and Trade Development Facility. Health benefits are being recognized by WHO through continued funding of TDS activities by WHO regional offices and support by WHO headquarters.

Participants elaborated on challenges they have faced in conducting TDS. While countries not conducting TDS reported their needs for both internal and external funding, some of those countries that already conduct TDS are, to varying degrees, also in need of additional resources to either expand the number of chemicals being analysed, improve their coverage of the food supply, or even to continue performing their TDS.

2.4 Total diet study planning

Discussion leaders: Oliver Lindtner, Matthias Greiner, Andreas Hensel, Germany

The joint working group of EFSA, WHO and FAO in 2011 defined two different TDS approaches. First, a simple TDS approach for screening purposes is most relevant when no data on concentration of harmful and beneficial substances in food exists in a country. Then the use of broad food groups and screening of a lot of chemical substances will facilitate prioritization for more detailed analyses. Second, a TDS approach for more detailed data collection enables refined exposure assessments. This presentation is given on the background of the experience in planning the first TDS, which was intended as a refined exposure assessment tool. Consequently, the presentation focused on this refined approach.

Planning is of vital importance for validity and interpretation of the outcome of a TDS. One crucial issue is the level of pooling that is applied in the TDS to keep it feasible and make it a cost-effective approach. A disadvantage of pooling is that statistical information will be limited to the mean concentration in the pooled foods. This could be partially overcome by using more than one pooled sample to describe some variability of interest, such as seasonal or regional variations. However, in planning a TDS, various sources of variability are of interest. Decisions whether different sources of variations will be averaged or distinguished within TDS are illustrated using bread as an example. If differences in concentrations of a substance can be expected among different types of bread, for example due to different cereals, it has to be checked whether appropriate consumption information on intake quantities of the respective type of bread is available in the population. In those cases in which it is, different pooled samples for types of bread are needed to avoid overestimation or underestimation of exposure for consumers with specific preferences and also to allow a correct weighted exposure estimate for the whole population. The same principle applies if concentration in food varies between brands. Different pooled samples for brands will enable consideration of brand loyalty in exposure assessment, while pooling of different brands will lead to an underestimation for consumers loyal to a brand with concentrations above mean concentration.

In planning of a TDS, it is important to consider available consumption data. The European TDS-Exposure (www.tds-exposure-eu) project has recommended as minimum standard that data for children and different age groups should be used to define the TDS food list. Additional information from other sources may be required to account for seasonal and regional consumption, applied kitchen procedures or preferences for organic products if such information is not available from the food consumption survey. In organizing a shopping list that ensures representative sampling from the market, information on market share for food groups and retailers will be of importance. Further information is needed, for example regarding the use of kitchen utensils as they can be an additional source of exposure.

In the European TDS-Exposure project, 12 subsamples were considered to be a statistically and pragmatically derived number. This can be read off from tables summarizing calculations of precision of mean estimates that can be reached depending on mean-variation-ratio and sample-size. However, besides statistical precision (i.e. the width of confidence intervals), the representativeness of the sample has to be considered. For example, for a number of 12 samples, the minimum market share that can be covered within the representative sampling is 8%. A larger number of subsamples is required if the type of foods or food preparation methods with a lower market share are to be considered.

Besides the consumption data, the availability of concentration data has an impact on TDS design. The Germany food monitoring programme is an example for a very comprehensive and representative source of concentration data. The knowledge of concentration data has an influence on prioritization of substances to be considered in TDS, as well as on the level of pooling to avoid pooling of foods with very different concentrations of substances. In Germany, two main areas were identified, where the TDS results are expected to fill important knowledge gaps. The first is to lower uncertainty in assessment of environmental contaminants, such as cadmium and lead that result in exposure levels

around the health-based guidance values as currently assessed using food monitoring data. The second relates to substances, which are not at all covered in the food monitoring programme, like processing contaminants, food additives and substances migrating from packaging material.

To consider the specific needs of each substance group for the first German TDS, a modular approach has been chosen. This means that for environmental contaminants, elements and others, a core module with a core food list will be derived in a first step. For each module of another substance group this food list will be modified. The required modification may be small, like for nutrients or mycotoxins, or quite substantial as in the case for food additives that will require a very different food list. For food additives that occur also naturally (e.g. aluminum), there is also a big overlap to the food list of the core module. But, for food additives that were only used as such, more substantial modification of the food list is needed. This is motivated to avoid dilution effects, to consider brand loyalty, or preferences to specific tastes and colors and to consider specific conditions of authorization of respective food additives. On the other hand, regional and seasonal variations considered in the core food list will be negligible for these food additives.

Another important consideration is the software to be used to document the TDS samples and to assess exposure. Two existing tools, FoodCaseRisk (<https://globis.ethz.ch/#!/project/tds-exposure/>) and MCRA (<https://mcra.rivm.nl>) will be adapted in the European TDS-Exposure project by ETHZ² and RIVM³ to specific needs of a TDS and new versions will be available from 2016.

Logistics should also be carefully planned considering all amounts of food and homogenized samples to be transported and stored at different temperatures within the TDS project.

The joint working group of EFSA, WHO and FAO in 2011 drafted a three-year schedule for a TDS. Based on the experience from the German TDS as an example of a country embarking on its first TDS as refined data collection for exposure assessment, at least the planning phase needs to be longer than six months. The support from an advisory board with international eminent experts provides access of extensive experience and ensures harmonization with and joint development of the international TDS best practice.

2.5 Total diet studies in the Republic of Korea

Discussion Leader: Hae Jung Yoon, Republic of Korea

The Republic of Korea has been conducting TDS on heavy metals, pesticides and aflatoxins since 2000. The Korean TDS is divided into four steps – namely, planning, implementation, exposure assessment, and report and announcement – and is conducted over a three-year period. A single meal in the Republic of Korea is comprised of more than five dishes that are prepared by cooking a variety of food commodities together. The TDS is conducted at a commodity level and not at a composite-form level. Upon carrying out the TDS master plan, persistent organic pollutants, and toxic chemicals unintentionally produced during food processing had been included in Korean TDS. Additionally, the target food commodities were expanded from 114 items in 2009 to 186 items in 2014. The Korea National Health and Nutrition Examination Survey (KNHANES) reported that Koreans have eaten more or less 734 food commodities, but only the most frequently and highly consumed 358 commodities were selected to be included in the TDS food list. Those commodities not selected considered later through mapping when exposures estimated to give the consumer intake. For analysis, the purchased food items were pooled for preparation in the consumed form. The prepared samples were then grouped together based on physical status (non-fatty solid, non-fatty liquid, fatty solid, and fatty liquid) and their target chemicals were analysed by the method validated by using four representative matrices (rice, apple juice, butter, and corn oil). The individual exposures had been estimated by combining the individual intake level and the concentration of their target chemical and

² Eidgenössische Technische Hochschule Zürich

³ National Institute for Public Health and the Environment in the Netherlands

aggregate these to form distributions of total population exposure that should be more realistic assessments of exposure.

2.6 Food consumption surveys

Discussion leader: Judi Spungen, United States of America

Good-quality, nationally representative data on types and quantities of foods consumed in a country are essential for developing an appropriate TDS food list and for accurate estimation of chemical exposures using TDS analytical data. Data from food balance sheets or GEMS/Food Regional Diets, which are available for all countries, can be transformed and used to develop food lists and to estimate per capita chemical exposures. Data from household budget surveys, available for most countries, can also be transformed for use in a TDS programme. Data from recent, nationally representative food consumption surveys of individuals are considered ideal because they can be used to estimate acute exposures, chronic exposures, exposures by subpopulations and exposures by high-end users. However, in planning for use of individual food consumption survey data in selecting TDS foods and in estimating chemical exposures using TDS analytical data, decisions must be made on how to handle food mixtures, generically described foods, inconsistently reported foods, and under-reporting of foods. Workshop participants may want to discuss the design, methodology, use, benefits, under- and over-reporting, limitations of various food consumption approaches, including food balance sheet data, GEMS/Food Regional Diets and food consumption surveys of individuals, such as diet history, food frequency, 24-hour recalls, food diaries/records and duplicate plate studies. Ingredient and recipe approaches are also important issues and may be addressed by developing a recipe database.

2.7 TDS food and sample list: towards harmonization

Discussion leader: Jiri Ruprich, Czech Republic

Practical steps in implementation of TDS studies in any country or region have to start with desk research oriented towards the collection and elaboration of relevant information needed to design basic components of TDS. One of the first steps is development of a TDS food list defining the most consumed foods for a particular area or population of interest for chemical substances of interest, including other legitimate factors. Quality and complexity of food consumption data are limiting factors for designing of a TDS. The same importance applies to the format of collected data and its standardization allowing harmonization and comparison of TDS results. The key element in this respect is a standardized food classification system, like European Union system *FoodEx2*. This hierarchic and descriptive food-classification system serves also as a guide for decisions concerning which foods may be pooled into simple (individual) specific TDS samples. It allows usage of the same food codes and names for each particular pooled TDS sample in various countries or regions. Experimental work revealed that a specific TDS food list is needed for at least two populations of interest – small children (0–3 years) and others (4 years and older). Selection of staple foods according to the relevant criteria is the first step in creation of TDS food list, followed by combining into food group subsets. This process is still based on both the evidence and eminence approach due to the fact that food consumption data are extremely complicated in their structure and format. Experience and knowledge of all parameters related to food consumption data used for development of a TDS food/sample list is one of the most limiting factors for the quality of TDS results. During the European Union project TDS-Expose, new TDS food/sample lists were created in five piloting countries with a target to harmonize approaches. Harmonization efforts were based on usage of the *FoodEx2* food-classification system in the first step nationally, followed by balancing of selected staple foods within each of 20 basic food groups and finally balancing of number of pooled TDS samples between food groups internationally. Independent quality check (validation of representativeness) has been based on comparison of energy intake/energy expenditure for expected level of physical activity in studied population groups for which TDS have been designed.

2.8 Sample collection and preparation

Discussion leader: Cho-il Kim, Republic of Korea

Once the food list for collection is determined, a plan for food sample collection should be made in such way that the representativeness of the samples can be maximized. While food surveillance and monitoring programmes need to consider sampling at certain areas of probable high contamination, sampling for TDS needs to focus on obtaining the average sample. In addition to this, selecting preparation methods for food samples also needs to reflect common and usual average methods used by the population of interest. Hence, it is desirable to use most recent national food (at prepared dish level) intake data in extracting appropriate preparation methods for TDS food list. The workshop may want to discuss various aspects of sample collection, including collection sites, logistics from store to central lab, and purchases among different brands. In regard to preparation, the workshop might discuss procedures to determine preparation methods, data used in determining preparation methods, equipment and utensils for preparation, personnel for preparation, and storage and logistics for prepared samples to laboratories.

2.9 Establishing priority chemicals for total diet studies

Discussion leader: Gerald Moy, Switzerland

The highly sensitive analyses of chemicals are one of the most expensive elements of a TDS. To stay within the available budget, prioritization of chemicals is always necessary. The 2011 EFSA/FAO/WHO document on harmonization did not include a list of priority chemicals, but offered criteria for selecting chemicals, including health data, recognized risks, chemicals with unknown exposures, budget issues, and political or socioeconomic reasons. ANSES in France has taken this a step further and developed an algorithm for ranking priority chemicals. In 2002, the 2nd WHO GEMS/Food international workshop in Brisbane developed three TDS priority lists for chemicals, namely core, intermediate and comprehensive, including the foods in which they are typically found. At the 4th international workshop in Beijing in 2006, a list of priority chemicals for TDS was also developed including the “usual limits of determination”. However, the latter was never completed. This workshop may want to discuss, revise or recommend core, intermediate and comprehensive lists of TDS chemicals from 2002, the need for a list of usual limits of determination for methods of analysis for TSD chemicals and a list of criteria for prioritizing chemicals.

2.10 Analytical methods

Discussion leader: Mark Wirtz, United States of America

The laboratory and the analytical methods have to be selected with greatest care to ensure high-quality analytical data in order to perform a relatively accurate dietary exposure assessment. In general, the analytical requirements for TDS are similar to food surveillance and monitoring programmes (e.g. quality assurance, laboratory and method performance) but TDS call for lower LOD/LOQ and extra difficulties because of the complex and varied food matrices. This was discussed in the joint EFSA, FAO and WHO document *Towards a Harmonized Total Diet Study Approach: A Guidance Document*. This workshop may want to discuss issues such as traditional and emerging TDS analytes, regional vs national priorities, contract analytical laboratories, laboratory QA/QC, limits of detection/quantification, scope of analytes to methods, multi Residue Methods versus Selective Residue Methods, trends – extraction simple and fast (technician) /determination, extremely complex (high-education) determinations, such as High Resolution Mass Spectrometry (HRMS), GC-QQQ and LC-QQQ and ICP-MS and library screening vs standard calibration.

2.11 Exposure assessment in a total diet study

Discussion Leader: Melva Chen, Hong Kong SAR (China)

Dietary exposure assessment is an essential part of the risk assessment process. The previous international TDS workshops concluded that exposure to chemical contaminants should be estimated using a step by step approach in countries, including TDS; beside the adult population, it is critical to estimate dietary intakes for infants and children; dietary exposures can vary widely depending on how

results below LOD are handled and it should be clearly described; and both average and upper percentile exposures of chemicals for each target population group should be obtained. Other than these previously concluded principles, the 2011 EFSA/FAO/WHO document on harmonization have made recommendations on exposure assessment for TDS. This workshop may want to discuss some of these recommendations such as, the lower- and upper-bound approach for handling results below LOD/LOQ, adjusting potential bias in population coverage in the consumption survey when calculating mean or percentile results, methods for estimating dietary exposure and specific statistical methods to narrow the distribution when applicable.

2.12 Total diet studies – risk communication

Discussion leader: Nick Fletcher, Australia

Risk communication is one of the three components that constitute the process of food safety risk analysis. In 2002, the 2nd WHO GEMS workshop in Brisbane recognized that there was a risk that information on concentrations of chemicals in foods and dietary intake could be misinterpreted by the public, and that this may discourage the public from eating foods that are nutritionally beneficial. A number of principles were proposed for reporting TDS, including that the results should be fully and openly reported with a focus on risk rather than hazard, and that the report be presented in a format that is easily understandable to the public. At the 4th international workshop in 2006, it was noted that consultation should occur early during the design of TDS and the public should be kept informed about the best management practices to minimize risks. The joint guidance of EFSA, FAO and WHO published in 2011 provides further guidance on TDS report preparation and communication of results, including the need for transparency and the presentation of full methodologies, assumptions, limitations and an assessment of uncertainties. The workshop may want to discuss actions to improve reporting and risk communication of TDS, including reporting analytical results, quality-assurance and quality-control measures, and describing the sources and types of uncertainties associated the dietary exposure assessment and how that impacts other parts of the risk assessment.

2.13 EU TDS-exposure project: organization and main objectives

Discussion leader: Jiri Ruprich, Czech Republic

TDS-Exposure project (Pan-European Total Diet Study; KBBE.2011.2.4-02; Project Number: 289108) is financed from the 7th Framework programme on research in European Union. The project started 1 February 2012 with a duration of 48 months.

TDS allow getting information on real dietary exposure to food contaminant consumption (such as heavy metals, processing contaminants, persistent organic pollutants) and estimating chronic exposure to pesticide residues in food and food additive intake. TDS consider total exposure from the whole diet and are based on food as consumed rather than contamination in raw commodities, thus ensuring a realistic exposure measure. TDS facilitate risk assessment (RA) and health monitoring (HM). Some European Union (EU) Member States and Candidate Countries (CC) have no TDS programme or use various methods to collect data, some of which have not yet been examined to tell whether they are comparable or not. This is of interest for EFSA and to WHO–FAO risk assessment bodies. Similarly it is important to harmonize methods to assess dietary exposure risks in Member States, CC and at the European level to compare with other world regions.

The methods proposed will aim for food sampling, standard analytical procedures, exposure assessment modelling, priority foods and selected chemical contaminants consistency across MS and CC. Various approaches and methods to identify sampling and analyses will be assessed and best practices defined. Contaminants and foods which contribute most to total exposure in European populations will be defined. Priority will be given to training and support in the EU, Member States and CC currently without TDS. It will demonstrate best practices in creating a TDS programme using harmonized methods in regions previously lacking TDS, and ensure consistency of data collected. A database will be set up describing existing EU studies and collating harmonized exposure measures and designed to allow risk assessors and managers handling dietary exposure more accurately and

more specifically. TDS-Exposure will spread competence in TDS throughout stakeholders and establish a legacy of harmonized methods for sampling and analysis, and science-based recommendations for future global studies.

2.14 EU TDS-exposure project: exposure modelling

Discussion leader: Jacob van Klaveren, Netherlands

TDS-Exposure project (Pan-European Total Diet Study; KBBE.2011.2.4-02; Project Number: 289108) is financed from the 7th Framework programme for research in the European Union. TDS consider total exposure from whole diets and are based on contamination of food as consumed rather than contamination from raw commodities, thus ensuring a realistic exposure measure. Within the EU TDS project, the exposure assessment approach is harmonized among the European countries that performed a TDS study at the national level and the countries setting up new TDS studies. The consortium partners were trained on how to organize their TDS data and how to use their TDS data in refined exposure assessments using the Monte Carlo Risk Assessment (MCRA) software. The MCRA software is a model platform including several probabilistic models for cumulative and aggregate exposure to pesticides and models for estimating the usual exposure over a lifelong exposure period.

Although a TDS study has advantages over other approaches, it also includes uncertainties: the number of subsamples taken, the extent of pooling foods together before analysing, and how the sampling plan accounts for regional and seasonal variation are major uncertainties. The consortium partners collected additional information on seasonal, regional and annual variation from their national monitoring programmes and they expressed the variation in the monitoring data as coefficients of variation (CVs). A new TDS exposure assessment model was programmed. The model combined the mean concentration of each food item from a TDS database and a CV derived from the monitoring data, and the team applied the model to several chemicals.

The risk assessor can use the new model to study the effect of the uncertainties on the exposure levels, in cases the real variation for a chemical is not well covered by the TDS sampling design. Furthermore, the new MCRA model offers possibilities for risk managers, e.g. the Codex Alimentarius or the European Commission, to study the impact of setting residue limits aimed at reducing exposure levels in cases where the exposure levels exceed the health-based guidance value. Other project details are available at the project web page: <http://tds-exposure.eu>. Information about the MCRA software is available at <https://mcra.rivm.nl>

2.15 Total diet studies in the United Kingdom of Great Britain and Northern Ireland

Discussion leader: Rufina Acheampong, United Kingdom of Great Britain and Northern Ireland

Unlike most countries, the United Kingdom food lists are not derived directly from its national food consumption data. The food lists are derived from a population-based family food survey; however the consumption data used for exposure assessments are derived from the United Kingdom National Diet and Nutrition Survey (based on individual food diaries). Recent changes to the design of the TDS aimed at harmonizing the underlying data and improving the transparency of the methods were described and its accompanying challenges highlighted. The results of recent TDS were also highlighted. The 2014 TDS analytical results of (i) metals and other elements; (ii) mycotoxins; and (iii) acrylamide in food are undergoing quality control and exposure assessments will be published in due course.

2.16 The fourth total diet study in China

Discussion leader: Xiaowei Li, China

China's fourth TDS was conducted in 2007. The dietary intakes of nutrient elements, heavy metals, harmful elements, organochlorine pesticides, pyrethroid pesticides, organophosphorus pesticides, carbamate pesticides, triazine pesticides, veterinary drugs (including clenbuterol and ractopamine), chloropropanols, acrylamide, persistent organic pollutants, mycotoxins, melamine and its analogues from China's fourth TDS were presented.

2.17 The Total diet studies in Thailand

Discussion leader: Thongsuk Payanun, Thailand

Thailand, as one of the world's major exporters of food, gives priority to the risk assessment activities which correspond to worldwide protocols. Concerns for food safety, focus on Thai people, and importer's populations around the world. The Department of Medical Sciences in the Ministry of Public Health – a government food testing laboratory – has conducted the exposure study of toxic substances in the Thai diet since 1980. At the beginning, a duplicate portion approach was employed. However, the study results were not suitable for real-life situations because the daily food intake amounts in three meals for one person were totally combined, which lead to the dilution of pesticide residue levels and the analytical limitations from the high content of lipids in food samples. From 1986, a TDS approach using composites has been used because it offered greater accuracy of data when assessing actual levels of toxic substances in food. The exposure data of pesticide residues, veterinary drug residues and toxic metals by Thais were compared to WHO's health-based guidance values, such as the ADI and PTWI, to assess safety of consumers. The annual reports are used by Thai Food and Drug Administration to determine the suitable of regulatory limits under the Thai Food Act. These TDS continually progressed through 2009 during which one TDS was conducted annually. From 2010 to 2012, the survey was performed every two years because of the tendency of results to be quite similar. The project was temporarily interrupted in 2013 due to budget limitations. However, funding for TDS has resumed and a TDS will be conducted again in 2016.

2.18 Indonesia total diet studies

Discussion leader: Nelis Imanningsih, Indonesia

The dietary intake of both nutrients and chemical contaminants can be used to characterize whether the population has adequate nutrition intake (too little or too much) and whether exposure to chemicals is at a safe level. A TDS is a cost-effective public health tool. Indonesia initiated its national TDS in 2014 and it was planned for two years. During the first year, Indonesia conducted the Individual Food Consumption Survey that covered 46 240 households with 162 041 individuals and a pilot project that was conducted in one province (Yogyakarta Province) before conducting national TDS in 2015.

From the individual food consumption survey, food consumption by food group and by age group was obtained as well as data of nutrient intake and adequacy, and more specific on sugar, sodium and fat consumption. From this data, a food list with 100 foods was generated. The food will then be sampled, prepared using the basic cooking process, homogenized and analysed in laboratory for selected pesticides, heavy metals, mycotoxins and food additives. The nutrient intakes and chemical exposures will be assessed. For the national TDS, one more chemical group has been added which is nutrient minerals. The Indonesian TDS hopefully will provide a valuable evidence base to develop, renew or amend relevant food standards and health policies.

Sample delivery may be one of challenges in conducting a national TDS in Indonesia due to geographical distance that separates the many islands of the country. Therefore the QC needs to take into account every step of sample handling. The variability of the sample is very high because of sources, land, agriculture practice, etc. The dilution of chemical content is likely to happen. Therefore, in the future, the TDS needs to be a more refined TDS by region. The Indonesian TDS consumption data is complete enough, but needs further analysis for specific groups or populations, such as gender or children under 5 years. In addition, the laboratory capability needs to be expanded, the methods of analysis need to have lower limits of quantification, and the laboratory needs to cooperate with regional referral laboratories to confirm the analytical results.

2.19 Use of total diet studies in risk management in Japan

Discussion leader: Toyohiro Egawa, Japan

TDS have been carried out over 30 years in Japan for estimating dietary intake of chemicals. The Ministry of Agriculture, Forestry and Fisheries developed the guideline for conducting TDS in 2007 to ensure consistency.

TDS are usually conducted as a cost-effective screening tool to estimate whether the dietary intake of a target chemical is sufficiently low compared with its health-based guidance value, e.g. PTDI/PTWI or ADI, and to determine if there is any health concern based on sound science. The results of TDS are used to prioritize chemicals for risk management, identification of major food groups contributing to dietary intake of the chemical, and understanding the annual variation of average dietary intake of chemicals.

While TDS are easy and not costly or time-consuming, they cannot provide information about distribution of dietary intakes of chemicals by population. For this reason, while estimated intake of a chemical from the TDS is lower than its health-based guidance value, it is possible that the dietary intake of that chemical constitutes health concern for certain populations in reality. To confirm dietary intake of a chemical is of no health concern, concentrations of the chemical in individual foods belonging to the major food groups contributing to dietary intake of the chemical should be analysed. A risk management decision should more appropriately be based on the results of the surveillance of individual foods.

2.20 Discussion session

Various topics were presented by participants over the course of the workshop. Summaries of many of these are presented in Annex 3. As there are many aspects of TDS, the discussions ranged over a wide variety of topics. One topic of general interest was the survey of the status of TDS around the world that was undertaken before the workshop. Participants further elaborated on some of the challenges they faced in conducting TDS.

While countries not conducting TDS reported their needs for both internal and external funding, some of those countries which already conduct TDS are, to varying degrees, also in need of more additional resources to either expand the number of chemicals being analysed, improve their coverage of the food supply, or even to continue performing their TDS altogether.

Pre-workshop discussions indicated the need to better convey the enormous benefits from TDS. Trade benefits are slowly being recognized by the active funding of TDS by the World Trade Organization (WTO) Standards and Trade Development Facility. Health benefits are being recognized by WHO through continued funding of TDS activities by WHO regional offices and support by WHO headquarters.

It was noted that the economic cost of exposure to chemicals was expected to total hundreds of billions of dollars each year. These costs of disease and illness are usually estimated by economists specialized in the field of morbidity and mortality, and calculating and reporting these costs have been instrumental in guiding health authorities to allocate resources where they provide the most benefit. While few and far between, calculations of this type have been done for lead, and the benefits of removing lead from gasoline in the USA United States of America resulted in lowering morbidity and mortality and cost savings of hundreds of billions of dollars annually. Similar savings were achieved by eliminating lead-soldered cans for storing foods.

China, as a result of identifying dietary lead exposure as an issue in their its first total diet study, followed up on this problem in subsequent TDSs. For the first time, an overall reduction in dietary lead exposure was reported in their China's last TDS. In terms of benefits to society, this translates to

fewer people with high blood pressure and related heart disease, as well as higher IQs of the overall population, which means more people with genius IQs, and fewer people requiring mental care support. The overall contribution to productivity is expected to be significant.

The New Zealand TDS avoided a health catastrophe with enormous economic implications by identifying iodine deficiency in the population, which could have resulted in permanent neurological damage to infants. As a result, the situation was corrected with fortification. Their The New Zealand study also identified and helped eliminate the sale of food products containing corn flour contaminated with high levels of lead.

In the Republic of Korea, their TDS identified for the first time the creation of acrylamide, a suspected human carcinogen, by heating pepper. This discovery may explain why previous attempts to statistically correlate acrylamide exposure with the incidence of cancer were unsuccessful. Correlations of this type are extremely difficult because many chemical carcinogens, both natural and human-made, are present in the diet and it is difficult to isolate the effects of one of them from the others. On the other hand, this information is valuable to the food industry and to individual consumers seeking to reduce acrylamide levels in food.

These are just some examples of the enormous economic and health benefits resulting from national total diet studies. It is likely that the real and potential benefits of a TDS exceed by hundreds of times the cost of conducting the study, and this is one of the fundamental reasons for continuing to promote and conduct TDS worldwide.

However, these examples still do not fully convey the global health and economic benefits offered by TDS, and a more quantitative assessment must await the results of global estimates of the disability-adjusted life years (DALYs) for certain chemicals in food that are being conducted by the WHO Foodborne Disease Epidemiology Reference Group (FERG).

One particularly important topic in the planning of a TDS is the selection of priority chemicals for inclusion in the TDS. The highly sensitive analysis of chemicals in food samples is one of the most expensive elements of a TDS. To stay within the available budget, prioritization of chemicals is always necessary. During the discussion, the workshop agreed to develop a list of criteria that might be considered when establishing chemical priorities for a TDS (see Annex 4). The workshop agreed to further develop three lists of suggested priority chemicals (core, intermediate and comprehensive) moving from a screening TDS to a refined assessment TDS (see Annex 5). These lists were originally developed at the TDS workshop in Kansas City and last updated in 2002. In addition, the workshop agreed to develop a list of characteristics of analytical methods, including the sensitivity of the method and instrumentation used (see Annex 6). In addition, Professor Juri Ruprich of the Czech National Institute of Public Health offered to make available to TDS practitioners a tool that he uses to automatically predict the required sensitivity of an analytical method to give measurable results for a given contaminant based on its health-based guidance value and consumption pattern. This is now available at totaldietstudies.org. Although it was recognized that the situation and history of TDS in countries were quite different, these considerations would be useful in the selection of priorities, particularly for countries that are planning their first TDS.

2.21 Closing

Dr Yoon, Chairperson, congratulated the participants on a very successful and productive workshop and noted that this was a joint effort by both experienced TDS practitioners and those in the initial stages of conducting a TDS. She thanked the participants of the workshop for their hard work, and hoped that everyone had enjoyed their visit to Seoul.

On behalf of WHO, Mr Hoejskov thanked the participants for their enthusiasm and contributions throughout the workshop. In recognizing the excellent local arrangements, he acknowledged the efforts of Dr Yoon and her staff at the National Institute for Food and Safety Evaluation and

Dr Cho-il Kim, Director General, Bureau of Health Industry Promotion, KHIDI, and her staff in making the workshop run smoothly and pleasantly. He stated how gratifying it is to see the tremendous progress in TDS. He emphasized that without TDS, it is difficult for countries to protect public health and to prioritize food safety efforts.

3. CONCLUSIONS AND RECOMMENDATIONS

The workshop achieved its objectives of promoting and assisting all countries in organizing and carrying out TDSs. The workshop contributed to strengthening the network and partnership among TDS experts and practitioners across the globe and to working towards greater harmonization of TDS approaches and methods.

At the end of the workshop, participants adopted the following recommendations:

- 1) All countries are encouraged to conduct TDS to assess the safety and nutritional quality of the diets of their populations.
- 2) Countries may want to expand their TDS to address gaps in their current studies as well as emerging food safety and nutritional issues.
- 3) All countries, but in particular low-income countries, are encouraged to explore opportunities for capacity-building as well as both short- and long-term financial and technical support to conduct TDS. This should include regional and/or international support through such agencies and instruments as the WTO's Standards and Trade Development Facility (STDF), the World Bank's Global Food Safety Partnership, the European Union's TDS-Exposure project, Asia-Pacific Economic Cooperation's Food Safety Cooperation Forum, the Association of Southeast Asian Nations Food Safety Network, the Joint International Atomic Energy Agency/Food and Agriculture Organization of the United Nations Division of Nuclear Techniques in Food and Agriculture, the International Life Sciences Institute, and WHO collaborating centres for food contamination monitoring.
- 4) Countries should use existing training courses and resources, such as the European Union-supported Summer School for TDS and those sponsored by national governments, including the Dutch National Institute for Health and the Environment's software for exposure assessment and Monte Carlo Risk Assessment tool, as well as hands-on experience and other transfers of TDS expertise among countries.
- 5) Countries are encouraged to use a harmonized and regional approach, whenever possible, when conducting TDS.
- 6) Countries should improve and/or develop detailed, transparent and regionally harmonized food classification and description systems that should be the basis for conducting their TDS.
- 7) In planning of their TDS, countries are encouraged to refer to the criteria for developing lists of priority chemicals and nutrients and to consider the suggested lists of TDS chemicals developed by the workshop. Countries may also wish to refer to the list of typical limits of determination of analytical methods needed to achieve measured results for various chemicals that was prepared by the workshop.
- 8) Countries are encouraged to actively use the GEMS/Food databases, as well as the GEMS/Food Cluster Diets (in the absence of their own food consumption data), and contribute data to GEMS/Food databases using the established reporting format.
- 9) Based on best practices in risk communication, all countries are strongly encouraged to communicate TDS results in a transparent, timely and easy-to-understand manner to all stakeholders.
- 10) WHO collaborating centres for food contamination monitoring are encouraged to strengthen their role in supporting low-income countries in the conduct of TDS through capacity-building, resource mobilization and provision of technical expertise.

11) Future international TDS workshops should be organized periodically with the purpose to share experiences and best practices in TDS. It is also recommended that future TDS training courses should be held with a particular focus on building TDS capacity in low-income countries. Workshops and training courses may be sponsored jointly by WHO, WHO collaborating centres, other international and regional organizations, and national agencies with experience in conducting TDS.

ANNEXES

Annex 1. Programme for the 5th International Workshop on Total Diet Studies

Day 1: 13 May 2015		
09:30–10:00	Welcome /Opening Ceremony	MFDS, KHIDI and WHO
10:00–10:30	Introduction: Aims and objectives of the workshop	Sae Jung Suh, Republic of Korea
Session 1: Background and Current Status		
10:30–11:00	Use of total diet studies (TDS) to inform policy, standards development and trade Summary of national TDS (ongoing and planned) and international TDS initiatives Planning a TDS	Peter Sousa Hoejskov, WHO Robert Dabeka, Canada Oliver Lindtner, Germany
11:00–11:30		
11:30–12:00		
12:00–12:30	Republic of Korea TDS	Hae Jung Yoon, MFDS
12:30–13:30	Lunch Break	
Session 2: TDS Design and Methodology		
13:30–15:30	Food consumption survey TDS food and sample list towards harmonization Sample collection and preparation Establishing priority chemicals	Judith Spungen, United States of America Juri Ruprich, Czech Republic Cho-il Kim, Republic of Korea Gerald Moy, Switzerland
15:30–15:50	Coffee break	
15:50–17:50	Analytical Methods Quality Assurance, SOPs and LODs Exposure Assessment Reporting /Risk communication	Mark Wirtz, United States of America Gae-Ho Lee, Republic of Korea Melva Chen, Hong Kong SAR (China) Nick Fletcher, Australia
17:50	Wrap up for the first day	
Day 2: 14 May 2015		
Session 3: New and significant TDS results		
08:30–9:30	EU TDS-Exposure project Risk assessment MCRA Software	Juri Ruprich, Czech Republic Jacob van Klaveren, Netherlands
9:30–9:50	Coffee break	
9:50–12:00	United Kingdom TDS China TDS Indonesia TDS Thailand Total TDS Viet Nam TDS	Rufina Acheampong, United Kingdom of Great Britain and Northern Ireland Xiawei Li, China Nelis Imanningsih, Indonesia Thongsuk Payanun, Thailand Trung Cao, Viet Nam
12:00–13:00	Lunch break	
Session 4: Promoting excellence of TDS		
13:00–15:00	Group discussion	Participants
15:00–15:20	Coffee break	
16:20–16:00	Conclusions and recommendations (adoption)	Peter Sousa Hoejskov, WHO
16:00	Closure	

Annex 2. List of participants

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Annex 3. Criteria for prioritizing chemicals

(not necessarily in order of importance)

Results of TDS in other countries: If another country has included the chemical in its total diet study (TDS), consideration should be given to the chemical, particularly if the results raised health concerns. To a great extent, this has been captured in the guidance provided from the lists of core (screening), intermediate and comprehensive (refined assessment) priority chemicals that should be considered for inclusion in a total diet study. These lists were reviewed and updated at the 5th International TDS Workshop in Seoul and should also be available shortly.

Risk characterization: When mean exposure of a chemical approaches exceeds 30% of health-based guidance value or has a margin of exposure of less than 100, for genotoxic and carcinogenic chemicals less than 10 000, estimated by international or national risk assessment bodies, the chemical should be considered for inclusion in a TDS.

Existing regulatory programmes or mitigation measures: Chemicals which have regulatory limits (MRL, ML, action levels, or guideline levels) and subject to compliance should be considered for inclusion to confirm that intervention measures are effective in maintaining exposure at safe levels. If such limits are often exceeded, the chemical should also be considered for inclusion in the TDS. This may include food additives, pesticides, veterinary drugs and certain contaminants.

Chemicals which have mitigation measures – code of practice (COP) – to reduce concentration in food are effective in reducing exposure levels. This may include certain process contaminants.

Chemicals likely to be present in the food supply: Chemicals that have been reported to be present in the food supply should be considered. Such data can be from production/importation statistics, marketing information, research and poisoning outbreaks.

Nutrients essential for health and other nutrients: Information on deficiencies and toxicity and/or adverse effect should be considered for these chemicals.

Severity of adverse effect: The chemical can cause death, severe or debilitating illness, irreversible effect, etc. at likely exposure levels.

Vulnerable groups: The adverse effects are borne by the fetus, infants, children, pregnant women or other vulnerable groups.

Existence of method of analysis at the required sensitivity of method: This is an important consideration and requires that the sensitivity of the method be estimated because this will determine the method, instrumentation and cost per analysis. Validated method should be used, otherwise validation of method should be done before analysing samples.

Homogeneity of chemical in the food supply: If sampling cannot overcome heterogeneity caused by seasonal, geographical or intrinsic heterogeneity (e.g. mycotoxins), a modified assessment approach should be considered.

Chemicals subject to an international convention: The Stockholm Convention on Persistent Organic Pollutants (POPs) was ratified by countries to eliminate or reduce the emission of POPs which have been associated with harm to health and/or the environment. Because of their lipophilic nature, these chemicals biomagnify in the food chain and fatty foods are the main route of human exposure. The convention has provisions for effectiveness assessment and level of POPs in human milk is used for this purpose. Currently, the Convention includes 21 POPs, many of which are considered by applying relevant criteria. Similarly, chemicals included in the Rotterdam Convention on banned or severely restricted chemicals should be considered for inclusion in a TDS, especially if a

country has agreed to import them. Chemicals for inclusion in a TDS should be preferentially considered on risks to human health.

Public opinions: Risk managers may convey opinions of the food industry, food scientist, technologists and other professionals, media, and consumers. This is especially important when consumer misperceptions of a risk may result in avoidance of otherwise healthy and wholesome food.

Incidental chemicals: Chemicals that are co-analysed with a priority chemical, with little or no additional cost should be considered for inclusion in the TDS but not be evaluated in the TDS report. Examples of such chemicals include trace elements.

Stability of the chemical in food: The stability of the food is a consideration because of the potential problems of handling, transport and shipping of samples. For some chemicals, degradation and/or metabolites may complicate the analysis.

Annex 4. Core, intermediate and comprehensive lists of chemicals including nutrients, suggested for inclusion in TDS

Core List (TDS Screening)

Name of chemical	Major food category
aldrin, chlordane, dieldrin, DDT (<i>p,p'</i> - and <i>o,p'</i> -), TDE (<i>p,p'</i> -), DDE (<i>p,p'</i> - and <i>p,o'</i> -), endosulfan, (α , β and sulfate), endrin, hexachloro- cyclohexane (α , β and γ), hexachlorobenzene, heptachlor and heptachlor epoxide and polychlorinated biphenyls	whole milk, butter, animal fats and oils, fish, cereals*, human milk
diazinon, fenitrothion, malathion, parathion, methyl parathion, methyl pirimiphos	cereals*, fruit, vegetables
cadmium	kidney, molluscs, crustaceans, cereals*
lead	milk, canned/fresh meat, kidney, cereals*, canned/fresh fruit, fruit juice, spices, infant food, drinking water
mercury	fish
inorganic arsenic	drinking water and seaweed
aflatoxins	milk, maize, groundnuts (peanuts), other nuts, dried figs, fermented soy products
iodine	milk and dairy products, fish and seaweed, salt (if fortified)
iron	meat and meat products, cereals*
vitamin A precursor (carotenoids)	vegetables

* Or other staple

Intermediate List (TDS Screening and Refined Assessment)

Name of chemical	Major food category
aldrin, chlordane, dieldrin, DDT (<i>p,p'</i> - and <i>o,p'</i> -), TDE (<i>p,p'</i> -), DDE (<i>p,p'</i> - and <i>p,o'</i> -), endosulfan, (α , β and sulfate), endrin, hexachloro- cyclohexane (α , β and γ), hexachlorobenzene, heptachlor and heptachlor epoxide and polychlorinated biphenyls (congeners No. 28, 52, 77, 101, 105, 114, 118, 123, 126, 138, 153, 156, 167, 169, 180 and 189)	whole milk, dried milk, butter, eggs, animal fats and oils, fish, cereals*, vegetable fats and oils, human milk,
diazinon, fenitrothion, malathion, parathion, methyl parathion, methyl pirimiphos	cereals*, fruit, vegetables
aldicarb, captan, dimethoate, folpet, phosalone	cereals*, vegetables, fruit
cadmium	kidney, molluscs, crustaceans, cereals*, flour, vegetables
lead	milk, canned/fresh meat, kidney, fish, molluscs, crustaceans, cereals*, pulses, legumes, canned/fresh fruit, fruit juice, spices, infant food, drinking water
mercury	fish, fish products
inorganic arsenic	rice, fish, drinking water
aflatoxins	milk, milk products, maize, cereals*, groundnuts, other nuts, spices, dried figs
radionuclides (Cs-134, Cs-137, Sr-90, I-131, Pu-239)	cereals*, vegetables, milk, drinking water
nitrate/nitrite	leafy vegetables, drinking water
iodine	milk and dairy products, seafood, salt (if fortified)
iron	meat and meat products
vitamin A precursor (carotenoids)	vegetables

* Or other staple

Comprehensive List (Refined Assessment)

Name of chemical	Major food category
aldrin, chlordane, dieldrin, DDT (<i>p,p'</i> - and <i>o,p'</i> -), TDE (<i>p,p'</i> -), DDE (<i>p,p'</i> - and <i>p,o'</i> -), endosulfan, (α , β and sulfate), endrin, hexachloro- cyclohexane (α , β and γ), hexachlorobenzene, heptachlor and heptachlor epoxide, polychlorinated biphenyls (congeners No. 28, 52, 77, 101, 105, 114, 118, 123, 126, 138, 153, 156, 167, 169, 180 and 189), dioxins and dibenzofurans (PCDDs and PCDFs), and perfluorooctane sulfate/ perfluorooctane sulfonyl fluorid	whole milk, dried milk, butter, eggs, animal fats and oils, fish, cereals*, vegetable fats and oils, human milk
diazinon, fenitrothion, malathion, parathion, methyl parathion, methyl pirimiphos, chlorpyrifos	cereals*, fruit, vegetables
aldicarb, captan, dimethoate, folpet, phosalone	cereals*, vegetables, fruit
dithiocarbamates	cereals*, vegetables, fruit, drinking water
neonicotinoids	cereals*, vegetables, fruit
cadmium	kidney, molluscs, crustaceans, cereals*, flour, vegetables
lead	milk, canned/fresh meat, kidney, fish, molluscs, crustaceans, cereals*, pulses, legumes, canned/fresh fruit, fruit juice, spices, infant food, drinking water
mercury	fish, fish products, mushrooms
inorganic arsenic	fruit juice, rice, seafood, drinking water
aflatoxins	milk, milk products, maize, cereals*, groundnuts (peanuts), other nuts, spices, dried figs
deoxynivalenol	wheat, cereals*,
fumonisin	maize, wheat
ochratoxin A	wheat, cereals*, wine
patulin	apple juice
radionuclides (Cs-134, Cs-137, Sr-90, I-131, Pu-239)	cereals*, vegetables, milk, drinking water
nitrate/nitrite	leafy vegetables, meat and meat products, drinking water

Name of chemical	Major food category
calcium	milk and dairy products
iodine	milk and dairy products, salt (if fortified)
iron	meat and meat products
selenium	
sodium	
vitamin A precursor (carotenoids)	leafy vegetables
zinc	

* Or other staple

Annex 5. Characteristics of analytical methods used in TDS

It is highly preferable that the analytical methods employed are standard or official methods which have stated validation parameters and have undergone inter-laboratory collaborative studies. It is even more crucial for a TDS, where the sensitivity of the methods may be several orders of magnitude higher than those required for routine regulatory or monitoring programmes. It is incumbent on laboratories and analysts, therefore, to verify their capabilities to replicate the key method characteristics, including precision, bias, limit of detection (LOD), limit of quantification (LOQ) and analyse specificity, prior to use of a method as well as ongoing monitoring of accuracy and precision during use.

Chemical or Chemical Group	Sensitivity of Method	Instrumentation
Simple organochlorine pesticides, by-products and degradation products	High ppb	GC/Flame photometric detector
Complex organochlorines, including PCBs, dioxins and dibenzofurans	Low ppt	HPLC/MS/MS
Pesticides, multiresidue	Low ppb	GC-MS/ECD/PFPD/Head space LC/MS/MS LC/HR-MS
Heavy metals	Low ppb	ICP-MS, ICP-OES
Total mercury	Low ppb	ICP-MS
Methylmercury	Low ppb	HPLC/ICP-MS
Total arsenic	As for heavy metals	
Inorganic arsenic	Low ppb	ICP-MS
Mycotoxins	Low ppb	LC/MS/MS
Minerals	Low ppb	ICP-MS
Vitamins	Dependent on vitamin; low ppb but also matrix dependent	HPLC (eg Vitamin C, Beta carotene)

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